



# Washington University in St. Louis HRPO Research Guide

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Submission Process Order



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# Do I Need to Submit to the IRB?

## **DEFINITIONS**

### **Key Concepts**

- The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) define human subject research differently.
- The DHHS defines research as a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge involving a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.
- The DHHS also defines research in terms of a clinical trial. A clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- The FDA speaks in terms of a clinical investigation. A clinical investigation means any experiment that involves a test article and one or more human subjects.
- If your study is human subject research, a clinical trial or a clinical investigation IRB approval is required.

**Tip** Non-human subjects determinations are now submitted in myIRB using the Non-Human Decision form.

# Do I Need to Submit to the IRB?

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## What Is Research (DHHS)?

Research is “A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” ([45 CFR 46.102](#))

- It is *systematic* in that it involves: A predetermined method for answering specific questions or achieving specified outcomes that has taken into account various factors that could affect data collected during the study.
- It is *generalizable* because it involves: An intent to contribute to your field of study by producing results that can be applied beyond the initial participant population.

The following activities do not constitute “research.” (45 CFR 46.102)

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

# Do I Need to Submit to the IRB?

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- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

## **What Is Human Subjects Research (DHHS)?**

According to DHHS, Human Subjects Research is research that involves “a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.” ([45 CFR 46.102](#))

- *About whom* = a living human individual about whom data are being collected.
- *Intervention or Interaction* = “both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.”
- *Identifiable Private Information* = “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.”

# Do I Need to Submit to the IRB?

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## What is a Clinical Trial? (DHHS)

A clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

## What Is A Clinical Investigation? (FDA)

The FDA regulatory definition of research is slightly different, given that the FDA has specific jurisdiction over research that involves drugs, biologics, devices, and related test articles (21 CFR 50.3). This definition also applies to all research activities involving FDA-regulated test articles. In this section of the FDA regulations, “research” is defined in terms of “clinical investigation”:

- *A Clinical Investigation is:* “Any experiment that involves a test article and one or more human subjects that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit.” (21 CFR 50.3(c))
- *A Human Subject is:* “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control or an individual on whose specimen a medical device is used. A subject may be either a healthy human or a patient.” (21 CFR 50.3(g))
- *A Test Article is:* “any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).” (21 CFR 50.3(j))

# Do I Need to Submit to the IRB?

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## **Newborn Blood Spots**

Secondary research involving non-identifiable newborn screening blood spots is not human subject research.

## **Course Related Student Projects**

Course related student projects designed to teach students how to conduct research are not generally subject to IRB review unless:

- 1) The project involves interacting or intervening with living humans OR accessing, collecting, and/or analyzing private, identifiable information

**AND**

- 2) Also falls into one or more of the following categories:

- Project results are intended to be shared or distributed outside the course
- Project results are intended to be shared in publications or poster sessions outside of Washington University
- Project is designed to meet Honors Thesis or graduation requirements for Latin honors
- Project is intended to contribute to the completion of a thesis or dissertation for an advanced degree
- Project results are intended to be submitted to the US Food and Drug Administration (FDA)
- Project involves data from or collected for a company, agency or organization and the results are intended to advance generalizable knowledge beyond the company, agency or organization
- Project is funded by a Federal Agency subject to the Common Rule.

# Do I Need to Submit to the IRB?

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## QA/QI

### Key Concepts

- Quality assurance (QA) and quality improvement (QI) projects may be considered research when there is a hypothesis or question being answered and if the information being collected is designed to contribute to generalizable knowledge.
- Whether these projects are research is determined by HRPO on a case by case basis.
- HRPO makes this determination by evaluating a group of factors including the purpose and intention of the project, level of risk, and methodology.
- Publishing or presenting QA/QI findings does not automatically make the project research.

### What Is QA/QI?

Quality assurance is defined as a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Quality improvement is a formal approach to the analysis of performance and systematic efforts to improve it.



# Do I Need to Submit to the IRB?

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## When Is QA/QI Also Research?

There is often confusion in determining whether QI or QA activities fall under the jurisdiction of the IRB. Publication of findings, methodological design, selection of subjects and hypothesis testing and generating do not necessarily differentiate research from QI and QA activities because these attributes can be shared by both research and non-research activities. The table below provides information that the IRB considers when trying to make this determination:

	<b>Research</b>	<b>QI/QA</b>
Purpose	To test a hypothesis	To assess or improve a process, program, or system OR to improve performance as judged by established/accepted standards
Starting Point	To answer a question or test a hypothesis	To improve performance
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future individuals	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit individuals
Risks/Burdens	May put subjects at risk	Does not increase risk to patients, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Improve a program/ process/system
Testing/Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards

# Do I Need to Submit to the IRB?

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Additionally, here are examples of several types of QA/QI projects and whether they would also be considered research.

## QA/QI activities that are NOT research:

- A QA initiative (with or without presentation/publication of results) that is conducted within your institution/department only, and that serves to measure or improve your institution/department's ability to meet or exceed an existing national standard of care or benchmark.
- Submission of data to a national or state registry/database that is mandated at the state or federal level with the primary purpose of improving the delivery of clinical care.
- Submission of data to a national or state registry/database that directly impacts reimbursements and funding available from the State, Department of Health, or Federal Centers for Medicare & Medicaid Services (CMS) based on performance and/or clinical or quality outcomes.

## QA/QI activities that **ARE** research:

- QA initiatives designed to develop a standard of care or benchmark.
- An activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients or providers or some hospitals (if part of a consortium or organizational effort) and not to others.

# Do I Need to Submit to the IRB?

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## How HRPO Makes A Determination

When the IRB evaluates a QA/QI project, we look at a variety of questions:

First, we assess whether the project meets the definition of research. Then we determine if the project involves human subjects.

**If the project is research involving human subjects, IRB approval is required.**

There are important considerations that the IRB uses when evaluating these projects:

1. Does the analytical or evaluative component of the activity change the way that the clinical care will be delivered in such a way that introduces or heightens risks to participants (may include randomization)?
2. Is there funding from an external organization (E.g. National Science Foundation or National Institutes of Health) based on support of a “research paradigm” to carry out the proposed activity?
3. Are participants randomized into different intervention groups in order to enhance confidence in differences that might be obscured by other selection methods?
4. Does the project seek to test interventions that are beyond the scope of current science and experience, such as new treatments?
5. Does the project involve care practices, interventions, or treatments that are not standard (neither consensus-based, nor evidence-based)?

**If the answer to ANY of the above is yes, the project is research and should be submitted to the IRB.**

Note however that if the project undertaken by or for WU AND the goal of the project is immediate improvement in WU patient safety or care, AND the intervention has been established in other settings AND the project will be adapted over time to accommodate WU initiatives, this is likely not research and would not require IRB submission.

# **Do I Need to Submit to the IRB?**

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## **What If I Want To Publish The Results Of My QA/QI Project?**

It is entirely appropriate to disseminate and replicate QI/QA successes, including through channels that are external to an organization such as conferences or publication. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI/QA project does not obligate IRB review as long as the publication makes it clear the publication is the result of a quality improvement or quality assurance as defined above.

# Do I Need to Submit to the IRB?

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## CASE STUDY/SERIES

### Key Concepts

- A case study is a retrospective review of a single patient's clinical condition and/or treatment that does not test a hypothesis or include data analysis.
- A case series is a case study that uses information about 2-3 patients instead of one.
- Case studies/series are considered research if they do not meet the definition above.
- If considered research, then consent and HIPAA authorization will be required unless the criteria for a waiver of consent and waiver of HIPAA authorization are met.

**Tip** If your case study/series is not research, contact the HIPAA office at <https://hipaa.wustl.edu/contact/> to learn about the HIPAA requirements that still exist for use of PHI.

### What Is A Case Study/Case Series?

A **case report** is a retrospective review of a single patient's clinical condition, course and/or treatment. The case report should not test a hypothesis or include data analysis. There should be no prospective intent, testing, or plan to generalize results involved with a case report. It should simply be thought of as one person with an unusual, or interesting case which may be educational when described to others in a presentation or publication.

A **case series** is the same as above, but with 2-3 patients instead of one.

# Do I Need to Submit to the IRB?

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## **Do I Have To Submit My Case Study/Case Series?**

If ANY of the below applies, then your proposal is considered “research” and will require IRB review via myIRB. Consent and HIPAA authorization will be required unless the criteria for a waiver of consent and waiver of HIPAA authorization are met.

- Interaction with the patient led you to develop a research question to further investigate.
- This case compares or contrasts with other cases, leading to a comparative study of multiple cases.
- Data collection is more extensive than under normal clinical practice.  
Examples:
  - You want to order additional laboratory tests or imaging which go above and beyond those needed to make a diagnosis or treat the individual.
  - You administer a survey that is not part of routine care or procedures to determine how the individual felt about the treatment or intervention administered.
- The intent is to publish an analytical report versus a descriptive review.

# Do I Need to Submit to the IRB?

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## **HIPAA Requirements**

Case reports and case series that are not considered research are still subject to HIPAA regulations.

HIPAA Authorization is required in the following cases:

- The data will include any of the HIPAA identifiers format.
- You will include dates in the case report or case series.
- The case is so unique that the patient can be identified from the data or the case report.
- You come across an individual that you think would make a good case study but you are not the treatment provider.

HIPAA Authorization is not required if you are only accessing records for which you are the provider. As long as no HIPAA identifiers are used (including dates) and there is no way the patient could reasonably be identified from the data.

# Do I Need to Submit to the IRB?

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## **RESEARCH WITH EXISTING SPECIMENS or DATA**

### **Key Concepts**

- Most uses of data or specimens that include identifiers require IRB approval, though not all.
- The IRB assesses each proposal for use of existing data or samples on a case-by-case basis to determine whether they are research.
- If you are using clinically obtained samples or data from deceased individuals AND the activity is not FDA regulated, no IRB approval is required.
- Any use of specimens or data collected as part of a research study requires review from the IRB, regardless of whether identification status.
- Uses of embryonic stem cells and induced pluripotent stem cells (iPSCs) always require IRB review as well as additional institutional approvals.

### **Tips**

- ✓ When the research method involves obtaining coded private information or specimens, and it is not FDA-regulated, the IRB will review the research according to parameters described in OHRP Guidance on Research Involving Coded Private Information or Biological Specimens. Activities that do not involve human participants, according to the current Guidance, will be designated as such.
- ✓ The IRB should be consulted when there are plans to conduct research involving coded private information or specimens, or de-identified information or specimens collected through research.



# Do I Need to Submit to the IRB?

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## **What Makes Data/Specimens Identifiable?**

Identifiable means that data or specimens contain information or labeling that allows someone to readily ascertain the identity of the individual to whom the data or specimens belong.

De-identified is a term related to HIPAA that means the data or specimens have had all of the HIPAA designated identifiers removed, but there may still be a link between the data or specimens and the identity of the individual from whom they came. This link is often a code. Coded data, when the code itself does not contain any meaningful, or information directly associated with the individual (such as hospital number or SSN) is considered HIPAA de-identified. However, this NOT the same as the data being anonymous (or anonymized) and does NOT necessarily mean that the data are de-identified under human subjects regulations.

Anonymized means that all identifiable information has been removed from the data or specimens and that no link remains between the data or specimens and the identity of the individual to whom they belong. The data or specimens could never again be associated with the individual by anyone.

# Do I Need to Submit to the IRB?

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## **When Do I Need IRB Approval To Use Each Kind?**

### **Identifiable**

A research project using identifiable data or specimens requires IRB approval because it meets the definition of human subjects research.

### **De-identified**

Projects using de-identified data and specimens sometimes require IRB approval and sometimes not.

Example scenarios:

- Study Team Crossover: If a researcher has access to identifiers (even if they don't need them for the study) by virtue of being a study member on the project where the data or specimens were originally collected, we consider the data to be identifiable. We call this "study team crossover" and it matters because we consider the study team on a project to be one entity, meaning that if one person on the team has access to identifiers, everyone has access.
- Coded data or specimens: If the data/specimens are coded AND there is no study team crossover, the project could be non-human subjects research (non-HSR) if a Code Access Agreement or Data Use Agreement (see DUA information below) is signed between the owner of the data/specimens and the recipient. A Code Access Agreement is a written assurance that the holder of the code will not re-identify the data to the recipient and the recipient will not attempt to re-identify the data by any means.

# Do I Need to Submit to the IRB?

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- A Limited Data Set is information from which certain identifiers have been removed, but other less obvious identifiers remain.

**All the following identifiers must be removed in order for health information to be a limited data set:**

- names;
- street addresses (other than town, city, state and zip code);
- telephone numbers;
- fax numbers;
- e-mail addresses;
- Social Security numbers;
- medical records numbers;
- health plan beneficiary numbers;
- account numbers;
- certificate license numbers;
- vehicle identifiers and serial numbers, including license plates;
- device identifiers and serial numbers;
- URLs;
- IP address numbers;
- biometric identifiers (including finger and voice prints); and
- full face photos (or comparable images).

**The health information that may remain includes:**

- dates such as admission, discharge, service, date of birth or death;
- city, state, five digit or more zip code; and
- ages in years, months or days or hours.

# Do I Need to Submit to the IRB?

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If the project involves a Limited Data Set, a Data Use Agreement (DUA) is generally required. A DUA outlines the acceptable uses and restrictions on the Limited Data Set once it is shared. Research using a limited data set under a DUA may be non-HSR.

When sharing specimens, a Material transfer agreement (MTA) could be required. This is an agreement that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

## Anonymized

If a researcher is using anonymized data, generally this would be considered non-human subjects research.

**Again, each project is considered on a case by case basis. If you are unsure whether your project requires IRB approval, please contact HRPO.**

# **Do I Need to Submit to the IRB?**

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## **What About Data Or Samples From Decedents?**

If your study is not FDA regulated AND all data/specimens that were collected for purposed other than research are from deceased individuals, the project would be non-HSR. This is because the HHS definition of a human subject specifies that the subject is “a living individual”.

However, the FDA definition does not make this distinction. Therefore, FDA regulated research with data/specimens from deceased individuals may be human subjects research.

## **What If I Am Using Embryonic Stem Cells Or iPSCs?**

If your research involves the use of embryonic stem cells or the use or creation of induced pluripotent stem cells, your study will require review by the Embryonic Stem Cell Research Oversight Committee (ESCRO). ESCRO must review all proposals for studies involving these cells and will determine whether formal ESCRO approval is required. ESCRO must approve the study, or state their approval is unnecessary, before HRPO will review your project. More information is located [here](#).

# Do I Need to Submit to the IRB?

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## **ENGAGEMENT**

### **Key Concepts**

- “Engagement” is a term of art used by federal regulators to define when a researcher requires IRB approval for their role in human subject research.
- The Office of Human Research Protections provides [guidance](#) on how to determine if an institution/researcher is engaged in human subject research.

### **Engaging In Human Subjects Research**

In the context of a human subjects research study, Washington University faculty, staff, and/or students (or such individuals affiliated with an organization where the WU IRB is the IRB of record) become engaged in the human subjects research when they:

- intervene or interact with the human subjects,
- have access to private identifiable information about the human subjects they are engaged in human subjects research or;
- receive federal funding for the conduct of human subjects research.

IRB approval must be obtained when faculty, staff, or students under the oversight of the WU IRB engage in human subjects research. This is true even if a majority of the research takes place at another site.

### **Prime Awardee of Federal Funds**

Federal regulations require that the prime awardee of federal funding have IRB approval at their institution, even if human subjects activities are not taking place there. Therefore, a researcher that falls under the oversight of the WU IRB and is the prime awardee of federal funds, must submit an application in myIRB and obtain IRB approval.

# Do I Need to Submit to the IRB?

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## **Recruitment Assistance**

WU/BJH/SLCH faculty, staff, students or other colleagues are often asked to participate in recruitment efforts for a research study. For example, a researcher might ask a colleague to pass out recruitment flyers to potentially eligible students or patients or to forward a recruitment email to these individuals. This form of recruitment should be described in the IRB application.

As long as the individual's involvement does not go beyond passing this information along (making these individuals aware of the existence of the study) they are not engaged in the human subjects research. However, these individuals should obtain any other institutional or departmental approvals needed. For example, obtaining permission from the appropriate Dean or Department Chair for mass emailing or obtaining permission from the appropriate individual to post a flyer in a clinical area.

When involvement goes beyond simply making individuals aware of a study (such as answering questions about the research study or obtaining informed consent), the individual is engaged in human subjects research and requires an IRB to oversee their activities. If the individual is not WU/BJH/SLCH faculty, staff or student, they will need to get IRB approval from their own institution. There are times when the WU IRB will agree to serve as the individual's IRB. This is determined on a case by case basis depending on the individual's involvement in the research and approval from their institution.

## **For-Profit Entities (i.e., Industry Sponsors)**

When for-profit entities request assistance with recruitment for a study in which WU/BJH/SLCH faculty, staff, or students are not otherwise involved in the conduct of the research, contact HRPO for assistance.

# SBIR/ STTR Grants

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## Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Grant Recipients

### **Key Concepts**

- The small business who is the recipient of the SBIR/ STTR grant must apply for and be granted a Federal Wide Assurance AND obtain IRB approval for their role as the prime awardee of the grant

### **Tip**

- ✓ Washington University's IRB approval of the research conducted by WU's faculty, staff and students DOES NOT extend to the small business.

## **Institutional (Small Business) Engagement in Human Subjects Research**

- The Office of Human Research Protections (OHRP) is the federal office that oversees HHS- conducted or -supported non-exempt human subjects research.
- By regulation, institutions who are engaged in human subjects research must have an OHRP approved Federal Wide Assurance and certify IRB review and approval to HHS ( <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/fwaf/file-a-new-fwa/index.html>)
- OHRP has issued [guidance](#) on when institutions are engaged in research  
OHRP has issued guidance stating that institutions are considered engaged in an HHS-conducted or -supported non-exempt human subjects research project when institutions receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research, even where all activities involving human subjects are carried out by employees or agents of another institution.



# SBIR/ STTR Grants

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*In summary, this means that the Small Business who is the recipient of the SBIR/ STTR grant must apply for and be granted a Federal Wide Assurance AND obtain IRB approval for their role as the prime awardee of the grant. Washington University's Federal Wide Assurance and IRB approval of the research conducted by their faculty, staff and students DO NOT extend to the small business and thus DOES NOT fulfill the requirement set by the terms of the award.*

## **Obtaining a Federal Wide Assurance (FWA)**

- All institutions engaged in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency must be covered by an OHRP-approved assurance of compliance.
- An assurance of compliance is a written document submitted by an institution that is engaged in non-exempt human subjects research conducted or supported by HHS in which an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.
- The assurance application process must be conducted online by the small business. The assurance application requires that the institution name an IRB.
- This should be the IRB that reviews the largest percentage of the research conducted by the institution covered under the FWA.
- This should NOT be the Washington University IRB. There are a number of independent IRBs that can be named.
- The small business can apply for an FWA here: <https://ohrp.cit.nih.gov/efile/>
- The FWA must be renewed every 5 years.

*In summary, the small business will need to apply for and obtain their own Federal Wide Assurance naming the IRB other than the Washington University IRB as they will not be the IRB reviewing the largest part of the businesses research.*

# SBIR/ STTR Grants

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## Pre-Grant Submission Information

- For any grant submitted on or after January 25, 2018, a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. SBIR/STTR grants fall under this requirement.
- Beginning January 20, 2020, for federally funded research any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.
- Washington University IRB acts as the IRB for the small business awardee of SBIR/ STTR on a case by case basis for Phase I SBIR/ STTR grants.
- There is a fee associated with Washington University acting as the IRB for the small business.
- Please contact the WU Human Research Protection Office PRIOR to grant submission to obtain confirmation that they are able to act as the IRB for the small business and to obtain budgeting information.
- Washington University does not have a mechanism that allows them to act as the IRB for the small business for Phase II SBIR/ STTR grants. This is due to conflict of interest requirements set forth in the NIH award to the business that cannot be appropriately addressed by Washington University.
- While a single IRB must review the protocol for both the small business and the Washington University researchers, the Washington University IRB CANNOT act as the IRB for Phase II SBIR/ STTR research.

# SBIR/ STTR Grants

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*In summary, Washington University may be able to act as the single IRB for Phase I but cannot for Phase II. Costs associated with IRB review should be considered during the grant submission phase.*

## **IRB Submission Information**

- If the Washington University IRB is going to act as the IRB for the study, Washington University and the small business must enter in to an IRB Authorization or Reliance agreement.
- An IRB Authorization or Reliance agreement is an agreement between the small business and Washington University that allows Washington University IRB to act as the IRB for the small business and defines the roles and responsibilities of each party.
- This agreement is needed in ADDITION to the sub-award and it is managed by the WU HRPO office.
- The Washington University PI should contact HRPO when they are preparing their IRB submission to begin the agreement process.
- This agreement must be kept on file at Washington University and the small business and made available upon request to federal regulatory agencies.
- If Washington University researchers are going to request to rely on another IRB for review of their part of the research, they will need to submit an administrative application in myIRB in order to obtain confirmation that Washington University is agreeable to relying on the particular chosen IRB.
- Washington University may have to enter in to an IRB Authorization or IRB Reliance agreement with the chosen IRB if one does not already exist.

## SBIR/ STTR Grants

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- Currently, Washington University may also use 2 Independent (Commercial) IRBs- WCG IRB and Advarra with agreement from, and appropriate submission of application to HRPO.

*In summary, written legal agreements are needed for Washington University to act as the IRB for the small business and for Washington University to rely on another IRB.*

# Research Team

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## **PRINCIPAL INVESTIGATOR ROLES & RESPONSIBILITIES**

### **Key Concepts**

- The Principal Investigator (PI) is the individual ultimately responsible for the scientific, legal and ethical performance of the research.
- The PI is responsible for the conduct of all members of their study team related to the conduct of the research.
- When leaving the institution, the PI must either name a new PI or close the study prior to departure.

### **What Is A Principal Investigator?**

A Principal Investigator (PI) is the person ultimately responsible for the conduct of the study.

While a study may have more than one PI, the IRB only allows for the designation of a single PI. Additional individuals should be listed as study team members in myIRB. Co-investigators can be listed as such in the protocol.

The individual listed as the PI on the IRB submission is responsible for the conduct of the study as well as the conduct of the study team members working under their supervision as related to their work on the research study.

The qualifications of a PI to conduct research at Washington University are documented by virtue of their faculty, staff, or student status.

# Research Team

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## **Who May Serve As A Principal Investigator?**

Only WU/BJH/SLCH faculty, staff, and students may serve as the PI of research overseen by the WU IRB unless the WU IRB:

- serves as the Single IRB for other entities; or
- has taken on broad oversight of research activities conducted at a specific entity.

All PIs are required to sign an assurance document for each study under their supervision that must be co-signed by the applicable Dean/Department Chair/Department Head (or stated designee) and faculty sponsor, if applicable.

## **Students As Principal Investigators**

Students can serve as the PI of a study. A student who is serving as the PI must have a faculty sponsor. The designated faculty sponsor becomes the individual most responsible for the conduct of the research as well as the conduct of the study team members (including the student PI) working under their supervision as related to their work on the research study.

# Research Team

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## **General Responsibilities Of The Principal Investigator**

The PI of a study has the following general responsibilities:

- Ensure adequate resources are available to conduct the study including; budget, facilities, qualified staff, access to participate population and equipment necessary to conduct the research as described in the study protocol
- To comply with all applicable IRB policies and procedures, all applicable regulatory requirements, and all applicable federal, state and local laws.
- Obtain IRB approval prior to the initiation of any human subjects research protocols and ensure that IRB approval does not lapse by submitting continuing review application in sufficient time for IRB review prior to the expiration date.
- Make alternative arrangements for oversight of the study should circumstances prevent the PI from overseeing the study. These arrangements must be submitted to the IRB for approval prior to the PI's removal from the study and/or institution.
- For sponsored research, the PI must ensure that the research described in the grant application or proposal is consistent with any corresponding study(s).
- The research team will only collect information essential to the conduct of the study. If protected health information is used or created, it will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, or those uses outlined in the application.
- The IRB requires the PI to ensure that all individuals engaged in the research disclose to the IRB all applicable financial interests via the myIRB application form. This disclosure includes any financial interests that the individual, individual's spouse, domestic partner, or dependent children have with the sponsor of the study, the supporting organization, or company that owns or licenses the technology being studied.
- Ultimately responsible for the general conduct of the study
- Ensuring all persons assisting with the research are adequately trained, informed about the study, and informed of their duties

# Research Team

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- Available to answer any questions, concerns, or discuss the study with potential participants and participants
- I have adequate resources, budget, facilities, and numbers of qualified staff to conduct the research at this site as described in the study protocol
- If during the course of the research study, it becomes apparent that the participant needs to be referred for further services, the PI should make such referral(s).
- Ensure that all research records are retaining in their original form or certified scanned electronic form for at least six years following the closure of a study with the IRB (or longer if required by the study's sponsor).
- Submit the required closure form at the completion of research activities

## **FDA Regulated Research - Additional Responsibilities For The Principal Investigator**

In a clinical investigation of an investigational drug or device, the investigator may be asked to sign the Form FDA 1572.

Per the FDA, the 1572 is:

an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

This form provides the sponsor with information about the investigator, including his/her qualifications and their sites qualifications. This form also provides the investigator with his/her obligations and commitments as related to the FDA regulations.



# Research Team

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## **Changes To A PI's Status**

### **Leave/Sabbatical**

PI's going on extended leave or sabbatical must assess if they will be able to complete the responsibilities of a PI as described in the assurance document and WU IRB Policies and Procedures. If the PI is unable to complete their duties, they must transfer responsibility for oversight of their research studies to another PI. A modification to designate a new PI must be submitted to and approved by the IRB prior to the PI's departure.

### **Leaving the Institution**

When a PI leaves, a modification must be submitted to transfer the study to the oversight of another PI. This modification must be submitted to and approved by the IRB prior to the PI's departure. If the PI does not intend to transfer oversight of their research study(ies) to another PI, the study(ies) must be closed with the IRB prior to the PI's departure.

Once a PI leaves, their access to myIRB will be terminated. A delegate's access to any studies not transferred to a new PI will also be terminated.

PI's who leave may wish to continue to collaborate on ongoing research studies conducted under the oversight of the WU IRB. This may occur in one of two ways.

- The new institution's IRB will oversee the collaboration. A modification should be submitted to add the former PI's new institution as a participating site.
- The WU IRB will oversee the former PI's collaboration with WU. A modification should be submitted to add the former PI as a Limited Access study team member.

In either instance the former PI must consult with their new institution's IRB. If unsure how to move forward, contact HRPO for guidance.

# Research Team

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For additional guidance when a PI is leaving the institution, refer to the PI Departure Checklist offered through the Vice Chancellor for Research office. <https://research.wustl.edu/pi-departure-checklist/>. If there are plans to take data or specimens, additional review by the PI's department, HRPO and other departments will be required.

## **IRB Review**

Research teams must submit modifications when a change in PI is needed. The modification must be submitted to the IRB for review and approval prior to the existing PI's departure.

The modification must address whether existing participants will be notified of the PI change. When notification will happen, the modification should address which participants will be notified and how the notification will occur. The plan for notification often depends on the participants' status in the study.

Participants that are completing in person study visits should be asked sign an updated version of the consent form or be provided a letter with the new PI's name and contact information.

If participation in the study is limited to phone calls, a verbal notification during the next phone call is appropriate.

If participants are no longer interacting with the study team (including those whose participation is limited to collection of existing medical record information) notification is not required.

Reconsent/notification documents must be submitted to the IRB as part of the modification prior to use.

# Research Team

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## **GUIDANCE FOR FACULTY SPONSOR RESPONSIBILITIES**

### **Prior to Submitting IRB Protocol**

- All members of the research team, including the faculty sponsor, must have completed the CITI training module on the HRPO website.
- Ensure that the research design is able to answer the specific research question(s), including:
  - whether the identified subject population is the appropriate source of data to answer the research question
  - whether the planned method for data collection is valid and will yield data that answers the study question(s)
  - whether the planned analysis of the data is appropriate and will answer the study question
- Ensure that all members of the research team have sufficient knowledge and experience to conduct the proposed research. This includes determining whether all members of the research team are knowledgeable about the regulations and policies governing research with human subjects.
  - Training by the faculty sponsor is especially important when the study involves collecting data from riskier or vulnerable populations (e.g., certain clinical populations, children, prisoners), as student researchers may lack experience collecting data from these groups.
- Ensure sufficient knowledge of any cultural sensitivities or cultural norms that may affect data collection in the sample of interest.
- Prior to signing the assurance document, read, edit, and approve the proposed IRB application and supporting materials.
- Keep informed about changes to policies and procedures of the Washington University IRB, the published guidelines for the ethical conduct of research relevant to the field of inquiry, and state and federal regulations.
- Report any current or potential conflicts of interest.

# Research Team

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## **During Conduct of the Study**

- Provide ongoing supervision of the student PI and research team.
- Meet with the student PI on a regular basis to discuss study progress and any concerns that have come up regarding human participant testing.
- Read and sign all correspondence between the student PI and the IRB (e.g., modifications, renewals).
- Ensure prompt reporting of any Reportable Events to the Washington University IRB. Please use link below for further information on reportable events.
  - [How to submit Reportable Events in myIRB](#)
  - [Deviation guidance](#)

## **Following Completion of Data Collection**

- HHS regulations require that research records be retained for at least 3 years.
- Ensure that any required forms necessary either to close the study or continue the study are completed. If the student leaves the University, they or the faculty sponsor must close the study or continue it solely under faculty sponsor's direction or name another student investigator.
- Ensure the confidentiality and security of all information obtained from and about human subjects
- Ensure that the privacy of subjects is maintained.
- Participate in any reviews or audits of the research activity as conducted by the extramural sponsor, the University, or state or federal regulators.

## **Additional Responsibilities**

- Provide oversight even if the research is conducted off-campus or outside the U.S. If the research is conducted off-campus, there must be a plan for regular communication that allows the advisor to meet his or her oversight responsibilities for the study. Oversight of the project includes:
  - Periodic review of the research to ensure that protocol is being followed in its entirety.

# Research Team

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- Fiscal management of the project and student spending.
  - Encouraging the student to publish or present the project at appropriate conferences or other venues.
- If the faculty sponsor is unable to supervise the research personally (e.g., sabbatical leave), arrange for an alternate faculty sponsor to assume direct responsibility and advise the IRB in advance of such arrangements.
- Serve as a respondent for any inquiries into regulatory non-compliance or scientific misconduct.

# Research Team

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## **NON-WU COLLABORATORS**

### **Purpose**

Washington University (WU) has many non-WU collaborators that want to participate in human subjects research being conducted at WU. These individuals range from undergraduate students to visiting faculty from other institutions. This guidance is intended to offer information and instructions on managing non-WU collaborators who will be engaging in human subjects research.

### **Determining if collaborators need IRB approval**

- In general, if a collaborator is performing any research procedures, interacting or intervening with research subjects for research purposes, or accessing identifiable data, they will be considered engaged in research and should obtain IRB approval.
- If a visitor will only be observing research procedures they do not require IRB oversight.

### **Determining the IRB of Record**

Washington University IRB is the IRB for Washington University employees (including faculty or staff) and Washington University students and must oversee all their research activities. Likewise, employees and students of other domestic universities fall under the jurisdiction of their own IRBs.

If your collaborator is an employee or student from an institution with a domestic IRB, they should obtain IRB approval from their own IRB for their role in the research and should not be added in myIRB as a study team member. They should contact their IRB to determine how to obtain approval.

# Research Team

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Please note, a collaborator may need to complete the Visiting Learner Process [website](#). *Note: Those with contingent worker statuses in Workday will not show up in myIRB and will not be able to be added to study teams in myIRB without an additional review process.*

## **Requesting WU IRB Oversight**

- If your collaborator is not employed by or a student of a domestic institution with an IRB or if their institution's IRB has confirmed they are not considering their role at WU to be related to their employment or student status, you may request that WU IRB take oversight for them to conduct human subjects research. The WU IRB does not oversee international collaborators conducting research in other countries.
- These requests are considered on a case by case basis and if approved, an agreement will be entered into for IRB oversight of the collaborator.
- If you would like to request that WU IRB take oversight of a collaborator, the individual seeking oversight must obtain a Limited Access ID. Instructions for how to request a limited access ID are available in the myIRB FAQ area on the HRPO website. <https://hrpo.wustl.edu/myirb-2/myirb-faqs/>
- Granting of the Limited Access ID does not mean the WU IRB has agreed to provide oversight.
- Once the Limited Access ID is obtained, the individual can be added as a study team member in myIRB. You will be prompted to explain the collaborators role in myIRB. This should be as specific as possible.
- In addition to describe the collaborator's role be sure to include the following:
  - Where will the collaborator conduct the research (e.g. on campus, remote or both)?
  - What security measures will be used to ensure transfer, use and storage of the data remains secure (WUSTL Box, VPN, RedCap etc.)
  - Any plans to access EPIC

# Research Team

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## **Training and Oversight**

Investigators must ensure that all collaborators are appropriately trained, qualified and overseen for the duration of their participation in research.

- As is required by institutional policy, any person engaging in human subjects research must complete CITI initial human subjects research training.
- Depending on the study type, there may be additional training required such as HIPAA or Good Clinical Practice. HRPO does not provide or track these requirements. Departments should ensure collaborators complete all other required trainings.
- If collaborators are accessing identifiable information, they must be made aware of all applicable institutional policies regarding use of personal electronic devices found [here](#).
- Data should be shared and stored using systems and methods approved by the Office of Information Security. Access to research data should be removed when the person has completed their role in the research.
- Institutional permissions are required to obtain access to EPIC for research purposes. Contact the HRPO Executive Director if there are plans to allow the collaborator to access EPIC.
- As is the case with WU employees and students, careful consideration should be given to who is obtaining consent from prospective research subjects and conducting study procedures. It is expected that collaborators are provided training on the consent process and any study specific procedures they will perform. This training is in addition to the institutionally required human subjects training.
- High school and undergraduate students should only obtain consent and perform study procedures under carefully monitored conditions for minimal risk research.



# Research Team

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## **Other Relevant Policies and Information**

[Youth Protection Policy](#)

[Human Subjects Education Policy](#)

[Good Clinical Practice Policy](#)

[Visiting Learner Process](#)

# Single IRBs

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## **RELYING ON AN EXTERNAL IRB**

The Human Research Protection Office (HRPO) works with investigators who have the role of a *participating* site in a multi-site study to identify and rely upon the appropriate external IRB. To request that HRPO defer IRB oversight to an external IRB, a Request to Rely (RTR) application must be submitted in myIRB.

Please see the [sIRB Research Guide](#) for information about submitting a RTR application.

## **WU IRB AS THE REVIEWING IRB / SINGLE IRB**

Washington University IRB does act as a single IRB. However, a decision about acting as the single IRB will be made on a case-by-case basis depending on the costs of sIRB review, number, type, and location of sites, complexity of the protocol, current capacity of the WU IRB, and ability to meet study review time lines. The WU Policy for Use of a Single IRB in Multi-site Research studies contains a decision matrix for use of an sIRB and is available for review on the HRPO website.

Please see the [sIRB Research Guide](#) for information about how to request that WU IRB act as the single IRB and additional information about the submission process.

# International Research Checklists

## Behavioral Prep Work Checklist – Prior to Creating IRB Application

Things to think about....		Yes	No	N/A
1.	<p>You may contact Cindy Brantmeier for consultation and advice while completing this checklist prior to IRB submission <a href="mailto:cbrantme@wustl.edu">cbrantme@wustl.edu</a>. For assistance preparing your IRB submission, or for questions about IRB requirements, contact an International Research HRPO Partner: Erin Higgs (<a href="mailto:ehiggs@wustl.edu">ehiggs@wustl.edu</a>) or Mitchell Saulisbury-Robertson (<a href="mailto:saulism@wustl.edu">saulism@wustl.edu</a>)</p> <p>Useful links include:</p> <ul style="list-style-type: none"> <li>Human Research Protection Office (HRPO) website: <a href="https://hrpo.wustl.edu/">https://hrpo.wustl.edu/</a> <ul style="list-style-type: none"> <li>HRPO International Research Guidance: <a href="https://sites.wustl.edu/hrpo/international-research-2/international-guidance/">https://sites.wustl.edu/hrpo/international-research-2/international-guidance/</a></li> </ul> </li> <li>HRPO Research Guide (for general information): <a href="http://online.fliphtml5.com/ikcz/ifub/#p=1">http://online.fliphtml5.com/ikcz/ifub/#p=1</a></li> <li>myIRB electronic submission system: <a href="https://myirb.wusm.wustl.edu/">https://myirb.wusm.wustl.edu/</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<p>Identify the international site's local regulatory requirements. For example, HHS Office for Human Research Protections (OHRP's) International Compilation can be a starting point for country specific information: <a href="https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html">https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html</a></p> <ul style="list-style-type: none"> <li><b>Please note: There are differences across and within countries. Each place the research is conducted should be treated as a separate entity and may be subject to different regulatory requirements.</b></li> <li>If you have funding associated with your project, you must adhere to the requirements of the funding agency.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<p>If local IRB or Ethical Committee review <b>IS</b> required:</p> <ul style="list-style-type: none"> <li>Identify the processes needed to obtain the review.</li> <li>Have you obtained the appropriate documentation (Letter of Approval)? NOTE: WU IRB approval cannot be granted until documentation is provided to the IRB. <ul style="list-style-type: none"> <li>Please note: depending on the location, this review may take the form of a letter of approval from an IRB or research ethics committee, national regulatory office, local university department sponsoring the research, institutional oversight committee.</li> </ul> </li> <li>Approval documentation should be uploaded into the "Misc." attachments section of your myIRB submission form prior to submitting the form to the IRB.</li> <li><b>IRB applications submitted prior to the completion of local IRB or Ethical Committee review will be withdrawn.</b></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4.	<p>If a country <b>DOES NOT</b> require local IRB or ethical committee review:</p> <ul style="list-style-type: none"> <li>Identify the appropriate Regulatory Official or individual who can provide you with <u>documentation</u> that local IRB or ethics review is not required OR documentation of what the local requirements for conduct of human subjects research are. <ul style="list-style-type: none"> <li>Documentation may include reference to a country's laws or policies online, or an email statement from the appropriate authority in the country. Documentation should be uploaded into the "Misc." attachments section in myIRB.</li> </ul> </li> <li>Identify a local context advisor/expert who can provide the IRB with the expertise necessary to assess the regulatory and cultural appropriateness of the research. This expert cannot be part of the study.</li> <li>The WU PI must provide the name and contact information of the local context advisor to the IRB at the time of submission. The IRB will consult with this individual during their review. For more information on the qualifications needed, see the International Human Subjects Research Guidance document section "Local Context Review": <a href="https://sites.wustl.edu/hrpo/international-research-2/international-guidance/">https://sites.wustl.edu/hrpo/international-research-2/international-guidance/</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Do your research documents need to be translated? Be sure to document the names and qualifications of translators for data collection instruments, informed consents etc. in the myIRB application.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	<p>Are specific international site permissions required?</p> <ul style="list-style-type: none"> <li>Do you know the processes for obtaining these permissions? Or when permission(s) cannot be obtained in advance, are you familiar with the procedures to acquire permission(s) prior to initiating research activities? <ul style="list-style-type: none"> <li>Note: some international sites may not allow you to obtain these permissions until you are in the country when the research commences. In these cases, it is good to know the process so you can communicate that to the WU IRB.</li> </ul> </li> </ul> <p>Once received, do you have documentation of the permission(s)?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Are there country-specific licenses, permits or other authorizations necessary for the procedures to be performed at the international site? For example, licensure for clinical procedures or permits for drugs, devices, or technology being brought into the foreign country.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	<p>Do you want to compensate or give class credit to your research participants?</p> <ul style="list-style-type: none"> <li>If yes, are there any local laws or regulations that prevent you from doing this?</li> <li>What is a culturally appropriate way to compensate them or offer extra credit?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	<p>Are you going to ask local individuals (non-Washington University faculty, staff or students) to assist with study procedures, recruitment, and informed consent in the international setting?</p> <ul style="list-style-type: none"> <li>If yes, briefly describe their role in myIRB 1.3 of your myIRB application.</li> </ul> <p>NOTE: WU IRB will not take on oversight of individuals in-country who are collaborating or assisting with the research. These individuals will need to obtain their own IRB/ethical committee review if there is a requirement for IRB/Ethical committee review in the country where the research will take place. For more information see: <a href="https://sites.wustl.edu/hrpo/files/2022/04/Flowchart-External-Collaborators-Will-WU-serve-as-the-IRB-for-your-Non-WU-collaborator-04.03.2022.pdf">https://sites.wustl.edu/hrpo/files/2022/04/Flowchart-External-Collaborators-Will-WU-serve-as-the-IRB-for-your-Non-WU-collaborator-04.03.2022.pdf</a>. There may be exceptions if the research is exempt. For more information see: <a href="https://sites.wustl.edu/hrpo/files/2022/09/Oversight-of-international-collaborators-04.03.2022-with-link-to-assurance-document-added-2022-09-20.pdf">https://sites.wustl.edu/hrpo/files/2022/09/Oversight-of-international-collaborators-04.03.2022-with-link-to-assurance-document-added-2022-09-20.pdf</a>.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10.	<p>Are there country-specific laws or regulations about data collection and/or data transportation?</p> <ul style="list-style-type: none"> <li>Are there any country-specific laws or regulations about storing consent forms, research data/documentation and/or any identifiable data?</li> <li>Have you reviewed WU's guidance on electronic storage of research documents? <a href="https://research.wustl.edu/electronic-storage-research-study-documents/">https://research.wustl.edu/electronic-storage-research-study-documents/</a></li> <li>For studies in the European Union, the General Data Protection Regulation (GDPR) applies: <a href="https://ec.europa.eu/info/law/law-topic/data-protection_en">https://ec.europa.eu/info/law/law-topic/data-protection_en</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	<p>If the research is federally funded, have you provided the Federal Wide Assurance (FWA) number assigned to the foreign site? Include the FWA number in your protocol or in the description of your study in myIRB 1.3. The foreign site must apply for the FWA. For information on filing for a FWA see: <a href="https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/file-a-new-fwa/index.html">https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/file-a-new-fwa/index.html</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	<p>Is your consent process culturally appropriate?</p> <ul style="list-style-type: none"> <li>Consider discussing the consent process with your informed local partner.</li> <li>Contact your WU International Research HRPO Partner for advice and guidance on different consent processes that may be used.</li> <li>Build in flexibility</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	<p>Have you built in flexibility into your research protocol?</p> <ul style="list-style-type: none"> <li>For example, if you plan to interview participants in several places and not just a single location, be sure to describe all options.</li> <li>Use the term "may" if one or more study procedure could be used. Be sure to ask your International Research HRPO Partner for suggestions if the "normal" process makes implementing the research too difficult or culturally inappropriate.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	<p>If you are a student, have you identified your WU Faculty Sponsor?</p> <ul style="list-style-type: none"> <li>Please review the following with your Faculty Sponsor: <ul style="list-style-type: none"> <li>All research team members, including your Faculty Sponsor, must have CITI human subjects training in order to be added to the research team in myIRB.</li> <li>This can cause delays if you or your Faculty Sponsor has not completed this training.</li> <li>IF non-WU individuals will be participating in the research, it is the PI's responsibility to develop appropriate training for the participating non-WU staff. For non-exempt research, this training should be described in the myIRB application.</li> <li>The Faculty Sponsor is ultimately responsible for overseeing the research you are conducting. It is highly important that you make arrangements (and document them) to review your research records with your Faculty Sponsor.</li> </ul> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15.	<p>Have you thought about your research documentation?</p> <ul style="list-style-type: none"> <li>It is very important that you document what you do, when you do it, and with whom it is done with. It is also equally as important to document when something cannot be done and why.</li> <li>Good research documentation includes maintaining records of all data and observations pertinent to the research and the research subjects. These records should be verifiable and record the original source the information was recorded from.</li> <li>Research documentation should be <b>ALCOAC</b>: <ul style="list-style-type: none"> <li><b>A</b>tributable – can you tell who wrote or performed the study procedure or observation?</li> <li><b>L</b>egible – can you read it, are all pages present etc.?</li> <li><b>C</b>ontemporaneous – Is the data current and collected within the correct time frame? For example, a notation recorded in the research record should be signed and dated by the person making that notation at the same time.</li> <li><b>O</b>riginal – and if not an original, an exact certified copy of the original. A <b>certified copy</b> is a copy of original information that has been <b>verified</b>, as indicated by a <b>dated signature</b>, as an exact copy, having all of the same attributes and information as the original.</li> <li><b>A</b>ccurate – real representation of fact. The consent should precisely reflect the event</li> <li><b>C</b>omplete – Research documentation should be completed to the fullest extent and should explain any discrepancies, missing, and/or incomplete data. <ul style="list-style-type: none"> <li>Always remember...If it's not documented, then it did not happen.</li> </ul> </li> </ul> </li> <li>The Human Subjects Research Website maintained by the Office for the Vice Chancellor of Research provides forms and templates that you can use to document your research: <a href="https://research.wustl.edu/topics/human-subjects-research/">https://research.wustl.edu/topics/human-subjects-research/</a> <ul style="list-style-type: none"> <li>Contact the Human Research Quality Assurance Program for additional resources or research documentation support. <a href="mailto:HRQA@wustl.edu">HRQA@wustl.edu</a> or +1 314-747-5525</li> </ul> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	Have you consulted the WU policies about taking data or research materials with you if/when you may permanently leave WU for a job at another university?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	<p>Is your research federally funded? If so, the consent form should include a “Key Information” section if it is more than four pages in length.</p> <ul style="list-style-type: none"> <li>Refer to the HRPO Research Guide for information on how to write the Key Information section: <a href="https://sites.wustl.edu/hrpo/guidance-3/research-guide/">https://sites.wustl.edu/hrpo/guidance-3/research-guide/</a>.</li> <li>Key Information templates are available on the attachments page of your draft myIRB application.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
18.	<p>Is your research federally funded by one of the <a href="#">Public Health Services Agencies</a> (PHS)? If so, describe the protections of the Certificate of Confidentiality (COC) in the consent form.</p> <ul style="list-style-type: none"> <li>The template language is found in the consent templates available on the attachments page of your draft myIRB application.</li> <li>The use of a document separate from the consent form is also an option. Contact your International Research HRPO Partner: Erin Higgs (<a href="mailto:ehiggs@wustl.edu">ehiggs@wustl.edu</a>) or Mitchell Saulisbury-Robertson (<a href="mailto:saulism@wustl.edu">saulism@wustl.edu</a>) to obtain a copy of the COC separate document.</li> <li>For more information on the applicability of a COC to your study see: <a href="https://research.wustl.edu/cocs/">https://research.wustl.edu/cocs/</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	

# International Research Checklists

## Biomedical Prep Work Checklist – Prior to Creating IRB Application

	Things to think about.....	Yes	No	N/A
1.	<p>You may contact Cindy Brantmeier for consultation and advice while completing this checklist prior to IRB submission <a href="mailto:cbrantme@wustl.edu">cbrantme@wustl.edu</a>. For assistance preparing your IRB submission, or for questions about IRB requirements, contact an International Research HRPO Partner: Erin Higgs (<a href="mailto:ehiggs@wustl.edu">ehiggs@wustl.edu</a>) or Mitchell Saulisbury-Robertson (<a href="mailto:saulism@wustl.edu">saulism@wustl.edu</a>)</p> <p>Useful links include:</p> <ul style="list-style-type: none"> <li>Human Research Protection Office (HRPO) website: <a href="https://hrpo.wustl.edu/">https://hrpo.wustl.edu/</a> <ul style="list-style-type: none"> <li>HRPO International Research Guidance: <a href="https://sites.wustl.edu/hrpo/international-research-2/international-guidance/">https://sites.wustl.edu/hrpo/international-research-2/international-guidance/</a></li> </ul> </li> <li>HRPO Research Guide (for general information): <a href="http://online.fliphtml5.com/ikcz/ifub/#p=1">http://online.fliphtml5.com/ikcz/ifub/#p=1</a></li> <li>myIRB research application program: <a href="https://myirb.wusm.wustl.edu/">https://myirb.wusm.wustl.edu/</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<p>Identify the international site's local regulatory requirements. For example, HHS Office for Human Research Protections (OHRP's) International Compilation can be a starting point <b>for country specific information</b>:: <a href="https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html">https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html</a></p> <ul style="list-style-type: none"> <li><b>Please note: There are differences across and within Countries. Each place the research is conducted should be treated as a separate entity and may be subject to regulatory requirements.</b></li> <li>If you have funding associated with your project, you must adhere to the requirements of the funding agency.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<p>If local IRB or Ethical Committee review <b>IS</b> required:</p> <ul style="list-style-type: none"> <li>Identify the processes needed to obtain the review.</li> <li>Have you obtained the appropriate documentation (Letter of Approval)? WU IRB approval cannot be granted until documentation is provided to the IRB. <ul style="list-style-type: none"> <li>Please note: depending on the location, this review may take the form of a letter of approval from an IRB or research ethics committee, national regulatory office, local university department sponsoring the research, institutional oversight committee.</li> </ul> </li> <li>Approval documentation should be uploaded into the "Misc." attachments section of your myIRB submission form prior to submitting the form to the IRB.</li> <li><b>IRB applications submitted prior to the completion of local IRB or Ethical Committee review will be withdrawn.</b></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<p>If a country <b>DOES NOTE</b> require local IRB or ethical committee review:</p> <ul style="list-style-type: none"> <li>Identify the appropriate Regulatory Official or individual who can provide you with <u>documentation</u> that local IRB or ethics review is not required OR documentation of what the local requirements for conduct of human subjects research are <ul style="list-style-type: none"> <li>Documentation may include reference to a country's laws or policies online, or an email statement from the appropriate authority in the country. Documentation should be uploaded into the "Misc" attachments section in myIRB.</li> </ul> </li> <li>Identify a local context advisor/expert who can provide the IRB with the expertise necessary to assess the regulatory and cultural appropriateness of the research. This expert cannot be part of the study.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	<ul style="list-style-type: none"> <li>The WU PI must provide the name and contact information of the local context advisor to the IRB at the time of submission. The IRB will consult with this individual during their review. For more information on the qualifications needed, see the International Human Subjects Research Guidance document section “Local Context Review”:  <a href="https://sites.wustl.edu/hrpo/international-research-2/international-guidance/">https://sites.wustl.edu/hrpo/international-research-2/international-guidance/</a> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Do your research documents need to be translated? Be sure to document the names and qualifications of translators for data collection instruments, informed consents, etc. in the myIRB application.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	<p>Are specific international site permissions required?</p> <ul style="list-style-type: none"> <li>Do you know the processes for obtaining these permissions? Or when permission(s) cannot be obtained in advance, are you familiar with the process to acquire permission(s) prior to initiating research activities? <ul style="list-style-type: none"> <li>Note: some international sites may not allow you to obtain these permissions until you are in the country when the research commences. In these cases, it is good to know the process so you can communicate that to the WashU IRB.</li> </ul> </li> <li>Once received, do you have documentation of the permission(s)?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Are there country-specific licenses, permits or other authorizations necessary for the procedures to be performed at the international site? For example, licensure for clinical procedures or permits for drugs, devices, or technology being brought into the foreign country.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	<p>Do you want to compensate your research participants?</p> <ul style="list-style-type: none"> <li>If yes, are there any local laws or regulations that prevent you from doing this?</li> <li>What is a culturally appropriate way to compensate them or offer extra credit?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	<p>Are you going to ask local individuals (non-Washington University faculty, staff or students) to assist with study procedures, recruitment, and informed consent in the international setting?</p> <ul style="list-style-type: none"> <li>If yes, briefly describe their role in myIRB 1.3 of your myIRB application.</li> <li>NOTE: WU IRB will not take on oversight of individuals in-country who are collaborating or assisting with the research. These individuals will need to obtain their own IRB/ethical committee review if there is a requirement for IRB/Ethical committee review in the country where the research will take place. For more information see:  <a href="https://sites.wustl.edu/hrpo/files/2022/04/Flowchart-External-Collaborators-Will-WU-serve-as-the-IRB-for-your-Non-WU-collaborator-04.03.2022.pdf">https://sites.wustl.edu/hrpo/files/2022/04/Flowchart-External-Collaborators-Will-WU-serve-as-the-IRB-for-your-Non-WU-collaborator-04.03.2022.pdf</a>. There may be exceptions if the research is exempt. For more information see:  <a href="https://sites.wustl.edu/hrpo/files/2022/09/Oversight-of-international-collaborators-04.03.2022-with-link-to-assurance-document-added-2022-09-20.pdf">https://sites.wustl.edu/hrpo/files/2022/09/Oversight-of-international-collaborators-04.03.2022-with-link-to-assurance-document-added-2022-09-20.pdf</a> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	<p>Are there country-specific laws or regulations about data collection and/or data transportation?</p> <ul style="list-style-type: none"> <li>Are there any country-specific laws or regulations about storing consent forms, research data/documentation and/or any identifiable data?</li> <li>Have you reviewed WU’s guidance on electronic storage of research documents?  <a href="https://research.wustl.edu/electronic-storage-research-study-documents/">https://research.wustl.edu/electronic-storage-research-study-documents/</a> </li> <li>For studies in the European Union, the General Data Protection Regulation (GDPR) applies:  <a href="https://ec.europa.eu/info/law/law-topic/data-protection_en">https://ec.europa.eu/info/law/law-topic/data-protection_en</a> </li> <li>You must adhere to all local requirements related data collection, storage, and transport of all research data and/or biospecimens regardless if they are “identifiable” or not. <ul style="list-style-type: none"> <li>Please note, the local definition for what is considered “identifiable” may differ from one place to another.</li> </ul> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	If the research is federally funded, have you provided the Federal Wide Assurance (FWA) number assigned to the foreign site? Include the FWA number in your protocol or in the description of your study in myIRB 1.3. The foreign site must apply for the FWA. For information on filing for a FWA see: <a href="https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafs/fwafs/file-a-new-fwa/index.html">https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafs/fwafs/file-a-new-fwa/index.html</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



12.	<p>Is your consent process culturally appropriate?</p> <ul style="list-style-type: none"> <li>Consider discussing the consent process with your informed local partner.</li> <li>Contact your WU International Research HRPO Partner for advice and guidance on different consent processes that may be used.</li> <li>Build in flexibility</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	<p>Have you built in flexibility into your research protocol?</p> <ul style="list-style-type: none"> <li>For example, if you plan to interview participants in several places and not just a single location, be sure to describe all options.</li> <li>Use the term “may” if one or more study procedure could be used. Be sure to ask your International Research HRPO Partner for suggestions if the “normal” process makes implementing the research too difficult or culturally inappropriate.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	<p>If you are student, have you identified your WU Faculty Sponsor?</p> <ul style="list-style-type: none"> <li>Please review the following with your Faculty Sponsor: <ul style="list-style-type: none"> <li>All research team members, including your Faculty Sponsor, must have CITI human subjects training in order to be added to the research team in myIRB.</li> <li>This can cause delays if you or your Faculty Sponsor has not completed this training.</li> <li>If non-WU individuals will be participating in the research, it is the PI’s responsibility to develop appropriate training for the participating non-WU staff. For non-exempt research, this training should be described in the myIRB application.</li> <li>The Faculty Sponsor is ultimately responsible for overseeing the research you are conducting. It is highly important that you make arrangements (and document them) to review your research records with your Faculty Sponsor.</li> </ul> </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	<p>Have you thought about your research documentation?</p> <ul style="list-style-type: none"> <li>It is very important that you document what you do, when you do it, and with whom it is done with. It is also equally as important to document when something cannot be done and why.</li> <li>Good research documentation includes maintaining records of all data and observations pertinent to the research and the research subjects. These records should be verifiable and record the original source the information was recorded from.</li> <li>Research documentation should be <b>ALCOAC</b>: <ul style="list-style-type: none"> <li><b>A</b>tributable – can you tell who wrote or performed the study procedure or observation?</li> <li><b>L</b>egible – can you read it, are all pages present etc.?</li> <li><b>C</b>ontemporaneous – Is the data current and collected within the correct time frame? For example, a notation recorded in the research record should be signed and dated by the person making that notation at the same time.</li> <li><b>O</b>riginal – and if not an original, an exact certified copy of the original. A <b>certified copy</b> is a copy of original information that has been <b>verified</b>, as indicated by a <b>dated signature</b>, as an exact copy, having all of the same attributes and information as the original.</li> <li><b>A</b>ccurate – real representation of fact. The consent should precisely reflect the event</li> <li><b>C</b>omplete – Research documentation should be completed to the fullest extent and should explain any discrepancies, missing, and/or incomplete data. <ul style="list-style-type: none"> <li>Always remember...If it’s not documented, then it did not happen.</li> </ul> </li> </ul> </li> <li>The Human Subjects Research Website maintained by the Office for the Vice Chancellor of Research provides forms and templates that you can use to document your research: <a href="https://research.wustl.edu/topics/human-subjects-research/">https://research.wustl.edu/topics/human-subjects-research/</a></li> <li>Contact the Human Research Quality Assurance Program for additional resources or research documentation support. <a href="mailto:HRQA@wustl.edu">HRQA@wustl.edu</a> or +1 314-747-5525</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16.	Have you consulted the WU policies about taking data or research materials with you if/when you may permanently leave WU for a job at another university?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	<p>Additional Considerations to think about:</p> <ul style="list-style-type: none"> <li>Does the trial need to be registered at <a href="https://clinicaltrials.gov">clinicaltrials.gov</a>? <ul style="list-style-type: none"> <li><a href="https://research.wustl.edu/clinical-trials-registration-guideline/">https://research.wustl.edu/clinical-trials-registration-guideline/</a></li> </ul> </li> <li>Are there regulations regarding the import of pharmaceuticals and/or medical devices?</li> <li>Are there regulations regarding the export of biomedical samples (especially potentially infectious material)?</li> <li>Are there any specific regulations regarding the use of local laboratories to perform clinical lab testing?</li> <li>Are there any specific regulations regarding use of diagnostic imaging?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	<p>Is your research federally funded? If so, the consent form should include a “Key Information” section if it is more than four pages in length.</p> <ul style="list-style-type: none"> <li>Refer to the HRPO Research Guide for information on how to write the Key Information section: <a href="https://sites.wustl.edu/hrpo/guidance-3/research-guide/">https://sites.wustl.edu/hrpo/guidance-3/research-guide/</a>.</li> <li>Key Information templates are available on the attachments page of your draft myIRB application.</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
19.	<p>Is your research federally funded by one of the <a href="#">Public Health Services Agencies</a> (PHS)? If so, describe the protections of the Certificate of Confidentiality (COC) in the consent form.</p> <ul style="list-style-type: none"> <li>The template language is found in the consent templates available on the attachments page of your draft myIRB application.</li> <li>The use of a document separate from the consent form is also an option. Contact your International Research HRPO Partner: Erin Higgs (<a href="mailto:ehiggs@wustl.edu">ehiggs@wustl.edu</a>) or Mitchell Saulisbury-Robertson (<a href="mailto:saulism@wustl.edu">saulism@wustl.edu</a>) to obtain a copy of the COC separate document.</li> <li>For more information on the applicability of a COC to your study see: <a href="https://research.wustl.edu/cocs/">https://research.wustl.edu/cocs/</a></li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	

# Research Conduct

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## **THE RESEARCH PROTOCOL**

### **Key Concepts**

- A protocol is a document that describes how a study will be conducted (the objective(s), design, methodology, statistical considerations and organization).
- Depending on the type of study, some sections of the protocol may not apply.

### **When is a Protocol Required?**

The IRB's electronic application, myIRB, includes questions that capture protocol-related information. However, these questions are not sufficient for all types of research. A separate research protocol is required for;

- All research studies that require initial review by the convened WU IRB.
- Multisite research studies relying on the WU IRB as the single IRB (WU sIRB).
- All request-to-rely (RTR) submissions for research studies that will rely on an external IRB.

### **What Information is Included in a Protocol?**

A research protocol should include the following sections:

#### **Background & Rationale**

- Provide a concise summary of what is already known about the topic under investigation and include references to prior research.
- Include essential background information explaining why this study is being performed.
- Include the scientific justification for the conduct of the proposed research?

# Research Conduct

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- What is the scientific justification for the exposure of human participants to the risks of the study?
- Provide sufficient justification for the inclusion of any vulnerable populations. Vulnerable populations can include, but are not limited to, children, pregnant women, fetuses, neonates, prisoners and decisionally impaired individuals.

## Investigational Agent, if applicable

- Include preclinical and clinical data
- Provide rationale for dosing of the agent or any other treatment plans

## Objectives

- Describe the aims and objectives of the research study. This includes all objectives; primary, secondary, and exploratory.
- Include the research question(s) or hypotheses.

## Participants

- Describe the population from which the participant sample(s) will be drawn.
- Include the inclusion and exclusion criteria that will be followed.
  - Note: the eligibility criteria may not exclude individuals based on gender, or ethnicity without a scientific rationale justifying any exclusions.
- Be sure to describe all participant groups including;
  - Control populations (as well as historical control populations assessed through the use of existing data or specimens even if under a waiver of informed consent)
  - Proxies who are individuals who will be asked to provide information about the enrolled participant. (e.g., teachers or parents providing information about a child participant's behavior).
  - 3<sup>rd</sup> parties who are other individuals that the main participant may provide information about to the research team. (e.g., family members).

# Research Conduct

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## Recruitment

- Provide a detailed description of the recruitment process including;
  - How participants are identified (including any existing sources of information that will be accessed for this purpose),
  - How initial contact is made with potential participants and by whom.
  - Use of social media or other communication platforms.
  - Use of any mobile devices, software platforms or 3<sup>rd</sup> party vendors.
  - Where recruitment will occur (where conversations or contact with participants may take place), and
  - What recruitment materials may be used
- Account for all participant populations, including any control populations.

## Consent and Assent Processes

- Provide a detailed description of the consent process including;
  - Who will be obtaining informed consent, where the consent process will take place, and when it will occur.
  - Materials used to facilitate the consent process.
    - This includes the use of social media or other communication platforms.
  - Describe the use of any mobile devices, software platforms, or 3<sup>rd</sup> party vendors.
  - The method for obtaining consent (e.g., will signed consent be obtained or will the study use a verbal consent process).
    - Where eConsent is used to obtain an electronic signature, describe how the eConsent will be presented to participants, how their questions will be answered, and how the participant will receive a copy of the final, signed consent.
  - How coercion and undue influence will be avoided.
- Account for all participant populations, including any control populations.
  - This includes populations enrolled under a waiver of consent.

# Research Conduct

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- For studies that enroll children, address how parental consent will be obtained.
  - Additionally, the assent plan must be described.
- For studies that enroll adults with limited decision-making capacity, address how consent will be obtained from the legally authorized representative.
- For studies that limit the time participants have to consider participation, justify the time limit.

## Study Procedures

- Describe in detail all research procedures that participants will be asked to complete. This includes any screening procedures that participants consent to complete through the end of the follow-up period.
  - Note: Any procedure that is dictated (the nature of the procedure, the timing of the procedure, the frequency of the procedure, etc.) by the protocol is a research procedure.
- When information is not obtained directly from participants, specify the source of the information.
- Research procedures include;
  - Interventions and interactions that will be prospectively performed on/with participants.
  - The collection of information or biospecimens from existing sources (e.g., obtaining information from a participants' medical record or obtaining biospecimens obtained during clinical care that would otherwise be discarded).
- If the study has multiple populations, this section must account for any procedural differences between populations.
- Randomization, cross-over, blinding or wait-list schemes.
- The description should include the number of study visits and their expected duration as well as where study visits will take place.
- For studies that involve the collection of biospecimens, the testing that will be performed for research purposes.

# Research Conduct

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- Describe any use of the following:
  - Social Media
  - Use of electronic survey platforms or any other electronic software platforms
  - Use of mobile or other electronic devices, as well as the use of any 3<sup>rd</sup> party vendors
  - Use of artificial intelligent, including but not limited to machine and deep learning algorithms.

## Risks and Benefits

- Describe all reasonably foreseeable risks associated with the research procedures and the steps taken to minimize these risks.
  - The risks of all research procedures should be included, not just those associated with the intervention or interaction under study.
- Include a description of potential benefits both to the individual participant as well as society.
- If applicable, include information about adverse events, serious adverse events including;
  - The definitions of such events
  - How events are to be reported, to whom, and the timeframe for reporting
  - How events are reviewed and by whom (the PI, a medical monitor, a data safety monitoring board).

## Statistical Plan

- Provide a description of the statistical/analytic methods to be used to address the research question(s).
- Provide a rationale or power analysis in support of the number of participants proposed to complete this study.

## Record Keeping

- Describe the confidentiality and security plans in place for research data and/or biospecimens.
- Describe the record retention requirements

# Research Conduct

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## Study Monitoring & Auditing

- Include a description of plans for the internal monitoring of research data.

## Study Management & Administration

- Provide a description of the overall organization of the research study and personnel including;
  - Identification and roles of participating sites.
  - Identification and responsibilities of the coordinating center
  - Communication between sites
- Identification and responsibilities of study committees (e.g., steering committees).
- Outline timeline for the study
- Describe training requirements for research team members.

Additional information (or protocol sections) may be necessary depending on the nature and design of the research study.

## **Protocol Templates**

HRPO has two protocol templates available for use. Researchers are not required to use these templates as long as the submitted protocol includes the necessary information previously described.

[Protocol template for studies involving a Drug or Device](#)

[Protocol template for studies that do not involve a Drug or Device](#)

The NIH also has protocol templates available for different study designs including clinical trials, observational research, and analysis of existing data or specimens.

<https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials>



# Research Conduct

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## **The Site-Specific Protocol Addendum**

The IRB approved protocol must describe the research as it will be conducted. A revision to the protocol is required when the research team needs to perform activities outside of those permitted by the IRB approved protocol.

There are times when the research team is unable to/does not plan to follow a certain section of the protocol but they are not able to modify the protocol because it is written or managed by a coordinating center or an industry sponsor. In these cases, a Site Specific Protocol Addendum is required.

The Site Specific Protocol Addendum documents what section (s) of the protocol will not be followed as written and what alternative the research team will implement.

Examples of when a Site Specific Protocol Addendum is required:

- The protocol does not allow for the inclusion of adult participants with limited decision making capacity, by the research team wants to enroll these individuals into the study.
- The protocol requires a fresh biopsy to confirm eligibility, but the study team intends to accept archived biopsy tissue, if available.

In addition to the addendum itself, approval from the entity that manages the protocol is required. Emails are acceptable documentation. The communication must clearly identify the individual that is representing the entity and that they approve of the content outlined in the addendum.

Provide both the addendum and documentation that the addendum was approved by the entity managing the protocol as part of the IRB submission.

[Site specific protocol addendum template](#)

# Consent and Assent

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## **INSTRUCTIONS FOR SIGNATURE LINES**

The research participant (or parent/legal guardian/legally authorized representative) *provides* consent. The member of the research team who explains the research to the participant *obtains* informed consent.

When the IRB requires documentation of consent:

- Read the IRB meeting minutes (if applicable) and approval documents for signature requirements as determined by the IRB.
- The consent document should only include those signature blocks appropriate for the IRB approved consent process(es).
- Signature blocks may NOT be altered in anyway.

### **Parental Signature Requirements**

Consent is a legal concept and only legally competent adults can give informed consent. A child is an individual who has not reached the legal age of consent as determined by the State where the research is taking place. Since children are unable to consent for themselves, permission must be obtained from the parent(s).

The Federal regulations require IRBs to review the research and make regulatory determinations based on the risk and benefit of the research interventions. These regulatory determinations determine whether one parent signature or two parent signatures are required for participation.

### **One versus Two Parent Signatures**

The determination for the number of parent signatures required is made by the IRB.

# Consent and Assent

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## One parent signature

One parent signature is usually sufficient for research that only involves minimal risk procedures or interventions. However, the IRB may determine that both parents are required.

One parent signature is also usually sufficient for research that involves greater than minimal risk procedures or interventions if there is benefit for the child.

Examples of studies that ***typically*** require one parent signature:

- A study where procedures involve asking participants to complete questionnaires.
- A study that only involves a behavioral intervention.
- A study where procedures involve blood draws and non-invasive imaging.
- A study using an investigational drug to treat a child's medical condition.

## Two parent signatures

The IRB has the ability to require two parent signatures in any study.

Two parent signatures are required by regulation when risks are more than minimal and there is no prospect of direct benefit to the child. In addition

- The risk must represent only a minor increase over minimal risk
- The intervention must be commensurate with the procedures or monitoring they would normally experience in their particular situation.
- The research must be expected to provide vital knowledge or understanding of the child's condition or disorder.

Examples of studies that ***typically*** require two parent signatures:

- A study that involves a research biopsy, but where the biopsy results will not be used in the child's care, but rather to obtain knowledge about the condition being studied.
- A study involving MRI scans with contrast agents, where the MRI and contrast are being done for research purposes only to obtain information about the condition being studied.

# Consent and Assent

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The IRB requirement for parent signature is documented in the approval memo in the myIRB system or on the minutes documents attached in the myIRB system.

## **The IRB meeting minutes for my study say I was approved for both a one and two parent signature. What does this mean?**

There may be different parental signature requirements for different participant populations within the same research study. In some scenarios, the IRB may indicate certain aspects of the study, specific procedures or certain groups, require two parents, while others only require one. The meeting minutes will clearly indicate this and explain when one or two signatures are required.

Some examples of this include:

- A study where the procedure(s) the IRB deem to require two parent signatures are optional. For example, the IRB determines a biopsy requires two parent signatures, but the biopsy is an optional part of the study. The IRB may require two parents for anyone who agrees to the optional part, but only one parent for anyone that does not agree to the optional part.
- A study where there are two groups of participants and only one group is determined to have procedure(s) requiring two parent signatures.

If the IRB determines that your study requires two parent signatures, you must obtain a signature from both parents of the child.

# Consent and Assent

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## How to Handle Only One Parent Being Available in a Study Requiring Two Parent Signatures

If your study requires two parent signatures, both parents must provide their written signature for their child to enroll into the research study. Two parents are required to sign unless one is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child.

If only one parent is present/available at the time you are attempting to obtain consent, and the other parent does not fall into one of the exceptions above, the participant cannot be enrolled until both parent signatures are obtained.

Examples on how to handle this scenario:

- Schedule consent when both parents are physically available.
- If only one parent can ever be physically present at a time, send the consent form home and discuss the study via phone. The parents can sign the consent form and send it back. No research activities can take place until the signed consent form has physically been received by the study team.

## When is a Parent Considered Not Reasonably Available?

“Not reasonably available” does not mean that the parent just is not at the appointment that day, has a busy work schedule, only one parent ever comes to the appointments, etc. If the parent can be contacted to discuss the study, then they are considered reasonably available.

Examples for when a parent is considered “not reasonably available”:

- A parent being absent due to overseas military service.
- A parent is incarcerated.

# **Consent and Assent**

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## **Using the Signature Lines for Assent**

In many instances, the IRB will require an assent process for the minor participants. The consent document may be used to obtain written assent only if the minor participant is of the age and maturity to be able to read and understand the information found in the consent document. If that is the case, the minor and the parent(s)/guardian may sign the same consent document. The minor should sign on the participant line of the consent document to document written assent.

Signature lines/boxes may not be added to the consent form to document a verbal assent process.

## **Decisionally Impaired Adults**

The consent document for studies involving individuals that are decisionally impaired will include a signature line for the legally authorized representative. In addition to this signature line, instructions on who should sign as the legally authorized representative will populate. These instructions should not be deleted from the consent document.

# Consent and Assent

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## Hearing Impaired Adults

An individual who is hearing impaired may be entered into the study using the following procedure:

- The individual must have the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study.
- A witness should be present during the consent process. The witness should not be a member of the research team.
- If the individual uses sign language as their usual method of communication, a sign language translator must be used.
  - The translator should not be a family member.
  - For complex studies or studies that involve medical terminology the translator must be qualified to communicate this information.
  - Documentation of the translator's qualifications should be included in the research record.
- If the individual does not normally use sign language for communication, a translator is not required.
  - If the study is complex or involves medical terminology and concepts the investigator is responsible for making a determination as to whether or not the individual understands the consent information and is able to have questions answered completely.
- The witness should sign and date the signature page below the signature blocks and include a written attestation stating:
  - that they witnessed the consent process;
  - that the individual agreed to participate in the research study.
- The person obtaining consent should document on the consent document the method used for communication with the individual.
- These documentation requirements and the witness signature may also be documented as a note to file in lieu of writing this information on the consent document.

# Consent and Assent

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- The research team should ensure that there is continuing support available to the participant to communicate information in the consent document such as: ongoing involvement in the study, potential risks and contact information for both the investigator and the Human Research Protection Office.

## **Visually Impaired Adults or Adults who Cannot Read**

An individual who is visually impaired (legally blind) or who cannot read may be entered into the study if the following are true:

- The individual retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study;
- The individual is able to indicate their approval or disapproval to enter into the study.

If the individual can “make their mark” on the consent document this would be considered a valid signature as long as they are competent to consent for themselves.

If the individual cannot “make their mark”, the following procedure should be used:

- A witness should be present during the consent process. The witness should not be a member of the research team.
- If the individual is unable to sign the consent document, the person obtaining consent should document on the consent document the specific means by which the individual communicated agreement to participate in the study.
- The witness should sign and date the signature page below the signature blocks and include a written attestation stating:
  - that they witnessed the consent process;
  - that the individual agreed to participate in the research study; and
  - what method of communication the individual used to demonstrate agreement.



# Consent and Assent

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- These documentation requirements and the witness signature may also be documented as a note to file in lieu of writing this information on the consent document.
- The research team ensures there is continuing support available to the participant to communicate information in the consent form such as: ongoing involvement in the study, potential risks and contact information for both the investigator and the Human Research Protection Office.

## **Adults who are not able to Physically Sign the Consent**

An individual who is not able to sign the consent document due to a physical impairment (e.g. amputations, paralysis, intravenous lines that restrict the ability to sign) may be entered into the study if both of the following are true:

- The individual retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study, and
- The individual is able to indicate their approval or disapproval to enter into the study.

Note: If the individual can “make their mark” on the consent document this would be considered a valid signature as long as they are competent to consent for themselves.

# Consent and Assent

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If the individual cannot “make their mark,” the following procedure should be used:

- A witness should be present during the consent process. The witness should not be a member of the research team.
- The person obtaining consent should document on the consent document the method used for communication with the individual and the specific means by which the individual communicated agreement to participate in the study.
- The witness should sign and date the signature page below the signature blocks and include a written attestation stating:
  - that they witnessed the consent process;
  - that the individual agreed to participate in the research study; and
  - what method of communication the individual used to demonstrate agreement.
- These documentation requirements and the witness signature may also be documented as a note to file in lieu of writing this information on the consent document.

## **Witness Signature Line**

A witness signature line is allowed only when specifically required by the IRB.

# Consent and Assent

## **INSTRUCTIONS FOR WRITING A CONSENT FORM**

### **Key Concepts**

- Use the consent templates available in the *myIRB* system to facilitate an efficient and consistent process and ensure compliance with federal regulations
- Wait until you've completed the *myIRB* application before generating the consent template as your answers will help to populate text into the consent form.
- Your consent form should be written in language understandable to the subject.
- To revise currently approved consents download the approved document from *myIRB*, use tracked changes in the document, and upload back into *myIRB* as the next version of the existing documents. Do not upload as a new consent document.
- HRPO does not permit use of consent addenda – instead, the regular consent form should be modified to contain the new information.
- Templates in *myIRB* include additional text for special situations such as enrolling children or cognitively impaired participants, describing conflicts of interest, and description of future use of specimens or data.
- The federal regulations require additional research protections for the enrollment of pregnant women and fetus into a research study.
- Unless your study is approved by the IRB for the inclusion of pregnant women and fetuses, you may not collect identifiable research data on pregnant individuals.
- A template pregnancy data collection consent form is available as an attachment in *myIRB*.
- If a sponsor requires pregnancy reporting within a 24 to 72 hour time frame and requires significant detail related to the pregnancy, please consider having a pregnancy data collection consent form approved by the IRB when you first submit your protocol.

# Consent and Assent

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**Tip** If your study protocol requires you to collect information on a participant or participant's partner who becomes pregnant, and the timeframe for reporting to the sponsor is short (i.e. within a few days), you may want to consider seeking approval for pregnancy data collection prior to any participants or partner's becoming pregnant.

## Making Your Consent Easy To Read

### DO

- Find someone unfamiliar with your study to read your draft consent prior to submission. A person who is representative of the population you will enroll would be an ideal reviewer.
- Use at least a 12-point font, a serif font, and as much “white space” as possible. Use larger size type if your population might have low vision.
- Write the consent as though you were speaking to the person who will read it using “you” and “your” rather than third person.
- Use language that can be understood by a junior high student.
- Put technical jargon into lay terms (e.g., describe the purpose of your study using lay language rather than copying and pasting your study abstract; use “cancer” rather than “carcinoma”).
- Clearly define complicated terms (e.g., randomization means the study treatment you'll receive will be decided by chance, like flipping a coin).
- Use bulleted lists rather than long sentences.
- Add additional headings and subheadings as appropriate to the *myIRB* template.
- Use tables and charts to explain when/where each procedure will take place as appropriate.
- Use pictures and diagrams to help describe devices or other information.
- Use the page numbering that is already provided in the templates. Note: the first page does not contain a page number.

# Consent and Assent

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## DON'T

- Provide technical information that participants don't need to know (e.g., complicated methods of determining drug doses, exhaustive lists of specific lab tests). The participant will retain more information if it is presented in a conversational tone.
- Add duplicative language that provides the same information that is already contained in the *myIRB* template.
- Revise template language. The consent template indicates area that the research team is expected to revise. Do not revise other parts of the template.
- Revise the HIPAA language. This language has been vetted and approved at the institutional level and cannot be changed.
- Revise the “stamp” in the upper right corner of the consent document or the insert your own date in the signature sections. This information is computer generated and editing this is considered noncompliance.
- Use “marketing” language.

# Consent and Assent

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## **Version Numbers, Headers, Signature Blocks, And Standard Language**

### **Version Numbers**

For record keeping purposes and to document which consent form a participant has signed we strongly encourage the use of version numbers for the consent form. This also helps you keep track of the current IRB approved version of the consent form. The version number can be placed in the footer of the document. Note: The template consent has a different footer on page 1 from the rest of the document. If you use a version number in the footer you will need to remember to change it in BOTH footers with every modification.

### **Titles**

If there are multiple consent forms within a study include a title on the first page of the consent form to differentiate the documents. For example the titles could be:

Informed Consent Document – Patients

Informed Consent Document – Healthy controls

### **Signature Blocks**

The signature blocks in the consent templates should not be modified in any way. The consent form will populate signature blocks based on how the application is completed. For example, if the study involves children or decisionally impaired individuals, signature blocks appropriate for these populations will be generated.

# Consent and Assent

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## **Standard Language**

The consent template will auto-populate study specific language depending on how you answer the questions in the *myIRB* application. Some examples include language describing: use of social security numbers, audio or video recordings, and future use of data/tissue/blood.

You should always generate the consent template after completing the application to ensure all required information populates to the document. Copies of consent templates should not be saved outside of the system for future use. A hard copy of the consent template with all possible language is available upon request.

## **Revising Your Consent Form**

When modifying an already approved consent form, all revisions should be reflected in track changes. Consent forms with colored highlights or comments (balloon or inline) will not be accepted.

If you want to provide additional information related to consent revisions when submitting the modification include your comments within Section XIV of the modification form. If you want to comment on the changes required by the IRB use the comment box located in the workflow.

## **Consent Addenda**

Federal regulations governing the consent form (45 CFR 46 and 21 CFR 50) outline certain elements that must be included in the consent form. Therefore, information that is considered a required element of consent will not be accepted in an addendum instead. Any information you want to put in an addendum should be incorporated within the body of the actual consent form.

# Consent and Assent

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## **Consent Forms For Studies With Minors**

Do not use “you/your child,” in the consent form. Instead use the word “you.” The consent template includes the following box on the first page of the consent when the study will include children:

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word “you” in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word “you” in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate. *NOTE: These two sentences should be deleted if the minor participant will not read the consent form itself.*

The consent form should be written in terms understandable to the population who will read it. Often it may be more appropriate to use an assent form for younger children or those with limited cognitive capacity.

## **Consent Forms For Adults Without Capacity To Consent**

The consent template includes the following box when the study will include adults who do not have the capacity to consent:

- If you are the legally authorized representative of a person who is being invited to participate in this study, the word “you” in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

The consent form should be written in terms understandable to the population who will read it. Often it may be more appropriate to obtain verbal assent from participants who do not have the capacity to consent.



# Consent and Assent

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## **Participants Or Partners Who Become Pregnant During Study Participation**

### **How to Collect Pregnancy Data**

This section is describing scenarios where a study is not enrolling pregnant women, but if a participant or their partner becomes pregnant during participation, and the study would like to collect data on the pregnancy and/or its outcome. This is typical in drug or device studies where the sponsor excludes pregnant women from the main study, but wants to collect data on the effects of the drug or device on pregnancy if a pregnancy occurs.

The federal regulations involving human subjects include specific protections for pregnant women and fetuses. Therefore, the regulations related to the inclusion of pregnant women or human fetuses will need to be met in order to enroll and collect data on a pregnant participant or pregnant partner of a participant. Since investigators would be obtaining private information from the pregnant participant/partner, the participant/partner is considered a subject in the research and should be consented for this additional data collection.

### **What do I do if I want to collect data on a participant or partner who becomes pregnant during their participation?**

You must obtain consent, using a specific pregnancy consent form that is approved and stamped by HRPO, from the individual who is pregnant (either the participant in the main study or the participant's partner).

Your study must be approved to enroll pregnant women and minors (to account for the infant).

### **When do I obtain consent for pregnancy data collection?**

This consent cannot be obtained until the participant/partner becomes pregnant (meaning you cannot obtain consent to collect pregnancy data prior to someone becoming pregnant).

# Consent and Assent

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**Can I just include a statement in the main consent form that we will collect pregnancy data if it occurs, instead of using a pregnancy consent form?**

No. While you are allowed to include a statement in the main consent form that you will/may want to collect pregnancy data if pregnancy occurs, this is solely to inform the participant that if pregnancy occurs you would be asking to collect data.

**What type of consent form do I use?**

HRPO has a template pregnancy consent form that should be used which can be found on the Attachments page in *myIRB*.

Documents such as “information sheets”, “release forms”, etc. are not allowed to obtain consent.

# Consent and Assent

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## When to Have a Pregnancy Consent Form Approved

The pregnancy consent form and data collection must be approved prior to collecting data. The study team should take into consideration the timeframe the sponsor requires in terms of providing pregnancy data to the sponsor.

Scenarios where it may be appropriate to have pregnancy data collection approved prior to anyone becoming pregnant:

- the sponsor requires you to send information regarding a pregnancy within a short time frame (i.e. 24 hours, 72 hours, etc.), and it is more detailed information than simply telling the sponsor that the participant or partner is pregnant
- you anticipate the participant population includes individuals who are likely to become pregnant

Scenarios where it may be appropriate to wait to have pregnancy data collection approved until someone becomes pregnant:

- the sponsor does not require detailed or identifiable information when the pregnancy is initially reported
- the participant population includes individuals who are unlikely to become pregnant

If you submit a modification to add pregnancy data collection, it will still be subject to the same timeframe as any other modification and will not be approved more quickly just because the study did not request approval until a pregnancy occurred.

While you may want to wait to have pregnancy data collection approved until after your study is initially approved, it may be a good idea to submit a modification after approval, prior to anyone becoming pregnant, to ensure you do not have any problems with time frames.

# Consent and Assent

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## **KEY INFORMATION**

### **What Is “Key Information” In The Context Of A Consent Form?**

Under 2018 Common Rule requirements, informed consent documents must begin with a “concise and focused presentation of key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.” (45 CFR 46.116(a)(5)(i)).

The key information section of a consent form should be included at the beginning of the consent document.

### **When Is A “Key Information” Section Required In A Consent Form?**

A key information section must be included in the consent document for any study that meets both of the following:

- ✓ Is being conducted under the 2018 Common Rule
- ✓ Has federal funding

Studies are conducted under the 2018 Common Rule if originally approved on or after 1/20/19 (the implementation date for the 2018 Common Rule) or if the research team would choose to transition the study to the 2018 Common Rule as part of a continuing review application.

Studies that are not federally funded are not required to include a key information section, but may choose to do so voluntarily.

Approved studies without a key information section will be required to add a key information section if and when either scenario below is true:

- ✓ A federally funded research study previously conducted under the pre-2018 Common Rule transitions to the 2018 Common Rule during the continuing review process (and is actively using the study’s consent form either for new enrollment or re-consent of existing participants).

# Consent and Assent

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- ✓ A study without federal funding conducted under the 2018 rule submits a modification to add a federal funding source.

When a key information section is required, the section must be added to the beginning of the study's consent form.

Consent forms that are four pages or less in length (excluding the signature blocks) prior to the addition of a key information section are considered to meet the requirements of a concise and focused presentation of the key information. A separate key information section is not required. The standard font size and spacing of the consent form cannot be altered to reduce the length of the consent form.

Consent forms that cover screening activities only and will be followed by a separate consent for participation in the main study do not require a key information section, even if the study is federally funded or supported.

## **How Do I Write A “Key Information” Section?**

The IRB has made available a variety of key information templates. These templates are available in myIRB on the attachments page located in the same drop down menu as the consent form templates.

Scroll through the key information document to select the template most appropriate for your study type.

Once the template has been populated with your study specific information it should be copied and pasted into the study consent document where indicated.

Use of a key information template is not required. In most cases, the points listed below will be the most appropriate information to include.

- ✓ The fact that consent is being sought for research and that participation is voluntary

# Consent and Assent

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- ✓ The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
- ✓ The reasonably foreseeable risks or discomforts to the prospective subjects
- ✓ The benefits to the prospective subject or to others that may reasonably be expected from the research
- ✓ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

Additional information may be included in the key information section. However, if any points listed above are not included, a justification must be provided as to why the omitted information is not necessary. The exception is alternative procedures or courses of treatment. If this element of consent is not required to be included in the main body of the consent (e.g., the study is not a treatment trial) it may also be omitted from the key information.

It is not necessary to list every foreseeable risk, benefit, and alternative. Rather, the key information section should focus on the risks, benefits and alternatives that are most likely to be of importance to a potential participant in weighing whether to participate in a research study.

Statements made in the key information section should not be repeated in the rest of the consent. Exceptions to this include:

- ✓ The risk section. While the key information section should focus on those risks most likely to be of importance to a participant, all risks should be included within the consent form's designated risks section.
- ✓ HIPAA authorization language. Both the standard HIPAA authorization language and language permitting email/text messaging must be included within the consent form in their entirety.
- ✓ Injury language. The injury language must be included within the consent form in its entirety.

# Consent and Assent

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- ✓ The IRB's future use language. While the key information section may include information about future use and sharing, the consent form should include the future use section in its entirety.
- ✓ Whom to contact with questions. This section of the consent form should be included within the consent form without change.

Key information sections for optional substudy consent forms (where there is a separate consent from the main study) should focus on information specific to the substudy. Information about the research study, found in the main study key information section, does not need to be repeated within every substudy consent form. The key information for the substudy should include:

- ✓ That the substudy is for research purposes and whether the participant may remain in the main study if they decline to participate in the substudy.
- ✓ The purpose of the substudy and information about procedures unique to the substudy.
- ✓ Reasonably foreseeable risks or discomforts unique to the substudy.
- ✓ Whether the substudy alone may result in benefit to the participant or others separate from any potential benefits identified in the main study.
- ✓ Appropriate alternative procedures or course of treatment, if any, that might be advantageous to the prospective subject (specific to the substudy)

Additional information may be added to the key information. If all elements listed above are not included in the key information a justification must be provided.

# Consent and Assent

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## **ELECTRONIC INFORMED CONSENT (eIC)**

### **What Is eIC?**

eIC uses an electronic format to provide information about a study to a potential participant and to document the consent of the participant or their legally authorized representative (LAR). An eIC contains the information usually found in a paper consent and must include the required elements of consent in language and format understandable to the participant. REDCap and DocuSign are the preferred methods for eIC. Other methods will be considered on a case by case basis.

### **Why Would A Research Study Use eIC?**

Electronic consent may facilitate the participant's understanding of the research study by providing an interactive interface and user-friendly format. The electronic process can facilitate documentation and storage of consents, tracking of consent versions, and communication with participants about consent modifications. In addition, eIC allows efficient consenting of participants in remote locations.

### **Which Studies Are Eligible For eIC?**

Any study that uses informed consent is eligible to use eIC, either in lieu of, or supplementary to, traditional written informed consent, as long as certain conditions are met. An important consideration is whether the eIC needs to be conducted in a manner compliant with 21 CFR Part 11, the set of FDA requirements that apply to electronic records and electronic signatures and to the electronic systems used to create, modify, maintain, archive, and transmit them. Any study that is being performed under an IND, IDE, is a non-significant risk device (NSR) determination, or will submit data to the FDA for a marketing application or labeling change can use eIC only if it is compliant with 21 CFR Part 11. Studies that are not subject to FDA regulations may use eIC that is not Part 11



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compliant, if other conditions are met (see below). For any study, IRB review and approval of the eIC format and process is required.

## **What Are The Necessary Components Of eIC?**

- The participant must have adequate time to review the consent, and there must be a mechanism to allow the participant to ask questions of the study team.
- There should be a time stamp on the participant's signature.
- The participant needs to receive a copy of the signed consent, either a hardcopy or an electronic file.
- The study team needs a mechanism to track consent version and to re-consent participants as needed when the consent form changes. (Note, all consent changes require IRB approval.)
- Appropriate technical securities must be in place to protect the confidentiality of the participant's information.
- 21 CFR Part 11 compliance will require additional elements, including acceptable ways to confirm the participant's identity. At Washington University, DocuSign is the only Part 11 compliant platform at this time. The user must have a 21 CFR Part 11 DocuSign account. For more information, go to the Washington University Information Technology website <https://it.wustl.edu/items/docusign-21-cfr-part-11/>
- This is different from the standard DocuSign Account which is described at <https://it.wustl.edu/items/docusign/>

## **What Should Be Submitted To The IRB?**

The IRB must receive a copy of all consent materials in Rich Text Format (“rtf”) using one of the available consent templates. This is required even if there are no plans to obtain a signature with ink on paper. This document will be used during the IRB review process to make edits as applicable.

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## REDCap

- If REDCap is used to obtain consent, HRPO will request a link to review the draft consent document after IRB review of the consent is finalized. It is only required that you provide a link at the time eIC is being added to your study or at the time of new submissions for studies planning to use eIC. Do not send a link to the consent at the time of submission or until you are requested to by HRPO staff.
- When using REDCap to obtain consent, the consent must be prepared using the [SOP: “Using the REDCap Template to Create an eConsent”](#) accessible through BOX on the mHealth website at <https://mhealth.wustl.edu/navigation-tools/redcap-e-consent/>.
- Recordings of workshops on how to use REDCap, such as the “REDCap Workshop – The WUSTL REDCap E-Consent Template,” can be found on the Becker Medical Library website at <https://becker.wustl.edu/services/data-management-and-sharing/redcap-workshop-recordings/>
- If consent will be obtained via REDCap, the first page of the consent should include the IRB ID #, Consent Title and Version#, Date of Consent Version,, IRB Approval Date and IRB Expiration Date (if there is no expiration date put “N/A”) as described in the SOP referenced above.
- Since the approval and expiration dates are not generated until the form is approved, for the approval and expiration dates, you will confirm the placeholder reads as “MM/DD/YYYY” in the REDCap Cloud eConsent submitted to the IRB prior to using the eConsent for the first time. Please note, Dates should be formatted MM/DD/YYYY.

## DocuSign

- When using DocuSign to obtain electronic consent, the DocuSign version should be uploaded as a Rich Text Format document in Consent Attachments.

# Consent and Assent

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## Alternate Vendor

- Additional vendors will be considered by HRPO on a case-by-case basis. When use of an alternate vendor is requested, the research team should provide the following documentation for IRB review.
  - Screen shots demonstrating how the consent form will be displayed and completed by participants.
  - A review by the Washington University Information Security Office will be required. Documentation of the review outcome must be attached as part of the IRB submission. Information on how to request this review can be located at <https://informationsecurity.wustl.edu/services/irb-security-review/>.
  - For studies that require compliance with 21 CFR part 11, documentation that the vendor's platform is compliant will be required and should be attached as part of the IRB submission.
  - Based on the vendor and/or study details, additional information or documentation may be required by the IRB.

## REFERENCES

eIC guidance from the FDA

<https://www.fda.gov/media/116850/download>

Part 11 guidance

<https://www.fda.gov/media/75414/download>

For assistance creating an eIC, researchers can contact the mHealth Research Core at <https://mhealth.wustl.edu/>

# Consent and Assent

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## **PHONE SCREEN CONSENT**

### **Key Concepts**

- Screening individuals over the phone is a common recruitment practice and limits your potential participant population to only the subjects who are most likely to meet eligibility criteria.
- You can have a general discussion about a research study without obtaining verbal consent.
- However, consent must be obtained prior to asking screening questions and recording participant responses.
- Since the consent process for the screening will be verbal, the IRB will need to grant a waiver of documentation of consent.
- A full HIPAA waiver may be required if you are a part of a covered entity to record health information collected during a phone screening.

**Tip** Don't go it alone. There is a template for a phone screening consent in the myIRB system. This template is located on the Consent Document & Other Attachments page in the drop down menu.

### **When Is Consent Required For Phone Screening?**

If you are asking questions that include private identifiable information over the phone to determine if an individual meets eligibility criteria and recording this information, a screening consent is required.

If the study team is asking participants to respond verbally to eligibility questions, but not writing down the answers, consent is not required for this activity. This is because no identifiable information about the participant is being recorded or retained in the research record.

# Consent and Assent

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## **Phone Screening Consent Process**

- Consent must be obtained prior to asking the screening questions and recording their responses.
- The IRB can approve a verbal consent process if certain criteria are met that will allow consent to be obtained without a written signature.
- Keep in mind that it is only the signature requirement that is not required when obtaining consent over the phone. All of the elements of consent normally required apply but instead of providing a written document there will be a verbal discussion.

## **IRB Review Requirements For Obtaining Consent Over the Phone**

In order to approve a verbal consent process over the phone the IRB must waive the requirement to obtain a written signature. This is called a waiver of documentation of consent.

Criteria required for the IRB to waive documentation of consent for phone screening:

- The research presents no more than minimal risk of harm to participants and;
- Does not involve procedures for which written consent is normally required outside of the research context.

If you are collecting protected health information (PHI) as part of the phone screen a HIPAA authorization is required in addition to the consent.

- To determine whether you are collecting protected health information go section on the guide that covers HIPAA requirements.
- The HIPAA authorization requirements are built into our consent template for phone screening. If you are not collecting PHI delete this section from the phone screening consent.

# Consent and Assent

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- In order to allow a HIPAA authorization without a signature the IRB must determine it is not feasible to obtain written authorization for this activity. When obtaining consent over the phone for screening purposes the IRB generally determines that is the case.

# Consent and Assent

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## **CONSENT FORM**

### **Key Concepts**

- A consent form is a document that provides information about the study so an individual can decide whether they want to participate.
- Consent forms must contain certain elements of consent as defined by the federal regulations. HRPO consent templates contain these required elements.
- There are several different HRPO consent templates that you may use depending on the type of study or consent process.
- If the study is FDA regulated or being conducted in compliance with ICH-GCP, there may be additional required language

### **Tips**

- ✓ The various options for consent templates are located on the Consent Document & Other Attachments page in the drop down menu.
- ✓ If you select the option of IRB review in compliance with ICH-GCP the additional consent requirements will automatically populate in to the consent template.

# Consent and Assent

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The consent form is the document or tool used by the researcher to help facilitate the consent process. This document also provides written information that the research subject may reference over the course of study participation.

The consent form should:

- include the required basic elements of informed consent
- include additional elements of consent as they apply
- be written in language understandable to the participant
- not contain exculpatory language where the participant is made to waive or appear to waive legal rights.

Each element of consent has a purpose and contributes to a complete understanding of the research. The required elements of consent present the full scope of what the participant is being asked to do, the risks and benefits of participating, and why the research is being done. The aim of the consent form and the process of informed consent is to make sure that the potential participant understands the research fully and that they are making an informed decision based on a complete representation of the research.

Note that consent is not a single event or just a form to be signed. The process of informed consent is a clear appreciation and understanding of the facts, implications and consequences of the decision to participate in research. More on the consent process can be found in the Consent Process section of this Guide.



# Consent and Assent

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## **Basic Elements Of Consent**

There are eight basic elements of consent the must be present in the consent form.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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## **Additional Elements Of Consent**

There are also additional elements of consent that should be included as appropriate.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

# Consent and Assent

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## **Additional Consent Requirements for FDA and ICH-GCP**

Both the FDA and ICH-GCP require additional elements of consent to be present in the document.

### **FDA Requirements**

A description of the test article and whether or not the test article is approved by the FDA or is investigational.

- A statement that notes the possibility that the “Food and Drug Administration” may inspect the records. NOTE: this may NOT be shortened to “FDA.”
- For studies that require posting to ClinicalTrials.gov the following statement: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

### **ICH-GCP requirements:**

- A statement indicating Research monitors, auditors, the study sponsor, the Institutional Review Board, and other regulatory authorities will be granted directed access to the original medical record to verify the conduct of the clinical trial procedures and/or data. This access will be permitted to the extent permitted by the applicable laws and regulations without violating the confidentiality of patient information.
- For randomized treatment trials, the informed consent should include the trial treatment(s) and the probability for random assignment to each treatment.
- An explanation of "The subject's responsibilities."
- An explanation of the reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

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- A statement describing anticipated prorated payment, if any, to the subject for participating in the trial.
- A list of the alternative treatments or procedures AND any of the important potential benefits and risks of alternative treatments or procedures. If the participant can receive the same study treatment or therapy without being in the research, that must be disclosed.

## **myIRB Consent Templates**

**Informed consent (may be used for adults and as an assent document for teenagers who are capable of understanding the information presented in the document)**

The full informed consent template is the standard for obtaining research consent. The informed consent template contains standard language that clearly and thoroughly addresses all required elements of consent and HIPAA authorization (when applicable).

If there is a reason that this template does not seem appropriate for your study, such as the method of data collection or the population under study, then consider use of the other available templates.

## **Consent Information Sheet**

The consent information is used for studies where written documentation of consent has been waived. This document is written in a less formal style than the full informed consent with different formatting and can be used in a variety of scenarios such as a survey or focus group study. This template can also be used for online studies. This template has broad applications across many types of behavioral and biomedical projects that are utilizing a waiver of written documentation of consent.

The template contains HIPAA language and is appropriate for use with studies involving PHI, but only where the requirement for written HIPAA authorization has been waived.

# **Consent and Assent**

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## **Consent Letter**

The consent letter is appropriate to use in non-exempt studies where, for example, the research is taking place by mail, the study is minimal risk, and the research team will not directly interact with participants. This template is written in a conversational format and is meant to be less formal than the full informed consent. Since this template is in a letter format, its most applicable use is for studies taking place by mail. For other projects with participant interaction and a waiver of written documentation of consent, the consent information sheet may be a better fit.

The template contains HIPAA language and is appropriate for use with studies involving PHI, but only where the requirement for written HIPAA authorization has been waived.

## **Exempt Information Sheet**

This form would be used only in exempt projects. Although these projects do not require a consent process since they are exempt from the regulations, the WU IRB normally requires that some information about study participation be provided to participants. The exempt information sheet template represents the best way to present this information. If you are working on a study you believe to be exempt, and you wish to modify the exempt information sheet, contact HRPO to ask about what language can be altered/removed.

## **Phone Screen Consent**

The phone screen consent is used where participants are being screened for eligibility over the phone prior to an in-person visit, and the information will be recorded. Often it is easier to ask potential participants to provide this information by phone before asking them to come in for a visit with the study team. However, consent is required when identifiable information is being recorded about an individual. Use of the phone screen consent allows researchers to obtain consent by phone only for the eligibility screening with full consent obtained at a later time point.

# Consent and Assent

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## ASSENTING MINORS

### Key Concepts

- Assent is an affirmative agreement to participate in research from an individual who (because of their age, illness or mental status) is unable to consent for themselves.
- The IRB may approve an assent process that is conducted verbally or in writing and tailored to the age or cognitive capacity of the individual.
- Multiple assent processes may be used within the same study.
- An individual should never be asked to sign a document (consent or assent form) they cannot read and understand.
- The IRB may waive the requirement for assent if an individual is too sick, too young, or if the study offers the potential for direct benefit. If assent is waived, consent requirements still apply for the Legally Authorized Representative or Parent(s).
- An assent template is available in the *myIRB* system on the attachments page.

**Tip** If the IRB has approved an assent process, then the child or cognitively impaired person CANNOT be enrolled if they say NO – regardless of whether the parent or legally authorized representatives says YES.

# Consent and Assent

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## **Assent Definition**

Assent is an individual's affirmative agreement to participate in research.

- The IRB may require that assent be obtained from the individual if, either by age or by cognitive ability, they are not capable of providing consent.
- Assent is not a legally binding action; however, the research team must respect the decision of a child or individual with limited decision making capacity to not participate in a study (even if their parent or legally authorized representative would consent to the research on their behalf)
- Assent is only obtained if an individual actively agrees to participate. A researcher has not obtained assent just because a child or individual with limited decision making capacity does not say no.
- Assent is similar to consent in that at any point in time in the research the participant may withdraw their assent.
- Assent may be written or verbal as approved by the IRB.

## **Age Guidance For Assenting Minors**

Age guidelines for assent when enrolling minors vary based on the study population and may not be the only factor to consider when developing your assent plan. Your assent plan should be tailored based on the populations you plan to enroll.

- For example: If a study will recruit minors who are knowledgeable about their disease and the types of procedures to be performed it may be appropriate to obtain assent at a much younger age compared to a study where the minors are not familiar with what is being studied or the research procedures.

# Consent and Assent

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## **Written Assent**

Written assent is when a participant provides a written signature documenting their willingness to participate in a study. Written assent is obtained in scenarios where the participant is able to read and understand the document they are being asked to sign.

- Example: An older teen is of an age or cognitive ability to read and understand the consent form and is able to provide a written signature.
- Example: A separate assent form is created using simple language and pictures to explain the research. As long as the assent form is in language the child or individual with limited decision making capacity is able to read and understand, they may provide written assent by signing the separate assent form.

## **Verbal Assent**

Verbal assent is when an individual verbally affirms agreement to participate in the research. The individual may be given a written description of the study or a verbal description of the research. The research team documents the assent through a note to file in the research record. The consent form should not be used as a way to document a verbal consent process.

- For example: A minor or individual with limited decision making capacity is of the age or cognitive ability to read an assent form OR to have a discussion of the study with a study team member (but not be given a form to read). The individual is able to understand what the study is and what they will be doing, but will not provide a signature.



# Consent and Assent

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## Waiver Of Assent

The IRB may consider approving a waiver of consent in some situations.

Remember that only the IRB can make the decision that it is appropriate not to obtain assent.

### **Waiver of Assent: Too young, too sick or the study offers potential for a direct benefit that is only available in the context of the research study**

The IRB may approve a waiver of assent meaning the minor or individual with limited decision making capacity is not asked to assent to be in the research study. The decision to participate in the research study is made solely by the parent or legally authorized representative.

- Too young - Minors do not have the capacity to assent
  - Example: the study involves minors who are newborns or toddlers
- Too sick - Adults or minors are too sick to provide assent
  - Example: An individual is in a coma
- Research offers direct benefit and is only available in the context of the research study - Minors have the capacity to assent but there is the potential for direct benefit that is only available via the research study.
  - Example: A treatment trial that is important to the health or well-being of the minor.

### **Waiver of Assent: Children or adults with limited decision making capacity are capable of assenting**

In this scenario, the minor or the cognitively impaired adult does not provide any assent, even though they would have the capability to assent. In this option, the study must be minimal risk and additional information will be requested justifying this request. Please contact the IRB prior to submission if you are planning to waive assent in participants who otherwise are able to provide assent.

# Consent and Assent

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## **LEGAL AGE TO CONSENT**

### **Key Concepts**

- The legal age to consent isn't always 18. The legal age to consent varies by state and by country.
- Emancipated minors are not of legal age but are considered by the state to be able to consent as adults. Rules for when a minor is considered emancipated may differ by state or country.
- Emancipated minors may consent for research without parental consent.

### **Tips**

- ✓ You are responsible for knowing and understanding the laws around consenting for research in the state or in the country where your research will be conducted.
- ✓ If you are unsure whether a minor is emancipated and can consent without parental permission, please contact HRPO before enrolling this participant.

### **Determining The Legal Age To Consent**

The legal age to consent is not always 18. For example, the legal age of majority is 19 in Alabama and Nebraska. The legal age to consent may be different outside the US as well. Keep in mind, that if research is taking place in multiple states or in multiple countries, the laws for each specific state and/or country must be followed.

# Consent and Assent

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## **Emancipated Minors**

An emancipated minor is an individual who is not of the legal age of majority in a state, but is recognized as an adult by the state. The definition of emancipation differs by state.

In Missouri, individuals are considered emancipated through the court system, if they are married, or if the individual is a parent/legal custodian of a child.

An Emancipated Minor is considered an adult by the state and can consent for themselves to participate in research.

There may be some circumstances where state law allows a minor to consent for clinical care or treatment; however, it's important to note that this may not extend to research.

If you are unsure whether a minor is emancipated and can consent for research without a parent, please contact HRPO for additional guidance.

## **REFERENCES**

Missouri state law regarding emancipated minors:

Missouri Statute Chapter 211, Section 211.442-487; and Chapter 431, 431.065, Chapter 404, Section 404.410

# Consent and Assent

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## **ENROLLING PARTICIPANTS WHO DO NOT SPEAK ENGLISH**

Researchers must carefully consider the ethical and legal ramifications of enrolling participants when a language barrier exists.

- If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective. The participant should not be enrolled.
- If the participant needs an interpreter at the time of enrollment, an interpreter should be available for each subsequent visit and point of contact (for example, by phone). If not, the participant should not be enrolled.
- A qualified interpreter must have sufficient fluency in both English and the other language. For medical studies, this individual must have a high level of health literacy in both languages. Typically, this is not a family member.

### **Inclusion of Non-English Speakers is Anticipated**

When the researcher expects that the study participant population will include non-English speaking individuals, or that the consent process will be conducted in a language other than English, the IRB requires that the information is given to the participant or their representative in a language understandable to the participant or representative.

- In these situations, the consent document or information sheet must be translated by a qualified translator to the language(s) appropriate for the participants.
  - The translated document(s) must be submitted to and approved by the IRB prior to use.
  - Any other assessments or documents that the participants will read and/or complete need to be translated and submitted to the IRB for approval prior to use.
  - For convenience and efficiency, it is acceptable for a study team to provide translated versions of documents to the IRB after the IRB has reviewed the consent and deemed it acceptable.

# Consent and Assent

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- An interpreter can assist in facilitating conversations with a non-English speaking participant, however, interpretation of the consent document is not a substitute for written translation in the potential participant's language. Conversely, a participant should not be handed a translated consent document without an informed consent discussion with interpretation.
  - A copy of the translated consent document (signed and dated) or information sheet must be given to each participant at the time of consent.
- The research team should have procedures in place to communicate with the participant throughout the conduct of the study including should the participant call with questions or concerns.

## **Inclusion of Non-English Speakers is NOT Anticipated**

If a non-English speaking participant is unexpectedly encountered, the researcher should first consider interpretation and translation responsibilities. If the researcher believes it is appropriate to enroll the participant given these considerations, the consent “short form” process must be used. (see 21 CFR 50.25 and 45 CFR 46.117.)

## **How to prepare for the short form consent process**

1. Participants may only be enrolled if they speak one of the languages represented in the list of currently translated short forms on the HRPO website.
2. Identify a qualified interpreter (typically not a family member).
3. Identify a witness to the consent process.

\* The witness cannot be a member of the research team and should be fluent in both English and the language of the participant.

\*Note: If using the Barnes Jewish Hospital Interpreter and Language Services, the witness must be a different person from the interpreter. The BJH interpreter will not sign as a witness. Therefore, the interpreter does not need to be in the room. On-call interpretive service is available 24 hours a day, 7 days a week at 314-747-5682.

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## Short form consent process

1. The interpreter must verbally and exactly interpret the IRB-approved English consent document or information for the study.
2. The participant (or legally authorized representative) reads the approved "short form" written consent document, in a language the participant understands. The short form must be one provided on the HRPO website. The short form consent documents that the required elements of informed consent were presented verbally.
  - a. The participant or their representative signs the short form.
  - b. The member of the research team who obtained consent signs the English consent document.
  - c. The witness prints, signs, and dates the short form consent and the English consent underneath the signature blocks, attesting to the short form consent process.
3. Following signatures, copies of the English consent document/ information sheet and the short form consent are provided to the participant or their representative.
4. For studies that are more than minimal risk and/or involve longitudinal follow-up, the research team should submit a translated consent document/information sheet to the IRB for approval. Once approved, this document should be provided to the participant who was consented using the short form process.\*

\*Although the PI should strive to present a consent document written in a language understandable to the non-English speaking participant, this is only strongly encouraged by OHRP. It is acceptable per the federal regulations to use verbal consent with a short form and a copy of the English version consent.

## Interpreter Services:

- Washington University utilizes interpreter services provided by Barnes-Jewish Hospital.
- Language. Access. Multicultural. People. (LAMP interpreters), 24/7 interpreter services, 877-240-6398.

# Consent and Assent

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## **WAIVERS OF CONSENT**

### **Key Concepts**

- When the IRB grants a waiver of consent, no information about the study is given to participants before their participation.
- If your study involves protected health information (PHI), you also need a waiver of HIPAA authorization

**Tip** If you are requesting a waiver for collection from a data source such as medical records, prepare a listing of the data points to attach to the *myIRB* application.

To request a waiver of consent, “no consent process (waiver of consent) must be selected in myProject 1.5 in your myIRB application.

### **What Is A Waiver Of Consent?**

When the IRB grants a waiver of consent, no information about the study is given to participants before their participation. They do not know they are research participants. Sometimes waivers are granted to allow researchers to collect data or specimens from participants before the participant provides consent, but most often waivers are used when participants are never informed of their involvement in research.

# Consent and Assent

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## **Criteria For Waiver Of Consent**

The federal regulations ([45 CFR 46.116](#)) state that certain criteria must be met for the IRB to waive consent for research participation. The below table provides each criterion with an explanation of the meaning and how the criterion can be sufficiently justified.

<b>Criterion</b>	<b>Explanation</b>
The research involves no more than minimal risk to the subjects	In order to satisfy this criterion, the researcher must show that the “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects	Out of respect for an individual’s autonomy, consent should be obtained when possible. When the IRB waives consent, the IRB is removing the choice of the participant. Therefore, researchers must justify how removing the participant’s choice will not negatively affect their rights and welfare.
The research could not practicably be carried out without the waiver or alteration	Since the ability to provide informed consent respects an individual’s decision to make a choice, the researcher must justify to the IRB that it would be impossible to do the research without a waiver of consent. Typically the rationale that you need to enroll everyone or that someone might say “no” to enrollment are not valid justifications.
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	Since the application of a waiver of consent removes the ability of an individual to make a voluntary choice regarding research participation, the research team should use the information and/or biospecimens that pose the smallest risk to privacy and confidentiality.



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Whenever appropriate, the subjects will be provided with additional pertinent information after participation	Sometimes participants provide informed consent, but certain information is withheld from them until after their participation. For example, investigators may request a waiver of certain elements of consent in order to disguise the true purpose of the project and then present additional information after completion of the study.
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## **Retrospective vs. Prospective Data Collection**

A common scenario for which the IRB grants a waiver of consent is a review of existing data or specimens. This is a project where the investigator has a research question they would like to answer by querying existing data or specimen sources such as electronic medical records, previously collected research data, and banks of specimens (collected in the past either clinically or for research purposes).

Retrospective means the data or specimens are in existence at the time of IRB form submission. Data or specimens that have not yet been created at the time of IRB form submission are considered prospective and may or may not qualify to be used under a waiver of consent.

- Example: On 4/1/2017, a researcher submits an IRB application requesting a waiver of consent to review medical record data created 1/1/2015 through 12/31/2017. Only the data created between 1/1/2015 and 4/1/2017 are considered retrospective because they are in existence at the time of IRB form submission. Data created 4/2/2017 through 12/31/2017 do not yet exist at the time of submission and therefore are considered prospective.

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## Prospective Studies

The IRB may grant a waiver of consent for prospective data collection. One example is where a study involves emergency room patients where a blood draw must happen within a specific time frame in order to gather the data necessary to answer the research question. But if the patient is unconscious or otherwise incapacitated, it would not be possible to get consent before collecting the blood. In this case, consent may be waived for the time sensitive blood draw as long as consent is later obtained. If the patient does not consent to the study, the blood sample and data must be destroyed.

## Waivers Of Consent To Avoid Bias

Generally, researchers receive a waiver of consent when they cannot contact participants to ask for consent. Sometimes a researcher is using a very large data set that someone else collected and the researcher does not have access to contact information. But there are instances where other justifications are appropriate. One example is a scientific or statistical bias.

Some research questions, by nature, require every available record in order to draw meaningful scientific conclusions. This could occur in epidemiological research where an investigator needs to obtain data about every flu diagnosis at Barnes Jewish Hospital during a specific flu season. Another example is an investigator studying a very rare disease, and in order to gather meaningful information about the disease, they must be able to access data about each case because there will be so few.

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## Alterations Of Consent & Deception Research

### Key Concepts

- An alteration of consent is where one or more of the required elements of consent are not disclosed to participants.
- Deception in research occurs when
  - 1) participants are not told information about the study (passive deception) or
  - 2) they are told false information (active deception).
- When deception is used in research, participants must be debriefed after participation. Debriefing involves a discussion of how the participant was deceived and a description of any information that was previously withheld.

### Tips

- ✓ Debriefing documents must contain the IRB stamp and be uploaded in the “Debriefing Statements” category of the attachments section of the application
- ✓ Have a study design involving deception? Call HRPO for help before submitting.

# Consent and Assent

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## Alterations of Consent

An alteration of consent occurs when consent is being obtained, but one or more of the required elements of consent are waived.

Alterations of consent most often occur when it is not possible to do the research if complete information about the research is disclosed. When information is not disclosed to participants or false information is provided, this is called deception.

## Deception Research

Deception is defined as providing false or incomplete information to participants for the purpose of misleading or misdirecting them. Deception is used where the research question cannot be answered if the participant knows:

1. The true purpose of the study; and/or
2. The true nature of all study procedures.

Examples of deception:

1. Withholding the true purpose of the study
2. Withholding an explanation of one or more study procedures
3. Giving participants false information

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## Active vs. Passive Deception

Active deception is the act of providing false information to participants in order to mislead them about the research. Passive deception is the omission of information in order to mislead participants.

An example of active deception:

- A researcher is doing a negotiation study. Participants come to the research lab and are told they are completing a negotiation task with another study participant who is in a different room. However, there is no other live participant and the negotiation task is being done with a computer program.

An example of passive deception:

- A researcher is doing a memory study. The participants come to the research lab and are told they are being tested on their science knowledge. The participants read a passage and answer a set of science questions, then complete “distractor tasks” such as multiplication tables or computer games. Participants are asked to return the next day to repeat the same science questions in order to test their memory of the material.

## Debriefing

In all instances of deception, the researcher is required to provide additional information to the participants after their participation is complete. This is part of the consent process and is called debriefing. During the debriefing the researcher provides a written explanation of any information that was previously withheld and disclosure of any false information. Participants are told why the deception was necessary and are sometimes given the option to “opt out” of the study once they learn they were deceived. The “opt out” option is not always required; it is generally used in cases of active deception where there is a higher likelihood of anger or other negative feelings as a result of study participation.

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## **WAIVER OF DOCUMENTATION OF CONSENT**

### **Key Concepts**

- A waiver of documentation of consent waives the requirement for a written signature on a consent document, but the required consent information is still provided to the participant either verbally or via a written document that is not signed.
- If your study involves protected health information (PHI), you also need a waiver of HIPAA authorization.

**Tip** If you are not getting written consent for phone screening or any study procedure, select one or both of the following in *myProject* question 1.5:

- ✓ Script for use either in person or over the phone with no signature
- ✓ Letter or information sheet with no signature.

### **Waiver of Consent vs. Waiver of Documentation**

A waiver of consent means that participants will not receive any information about the study or be told they are a participant before or potentially after their participation. The waiver of documentation of consent removes the requirement for a written signature on a consent document or written materials.

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## **When Can Documentation of Consent Be Waived?**

The IRB may approve a consent process where participants consent but a written signature is not obtained. Since the written signature is required by the regulations, it may only be waived if certain criteria are met.

There are three circumstances that allow for a waiver of documentation of consent:

1. The research is minimal risk and there are no research procedures which would require written consent outside of a research setting.

This option is allowed for all research regardless of whether it is FDA regulated.

DHHS regulations can be found [here](#).

FDA regulations can be found [here](#).

Examples where this criterion may be used:

- studies involving questionnaires, assessments, or psychological tasks over the phone or online,
- a mailed survey that includes a cover letter/information sheet with all elements of consent, and returning the survey indicates consent.
- benign behavioral interventions or assessments, tasks, and economic negotiation studies in person or remotely.
- Screening for eligibility over the phone

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2. The consent form is the only document linking the subject to the research and the main risk to subjects would be if their information is accidentally disclosed.
  - This is allowed only for research that is not FDA regulated.
  - There must be no other identifiers collected or retained at any time during the course of the study – all other data must be collected and stored in an anonymized fashion.
  - This is not limited to minimal risk research.
  - If this option is used, participants must be offered the opportunity to sign a consent form.
  - Examples where this criterion may be used:
    - A researcher will obtain highly sensitive information that may put the participant at significant criminal or other risk if there were a breach of confidentiality.
    - The nature of the study involves asking participants to disclose participation in illegal activity, especially if the nature of the culture in which the study is being conducted raises the risk level for participation.
3. The participants or their legally authorized representatives are members of a distinct cultural group/community where signing consent forms is not the norm, the research presents no more than minimal risk, and there is an alternative means of documenting that informed consent was obtained.
  - This is allowed only for research that is not FDA regulated.
  - This is limited to minimal risk research.
  - If this option is used, the research team must include the alternative method for documenting informed consent in the description of the consent process in myIRB.



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## **PHI and Waivers of Written Documentation of Consent**

[HIPAA](#) applies to researchers under WU's covered entity who are using information that qualifies as Protected Health Information (PHI). If you are requesting a waiver of documentation of consent AND you are collecting PHI, the IRB will also assess whether the criteria for a full HIPAA waiver are met.

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## **GUIDANCE ON CONSENT FOR GENOMIC DATA SHARING FOR RESEARCHERS**

Consent for genomic data sharing is critical for moving forward with translational genomics and precision medicine research. Per the [NIH Genomic Data Sharing policy](#), researchers generating large-scale human and non-human genomic data, as well as other –omic datasets, are expected to share data for which consent was obtained for future research purposes.

Several issues associated with the nature of an individual’s genomic data must be considered. Specifically, genomic data

- *is personal, unique and cannot be anonymized.*
- *inform individuals about susceptibility to a broad range of conditions (some of which are unexpected given personal or family history).*
- *can be reinterpreted and change in relevance over time.*
- *raise privacy concerns (in part because of the risk of re-identification).*
- *are relevant for family members and reproductive decision-making.*
- *may be stored and used indefinitely.*

Researchers should address these considerations when designing an informed consent process and consent form for their study. The WUSTL IRB application provides templated consent language to assist researchers with these issues.

ICTS Precision Medicine at Washington University provides best practice guidance for investigators on the critical issues associated with genomic research and promotes precision medicine by facilitating the use of genomic databases on the WU School of Medicine campus. Visit the [ICTS Precision Medicine at Washington University website](#) for more information about best practice guidance or available genomic databases.

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## Frequently Asked Questions

### **Why Should I Care About Genomic Data Sharing?**

- Genomic data sharing is currently a NIH requirement for grant projects that generate human genomic data.
- Genomic data sharing maximizes the value of collected specimens and minimizes the ethical burden of risk by distributing human subject derived resources among many projects. If genomic data sharing is not undertaken, more participants will be needed to answer scientific questions and therefore more people will be exposed to risk.

### **Is Genomic Data Sharing Ethical?**

- In the majority of situations, genomic data sharing is ethical and many IRBs have guidance for crafting consent language that discloses the benefits and risks associated with genomic data sharing.

### **Shouldn't I Just Make Genomic Data Sharing An Optional Component Of My Study?**

- If you are conducting genomic research supported by federal grants, consent for genomic data sharing is required by NIH policy.
- Allowing for some participants to opt out of genomic data sharing places a responsibility on the investigator to appropriately track participants decisions on sharing of their genomic data. Violating the choice made by the participant and inadvertently sharing genomic data is an ethical breach.
- In some clinical trials when your research project has an intervention with potential direct benefit to the participants, genomic data sharing must be optional if the data includes identifiers. In those cases, some investigators choose to have a separate consent for genomic data sharing, which can make tracking easier.

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## **Will I Have A Harder Time Recruiting Research Participants If I Require Genomic Data Sharing To Participate?**

- The vast majority of participants (95%) opt-in to genomic data sharing  
See Manolio, 2006; Hartz et al., 2015.

## **What Happens If I Decide Not To Include Broad Sharing In My Research Design?**

- NIH may not fund your project.
- There are large specimen repositories at Washington University for which consent for genomic data sharing was not obtained at the time of participation. If collected after the effective date of the GDS policy, the data derived from them typically cannot be approved for sharing unless the IRB approves a process of recontacting subjects for consent.
- **If consent for data sharing was not obtained, you will not be able to share genomic data with anyone outside of the research team. The IRB will approve protocols nor be able to certify contribution of the data to repositories such as dbGaP.**

## **CITATIONS**

[Garrison, N.A. et al. \*Genetics in Medicine\* 2016, 18:663-671.](#)

[Manolio, T.A. \(2006\) \*The American Journal of Bioethics\*, 6:6, 32-34](#)

[Hartz, S.M. et al. \(2015\) \*Genetics in Medicine\*, 17:5, 374-379](#)

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## **RECONSENT OF RESEARCH PARTICIPANTS**

### **Key Concepts**

- Informed consent is an ongoing process and conversation between the research team and participants.
- Participants should be made aware of new information learned during the conduct of the study that may impact their willingness to continue their participation in the study.
- Changes to a participant's status (a child reaching the age of majority) may mean that the study team no longer have legally effective informed consent.

### **Why A Research Team May Need to Reconsent**

Informed consent is an ongoing process. After the initial consent discussion takes place and the consent form is signed there may be situations where additional information must be provided to participants.

The human subjects regulations require that participants be provided, when appropriate, with a “statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.”

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This may occur when:

- There are significant changes to the study design (e.g., adding new research procedures)
- New information that alters the existing risk/benefit information (e.g., the identification of new risks or increases in the frequency or severity of known risks)
- There are changes to the reimbursement plan and/or costs to the participants
- Status changes with existing participants, such that the study team no longer has legally effective informed consent (e.g., a minor participant who reaches the age of majority, a participant who regains decision making capacity).
- Change in Principal Investigator (PI) (depending on the participant's continued involvement in the study).

## **How to Reconsent**

When reconsent is necessary, there are a variety of ways in which the research team may communicate the new information to participants.

Research teams should consider what new information is being relayed, the urgency with which the information should be relayed, and the current status of the existing research participants (i.e., are participants actively participating, in long term follow-up only, etc.). Depending on these factors, the research team may request to implement one or more of the following options.

**Revision of the Original Consent Document** – Research teams may present participants with an updated version of the original consent form revised to incorporate the change/new information. This method is most commonly used to reconsent participants who are still actively participating in a research study.

**Letter** – Research teams may use a letter to accompany a revised original consent document. The purpose of the letter would be to inform a participant as to why they are receiving an updated consent form and to highlight the new information.

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What the new information is and where it may be found within the revised consent document.

A letter may also be used as a stand-alone means to notify existing participants of new information. Often, a letter is used with participants who are no longer actively participating in the study. For these participants, the use of a letter prevents the new information from being lost in the original consent form. Letters are often used to inform participants of a change in PI, or to notify participants of newly identified long-term risk information.

**Telephone** – A telephone call is typically the most rapid means of communicating urgent new information to an existing participant. Telephone contact is often most appropriate for relaying urgent safety or risk related information to participants. Often, this will then be followed up by having active participants sign a revised consent form.

## **IRB Review**

Research teams must submit revised consent forms and letters to the IRB for review and approval prior to use.

Research teams should clearly identify what participants will be reconsented as well as how and when the reconsent process will be conducted. Often, existing participants may reflect a variety of different statuses (i.e., in screening, actively participating, in follow-up, off study). Not all new information may be applicable to all participants given their current status. For example, participants in follow-up, long term follow-up or who are complete do not need to be notified of newly identified injection reactions. It is the responsibility of the research team to provide the IRB the reconsent plan.

This information may be provided in the Modification Checklist portion of the myIRB application.

## **Children Who Reach the Age of Majority**

According to the Office for Human Research Protection (OHRP), “Investigators should seek and obtain the legally effective informed consent, as described in

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CFR 46.116, for the now-adult subject for any ongoing interactions or interventions with the subjects.”

“Similarly, if the research does not involve any ongoing interactions or interventions with the subjects, but continues to meet the regulatory definition of “human subjects research”, then it would be necessary for the investigator(s) to seek and obtain the legally effective informed consent of the now-adult subjects.”

Children enrolled into a research study with their parent’s consent must be reconsented:

- Prior to participating in any further research interactions or interventions once reaching the age of majority
- Prior to the research team collecting any additional information about these individuals from any existing source such as continued collection of information about the individual from their health care record
- Prior to the research team continuing to access or use identifiable research data previously collected on these individuals. This would include continued data analysis, as well as future use and sharing

The reconsent plan for these participants should be proposed to the IRB at the outset of the research. The research team must identify in myIRB section 2 whether children enrolled into the research study will reach the age of majority during the conduct of the study and if so, a detailed plan for addressing legally effective informed consent (including a waiver of consent or anonymization of data) must be provided.

When reconsent is not possible, the research team may request:

- The IRB approve a waiver of consent for the continued access and use of existing identifiable research data previously collected on these individuals.
- Continued access to and use of existing research data previously collected on these individuals with the caveat that the data will be anonymized. This would be in lieu of seeking a waiver of consent from the IRB.



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## **IRB Review**

A research team may need to incorporate multiple strategies for participants who reach the age of majority during the course of a research study. A research team may wish to reconsent these individuals, but must have a plan in place for those individuals who are unable to be contacted.

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## **RECRUITMENT METHODS**

### **Existing Registries/Databases**

Other research studies: When a research team recruits participants from an existing research study, the myIRB ID number for the study must be provided. Permission from the Principal Investigator (PI) of the registry/database is required, if different from the PI wanting to use the information. Listing the PI of the registry/database as a member of the research team does not negate the requirement for documentation of his or her approval.

An email is sufficient documentation as long as it is clear on the terms of the approval (e.g., include the title of the study and HRPO ID number).

When this recruitment method involves the use of Protected Health Information (PHI), which is a combination of an individual's identifiers and their health information, a **partial HIPAA waiver** must also be granted by the IRB. You must select "medical records or other PHI" in your myIRB application.

Research Data Core (RDC): The Research Data Core is a patient data warehouse that collects, integrates, and stores data from the electronic health records generated during patient care at BJC and Washington University Medical Center facilities.

Use of the RDC for recruitment purposes is restricted to investigators at WU, BJH, and SLCH recruiting patients at WU, BJH, and SLCH.

As this recruitment method involves the use of PHI, a **partial HIPAA waiver** must also be granted by the IRB. You must select "medical records or other PHI" in your myIRB application.

<https://informatics.wustl.edu/research-data-core-services/>

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Other existing registry/database: When a research team wants to recruit from an established registry (e.g., Research Participant Registry), additional approvals are not needed. However, the registry or database should be identified in myIRB.

## **Subject Pool**

There are three established participant pools at Washington University

- The Psychology Department Subject Pool  
<https://wupsycho.sona-systems.com/Default.aspx?ReturnUrl=%2f>
- The Olin Business School Participant Pool  
<https://olin.wustl.edu/EN-US/Faculty-Research/research/Pages/behavioral-lab.aspx>
- The MISSEL Participant Pool  
<http://www.missel.wustl.edu/template/file/subject%20pool%20only.pdf>

These participant pools are managed by pool administrators within the applicable schools/departments. All questions pertaining to the use of these pools, their policies, and permission to use the pool for recruitment purposes should be directed to the appropriate pool administrator.

## **Colleague Referrals**

An Investigator's colleagues may assist with recruitment of participants by referring potentially eligible individuals to the research team for more information. Letters from the investigator to a colleague requesting referrals do not need to be submitted to the IRB.

These colleagues may hand out IRB approved flyers, brochures, or other IRB approved recruitment materials (including a copy of the IRB approved consent form) to individuals who may be interested.

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These colleagues also can request permission from the interested individual to share their name and contact information with the research team.

While these colleagues may make individuals aware of the existence of a research study or pass along contact information to the research team, anything in addition to this may be considered the start of the consent process. The start of the consent process includes answering study specific questions or reviewing the consent form with the individual. If the colleague is involved in the consent process they are considered involved in the conduct of the research and must be approved by the IRB as a study team member.

## **EPIC**

Best Practice Advisories (BPAs) are part of Epic's framework for clinical decision support, which can be configured to evaluate clinical data and display information or suggest follow-up actions. When used as a recruitment method, a BPA may send a notification in EPIC to study staff that a patient meets certain study eligibility criteria.

## **MyChart:**

*Research Recruitment Functionality:* The MyChart research recruitment functionality can be used to send potential participants notices that they may be eligible for a research study. MyChart recruitment notices require IRB approval prior to use. The use of MyChart for recruitment purposes should be identified as a recruitment method in your IRB application. The proposed recruitment message specific to MyChart must be included with the submission.

IRB review and approval of MyChart recruitment messages is required regardless of study type. Studies that qualify for exempt review that wish to recruit using MyChart are required to provide the recruitment message to the IRB for review and approval.

When using an external IRB, the external IRB must review and approve the use of MyChart as a recruitment method along with the recruitment message.

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For more information about using MyChart as a recruitment tool, contact the EPIC team.

*Direct Messaging in MyChart:* Participants who are enrolled in clinical trials may receive direct messages through the MyChart message center. The definition of a clinical trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) as well as the [NIH website](https://www.nih.gov). These participants must provide permission within the study consent form to receive these messages.

Direct messaging using the MyChart Message Center is prohibited for all research recruitment purposes.

## **Recruitment Enhancement Core (REC)**

The Recruitment Enhancement Core (REC) in the Volunteer for Health Office (VFH) provides recruitment assistance to investigators with IRB approved clinical trials. The REC provides many services, such as creation of recruitment materials, a list of names and contact information of potential participants from the Research Participant Registry (RPR), e-mailing RPR registrants, and community engagement. The Research Participant Registry (RPR) is a database of individuals who have consented to be contacted for research opportunities.

The myIRB application should identify what services the REC will provide.

When the REC provides recruitment materials the materials must be submitted to the IRB for review and approval. The REC should not be listed as a recruitment method until all recruitment materials are available for IRB submission.

If REC staff members will be actively involved in recruiting (i.e., calling individuals enrolled in the RPR to screen them for eligibility or recruiting them into the study) these REC staff members must be listed as members of the research team.

<https://sites.wustl.edu/wuvfh/>

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## **ACCESSING PROTECTED HEALTH INFORMATION (PHI)**

### **Key Concepts**

- Providers may access, use, share a patient's protected health information for treatment, payment, or operational purposes without obtaining the patient's HIPAA authorization to do so.
- RESEARCH is outside treatment, payment, or operational purposes and thus requires HIPAA authorization or a waiver of HIPAA authorization to access PHI for research recruitment.
- Sources of PHI can include electronic medical records, billing records, as well as existing research studies.

### **What Is Protected Health Information (PHI)?**

Protected Health Information is the combination of health information with one or more of the designated HIPAA identifiers (list included below).

Identifiable health information becomes PHI when it is maintained by a “covered entity.” Washington University is a hybrid entity, which means some components of the University are covered components that must comply with HIPAA while other components are non-covered components. A listing of all covered components is available on the [HIPAA Privacy Office's website](#).

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## **How Do I Request Access To Existing PHI For Recruitment?**

If a researcher is accessing PHI to determine eligibility before contacting individuals, the IRB must issue a **partial waiver** of HIPAA authorization.

The request must be made in the recruitment section of myIRB. There is a selectable box for accessing medical records or other PHI. You will then be prompted to enter the source of the records you are requesting to access. To access PHI held by a covered entity other than WU, BJH, SLCH, documentation from the appropriate authority at that entity will be required. The documentation must be the WU IRB's HIPAA Waiver Letter. The HIPAA Waiver Letter must be completed and signed by the covered entity's appropriate authority.

Investigators cannot access PHI for recruitment from other BJC entities for recruitment without the HIPAA Waiver Letter from that entity.

The HIPAA waiver letter or IRB Approval must be included with the IRB submission. A template for the HIPAA waiver letter is available [here](#).

The IRB will carefully consider any request to use PHI from another entity for recruitment as it relates to subject privacy and confidentiality. There are separate selectable boxes for recruitment strategies using EPIC that also require a partial HIPAA waiver. These include use of the EPIC Best Practice Advisories (BPA) and MyChart.

The individual data elements, including identifiers, that you plan to access must be provided to the IRB. These will be reviewed in conjunction with the stated inclusion and exclusion criteria to ensure that only information necessary for assessing study eligibility will be gathered.

As this information is being obtained without consent and without HIPAA authorization, the privacy of the individual must be protected. Information that is needed from a source of PHI for study purposes beyond assessing eligibility may only be obtained after the individual has consented and provided HIPAA authorization.

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Although it may be efficient to gather all medical record information at a single time point, a research team is only permitted to gather the data points approved by the IRB for recruitment.

## **PHI From A Research Study/Registry**

To access PHI held by another WU investigator (i.e., recruit from another investigator's past participant pool using their identifiable health information) documentation is required at the time of IRB submission from the PI of the other study/registry granting approval of this access and use. Email is an acceptable form of documentation.

## **Creation Of PHI During A Phone Screen**

Whether health information collected during a phone screen is considered PHI depends on two things:

1. Does the health information contain one or more HIPAA identifiers and;
2. Where is the academic "home" of the PI? Is the PI from a Department/Institution that is part of the covered entity?

A "yes" to both of these questions means that any health information collected during the phone screen is PHI.

A **full waiver** of HIPAA authorization is required when obtaining PHI directly from the participant during a phone screen when identifiable information is being **recorded**. Informed consent must also be obtained; however, in these instances the IRB will typically approve a waiver of written documentation of consent to allow a verbal consent process.

Use the phone screen consent template available in myIRB, which includes all of the appropriate HIPAA authorization language and required elements of informed consent. Identify use of the verbal consent process in the myProject section of the myIRB application.



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If, during the phone screen, the individual's answers are not recorded then informed consent and a waiver of HIPAA authorization is **not required**. This would apply if the research team read off a list of exclusionary conditions to the individual and at the end the individual responds with a single statement that they are or are not eligible.

In this situation, the phone screen consent template does not need to be used; however, a telephone script would still be required if the individual has no prior relationship with the research team. In this instance the phone script would serve only as a recruitment material and not a consent document.

## **Creation of PHI Via MyChart Screening Questionnaire**

A **full waiver** of HIPAA authorization is required when PHI is created through the administration of a MyChart Screening Questionnaire. Informed consent must also be obtained; however, the IRB will approve a waiver of written documentation of consent.

Use the MyChart Screening Questionnaire consent template available in myIRB, which includes all of the appropriate HIPAA authorization language and required elements of informed consent. When submitted for IRB review, the default naming convention should not be deleted. Identify use of the "Letter or Information Sheet with No Signature" option in the myProject section of the myIRB application.

The screening questions must be provided to the IRB for approval. MyChart permits no more than 10 questions. The MyChart Research Screening Questionnaire has a designated attachment location in myIRB. This is found in the recruitment methods/materials section of myIRB (myIRB 1.8). Do not attach this specific screening questionnaire in myIRB 1.15.

The use of MyChart Screening Questionnaires is limited to adult participants.

When using an external IRB, the external IRB must review and approve Screening Questionnaire Consent Form and MyChart Research Screening Questionnaire.

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## **Information Considered To Be Identifiers**

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

Initials and audio recordings are also considered to be identifiers.

# Recruitment

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## **RECRUITMENT MATERIALS**

Recruitment materials must be submitted to the WU IRB before use. This includes all items that the research team will use to recruit potential participants. When a study sponsor or Clinical Research Organization (CRO) is providing recruitment materials, only submit those that will be used by the WU research team to recruit.

Recruitment materials include (but are not limited to):

- Print/online advertisements
- Radio and TV spots
- Flyers or brochures to hand out or leave available
- Posters that will be displayed
- Emails and print mailings to be sent directly to potential participants
- Phone scripts
- Website and social media postings or listings
- Powerpoint presentations

### **Do's And Don'ts**

At a minimum, recruitment materials must include basic information about the research study to allow individuals to gauge their interest in the study and to enable contact with the research team.

Recruitment materials may:

- Describe the project as a research study
- Describe the purpose of the study
- List the institution that is doing the study
- Provide a brief explanation of the procedures
- Provide key inclusion and exclusion criteria
- Include information about payment as long as it is not presented in a manner that is unduly influential

# Recruitment

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- The time commitment required
- Provide contact information

Recruitment materials may NOT:

- Use language that could be misleading or coercive (e.g., New and exciting treatment opportunity).
- Emphasize compensation through bolded or underlined text or enlarged fonts or including large sums
- Describe compensation as a benefit
- Promise “free medical treatment” when the intention is to tell potential participants that they will not be charged for research required treatments or exams.
- Claim that an investigational drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- Describe a drug, biologic, or device as “new”, without clearly explaining it is investigational. The term “new” should be replaced by investigational.
- State or imply any certainty of favorable outcome or other benefit if this is not guaranteed.
- Include coupons for discounts on the purchase price of investigational drugs, biologics, and/or devices (to be used once they receive FDA approval) may not be offered as compensation.

# Recruitment

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## **Posting Of Recruitment Materials**

Recruitment materials can be posted in public areas of the WU/BJH/SLCH campus without providing the IRB with additional permissions.

Posting recruitment materials in public areas off campus does not require additional permissions.

The WU IRB considers public areas to constitute places that are open to anyone to post materials with no approval process required by the entity (e.g., community use billboards in grocery stores or libraries).

Posting recruitment materials in non-public areas will require documentation that the site or facility has provided permission to post the recruitment material. Email documentation is sufficient as long as it includes the name and title of the person providing permission and it is clear in the thread to what the permission applies. Examples of non-public areas would include the waiting room of a physician office, clinic, or an urgent care center.

Additional permissions are not required when posting recruitment materials to a controlled medium. A controlled medium means the researcher is not able to post the information on their own, but rather must work with an individual associated with the platform or venue. Examples would include a website, an online forum (if the researcher is not able to post on their own), a kiosk or video board.

In all cases, you should describe where recruitment materials will be used in the IRB application

# Recruitment

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## **Materials Provided By A Sponsor Or Lead Site**

Often research sponsors, CROs or lead sites will provide recruitment materials to participating sites. When these materials are to be used by the WU research team, myIRB should be completed to reflect the appropriate material type and the materials should be attached in the appropriate categories.

When these materials cannot meet WU IRB requirements for recruitment materials (e.g., the document does not contain site-specific contact information because that will be added via a sticker) the issue and the reason for it should be documented in myIRB. The appropriate place for this documentation is the notes field available to research teams when attaching a document.

Some sponsors, CROs, or lead sites may use a recruitment method that is managed solely by them. These entities develop the materials and manage the process and mechanism for recruitment. Once a participant is identified via these methods, the WU site will receive a referral. In these instances, the WU research team should indicate referrals from the sponsor, CRO, lead site as a recruitment method. However, the materials controlled and used by the sponsor, CRO, lead site are not to be submitted to the WU IRB for review and approval. These materials will be deleted if they are provided.

## **Recruitment Materials Created By Vendors**

When a research team intends to use a vendor to create advertisements for a research study, the final version that will be seen and/or heard by potential participants must be approved by the IRB prior to use.

Given the costs associated with the creation of these materials, a draft version of the material can be submitted to the IRB for review and approval with the understanding a modification must be submitted and approved by the IRB prior to use.

# Recruitment

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Drafts in this scenario would typically mean scripts for radio or television ads. The IRB will review the drafts for wording and descriptions of visual or auditory information. However, as tone and visual information can be unduly influential, the final material, including audio or video, must be submitted for IRB approval via a future modification.

When providing draft material, the draft status should be documented in the notes field where the document is uploaded.

## **Telephone Scripts**

Telephone scripts are not always required by the IRB when recruitment will take place during phone conversations.

Telephone scripts will be required in the following situations:

- Calling individuals who have no prior relationship to the research team and who have not agreed to be contacted for future research opportunities.
- When there will be a screening component to the recruitment call that requires a consent process. In this situation, the phone screening consent template must be used.

Note: Consent is required for phone screening when information collected from the participant will be retained. When screening questions are asked, but no responses are recorded a consent process is not required.

## **Websites**

For websites under the direct control of the research team: the IRB requires that all recruitment related pages and text be provided to the IRB prior to publication of the material. The page, as it will be published, not just the text, must be submitted for review and approval prior to use.

# Recruitment

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For websites under the control of another entity: the IRB requires that the research team submit the information that will be provided to the entity to publish on their website. The information provided to the IRB should match the text and graphics that will be included in the final website posting.

One exception: when the website restricts postings to basic clinical trial information only (i.e., the title, purpose of the study, protocol summary, basic eligibility criteria, study site locations, and information about how to contact the site for more information) the posting does not need to be approved by the IRB. This is in accordance with WU IRB policy and applies only in those situations where the nature of the website restricts postings to the above listed elements. The most common example of this is [clinicaltrials.gov](https://clinicaltrials.gov).

Use of personal websites: Prior to submitting to the IRB, contact the WU Department of Marketing and Communications to determine if use of these websites will be allowed.

## **Social Media**

Social media platforms may include, but are not limited to Facebook, X (formerly known as Twitter), Instagram, SnapChat, LinkedIn, and other types of online forums. For use of any social media platform, the study team must ensure that the platform's terms of use are not violated. The process used by the study team to verify this should be described in the IRB application. Do not provide copies of the terms of use.

All social media postings must identify that they pertain to a research study. The post must be submitted for IRB review as a screen shot/printed page prior to publishing the post.



# Recruitment

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## Social Media Communities:

When a study team member is part of a social media community (e.g., a Facebook group, chatroom) and wishes to post a recruitment flyer or other material, a letter of support is not required if the ability to post must go through an approval process managed through the social media platform. Otherwise, a letter of support should be provided to the IRB.

The researcher must clearly identify themselves as a researcher and communicate to the users that they should not talk about sensitive information, including health information.

Ideally, posts should be made to a page with security settings in place that do not permit the audience to comment. The plan to ensure participant privacy (e.g., disabling features such as comments; informing participants that they should not disclose any sensitive personal information, including health information; how disclosures of sensitive or health information will be handled by the research team) should be provided to the IRB.

In situations where communication from the audience cannot be disabled, the study team should outline their plan for monitoring the social media account for posts that contain health-related or other sensitive information.

Use of social media will require a security review through the Information Security office. See the link below for more information.

<https://informationsecurity.wustl.edu/services/irb-security-review/>

Direct messaging: Given the privacy and security concerns that exist with direct/personal messaging, the IRB rarely approves the use of such messages as a means of recruitment. If you would like to use this as an option for recruitment, contact HRPO prior to submitting your application.

Targeted Advertising: Directing general research recruitment ads to a selected audience (i.e., based on demographics, search/post history) may be approved by the IRB when the following conditions are met:

# Recruitment

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- The targeted advertising does not violate the social media platform's terms of use.
- The targeted advertising is conducted in a manner similar to other targeted paid advertising that may occur on the platform.

Use of personal social media accounts: Recruiting on personal social media accounts is generally not permitted.

Please contact the [Department of Marketing and Communications](#) for more information.

## **Emails**

When email is used as the initial means of contacting an individual for recruitment purposes, the IRB must ensure privacy is safeguarded. This includes both how the research team has access to the individual's email and when necessary, obtaining permission from the individual for their email to be used for this purpose.

Publicly available: Publicly available means anyone can obtain these email addresses for any purpose (e.g., a Department's contact page). Additional approvals and/or safeguards from a privacy perspective will not be required to use publicly available email addresses.

Listserv's and/or distribution lists: Use of email addresses that are part of a listserv or other distribution list require documentation of approval from an individual that has the authority to approve the use of email to contact individuals for research purposes. An email is sufficient as long as the email includes the name and title of the person who provided the permission and the thread clearly indicates an understanding of how the email addresses will be used.

Mass emailing: Mass emailing at WU is prohibited unless you have the approval of the applicable WU department.

# Recruitment

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## Email Addresses in Medical Records

Email addresses found in a patient's medical record provided for healthcare reasons should not be used to make an initial research contact regardless of the investigator's prior relationship with the participant.

It is not appropriate to assume that the presence of an email in a patient's healthcare record indicates their willingness to communicate with researchers in this manner. This includes researchers who may otherwise be involved in the patient's healthcare.

## Emailing PHI:

Emails sent from an individual affiliated with a HIPAA covered entity include PHI when either the body of the email or an attachment to the email includes information about the health of an individual.

For recruitment purposes, these attachments may include blank consent forms, flyers, brochures, or other IRB approved recruitment materials. Even if the potential participant's name is not included within the attachment, if the attached document requires participants in the study to have/be at risk for/or are undergoing evaluation for any disease or condition, then the email is considered to include PHI.

Email invitations to participate in a research study include PHI if a reasonable person could infer that the recipient of the email has/is at risk for/or is undergoing evaluation for the disease or condition under study.

When recruitment emails include PHI, the email must be encrypted by including [secure] in the subject line of the email. Sending an unencrypted email that includes PHI to a potential participant without their written authorization is a violation of their privacy rights under HIPAA.

Written authorization to send an unsecure email can be obtained using the email authorization form available on the HIPAA privacy office's website. This

# Recruitment

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authorization form must be signed and returned prior to sending **any** email containing PHI where [secure] does not appear in the subject line.

Verbal authorization allowing transmission of PHI via email in an unsecured fashion is not permitted. Written authorization (either wet ink or electronic) must be obtained.

Encryption of the entire email by placing [secure] in the subject line of the email is not required if all three of the following are true:

- The body of the email does not include any health information. This means that a reasonable person reading the email would not be able to infer that the email recipient has/is at risk for/is being evaluated for any disease or condition,
- Any email attachment that includes health information is encrypted, and
- The name of the attachment(s) does not reference any health information (e.g., juvenile diabetes consent.doc)

When attachments are encrypted, the password or key may not be sent in the same email.

For assistance with encrypting documents, contact your department or school's IT support staff.

More information about the University's encryption requirements may be found on the [Information Security website](#).

## Responding to emails

IRB approval is not needed to respond to a potential participant's email inquiry about a research study (i.e., a potential participant emails a study team contact using an email address found on an IRB approved brochure; a past participant emails a study coordinator about the existence of new research opportunities). However, if the email responses will include PHI, the emails must be encrypted by adding [secure] to the subject line of the email.

# Recruitment

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## **SCREENING LOGS**

A screening log is a spreadsheet or other record that is used to track the eligibility status of individuals being evaluated for inclusion in a research study. A screening log may capture identifiable information (including health information) on individuals who have not consented to participate in a research study.

These individuals may not yet have been approached by the research team, may have been approached but declined participation, or may not be eligible.

When a screening log will include identifiable health information, the research team must select “medical records or other PHI” as a recruitment method in myIRB. This prompts the IRB to consider a partial waiver of HIPAA authorization to allow the research team to temporarily retain identifiable health information on individuals who have not provided consent to participate during the enrollment period.

## **Collection And Storage Of Information About Individuals Who Do Not Consent**

An individual’s identifiable information may be retained on a screening log in order to avoid re-contacting individuals who refused or were ineligible.

All identifiers must be permanently removed (including all dates of contact) at the earliest time-point consistent with the conduct of the research. This means that, if identifiers are being retained to avoid re-contacting uninterested or ineligible individuals, the identifiers should be permanently removed at the point that the study closes to new enrollment.

# Recruitment

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Identifiable information about an individual, such as the reason for ineligibility, cannot be maintained on a pre-screening log indefinitely, unless the individual ultimately consents to participate in the study or the IRB grants a waiver of consent.

If the identifiable information meets the definition of Protected Health Information (PHI) then HIPAA authorization, or a waiver of HIPAA authorization, would also be required.

Permanent removal of identifiers means that all information about individuals who did not consent to participate has been anonymized. This would preclude the use of codes that link back to identifiers held elsewhere.

## **Sharing The Screening Log**

Sharing of screening data outside of the research team (such as with the sponsor of a study) should be limited to information that does not include identifiers or links to identifiers. Sharing identifiable screening data beyond the research team would require either a waiver of consent or consent from the individuals.

If the information shared represents protected health information (PHI) then a waiver of HIPAA authorization, or signed HIPAA authorization, from the individuals would be required as well.

# Recruitment

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## **Identifiers**

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

Initials and audio recordings are considered identifiers.

# Return of Results

## **GENETIC/GENOMIC DATA**

### **Key Concepts**

- Only results obtained in an environment certified as analytically valid (e.g., CLIA-certified) may be used for clinical decision-making. Results generated in a non-certified lab may be returned to participants under certain conditions, but the results must be verified in a certified lab before they are used for clinical decision-making.
- The implications and limitations of the results must be presented to participants. The investigator should provide the opportunity for the participant to discuss the findings with a licensed health care provider. This individual must have sufficient expertise to be able to explain the significance of the information and to address the participant's questions and concerns.
- Participants should have the option to decline receiving genetic results.
- The IRB must review and approve the return of results plan, including any written communications sent to participants to notify them of their results.

### **Return Of Primary Findings**

Primary findings are an anticipated outcome of the study. As such, the study team should have a detailed plan for returning results to participants.

If the primary findings are not obtained in a certified analytically valid lab, the limitations of the results should be clearly and completely explained in the consent form. Results must be verified in a certified lab before they are used for clinical decision-making.

Regardless of the lab generating the results, the consent should include explanations of (1) the significance of the findings and (2) the limitations of the information. Participants should be given an option not to receive results, unless receipt of results is integral to the study design. Consultation with a genetic counselor may be offered or required.



# Return of Results

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## **Return Of Secondary (a.k.a., Incidental) Findings**

Before returning secondary findings, the study team should confirm that the participant consents to receive genetic results.

If the findings are not obtained in a certified lab, they should be confirmed in a certified lab before returning them to the participant, if possible. If the findings are not confirmed in a certified lab, they should be returned only after explaining the limitations clearly and completely. Results that are not analytically valid may not be used for clinical decision-making.

Return of results that are not clinically valid and actionable is discouraged. If results with uncertain clinical validity and utility are identified, consultation with the IRB is required before notification of the participant. The IRB, in consultation with experts, will weigh the risks and benefits of returning a secondary result of unclear significance to a participant.

ICTS Precision Medicine at Washington University provides best practice guidance for investigators on the critical issues associated with genomic research and promotes precision medicine by facilitating the use of genomic databases on the WU School of Medicine campus. Visit the [ICTS Precision Medicine at Washington University](#) website for more information about best practice guidance or available genomic databases.

## **Requirements For Informed Consent**

All studies that include genetic/genomic research and return of results should include the following in the informed consent document:

1. A definition of "genetic testing" in lay terms along with any other terms related to the genetic testing in lay terms. (DNA, RNA, etc.).
2. A description of the planned testing and what data will be generated in lay terms. For example, specific mutation testing required by the protocol, sequencing of specific candidate genes only, whole genome sequencing, whole exome sequencing, or creation of cell lines if these lines will be used as a future source of genetic material.

# Return of Results

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3. Risks associated with genetic information, including re-identification.
4. A statement describing any protections for genomic findings, i.e. GINA.
5. A statement describing plans for data and sample sharing. If the research is funded by NIH, language describing deposition into dbGaP (or comparable database) is required. It is highly recommended that the informed consent specifically state that the sequence data will be shared for general biomedical use, and not impose restrictions for the type of future research that is permissible. Please refer to the NIH Genomic Data Sharing policy (<http://gds.nih.gov/index.html>).
6. If secondary (incidental) findings are possible, a statement that explains this possibility and describes what secondary findings are in lay terms. It should be stated whether or not secondary findings will be returned to the participant.
7. If the investigator intends to return results, including primary and/or secondary findings, the participant must be given the option to choose whether or not they wish to receive the results, unless receiving the results is integral to the scientific aim of the study. This choice should be indicated clearly on the consent document by way of a yes/no area to initial.

If the investigator plans to return primary research results, the following additional elements are required:

1. If primary research results are not generated in a way that can be determined to be analytically valid, this must be clearly indicated in the consent document. The limitations associated with the results must be clearly explained in lay terms.
2. A statement describing the clinical utility of the result; in particular, if the result is not from or has not been confirmed by an FDA approved test, a statement that these results may not be appropriate to use for the diagnosis, treatment, or prevention of a disease or condition

# Return of Results

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3. A clear description of how the results will be returned, including who will return the results, what type of information they will receive, and what mechanism will be used to return the results
4. A clear description of the timeframe in which the participant should expect any results

## **ICTS Precision Health**

At Washington University, ICTS Precision Health provides best practices for investigators on returning both primary and secondary genetic results.

Additionally, ICTS now offers a Genomic Return of Results Service. For information about this service or to begin the intake process, visit the ICTS Precision Health website.

<https://icts-precisionhealth.wustl.edu/genomic-tools/return-of-results/>

The ICTS' return of results process has been approved by the IRB. However, research teams using this service must still disclose within their IRB approved protocol (or description of research procedures – myIRB 1.13) that the ICTS Precision Health Return of Results Service will be used. The confirmation email received upon enrollment into this service must be included as part of the IRB submission.

# Vulnerable Populations

## **WARDS OF THE STATE (FOSTER CHILDREN)**

### **Purpose**

This guideline provides an overview of HRPO's procedures for enrolling children who are "Wards of the State" in human subjects research as research participants. This guideline applies Federal regulations and Missouri State laws.

### **Role of Foster Parents in Research**

Foster parents cannot consent for foster children (Wards of the State) in their care to participation in experimental treatments and procedures or to participate in research. The guidelines below describe the proper steps required to enroll a foster child (ward of the state) in a research study

<b>Type of Study</b>	<b>WU IRB Requirements</b>	<b>MO Children's Division (CD) Research Committee Requirements</b>
I. Research targets or there is a high probability Wards of State included.	Submit to WU IRB indicating in myIRB section 2 that Wards of the State will be enrolled.	Submit to CD Research Committee with WU IRB Approval and Written consent document.
II. A. Research does not target or anticipate enrolling Wards of State, but a Ward is identified during the course of the study that would	Submit a modification to the appropriate myIRB study and Section myIRB 2 to indicate Wards of the State will be enrolled.	Submit to CD Research Committee with WU IRB Approval and Written consent document.

<p>be eligible to participate.</p> <p>II. B. A child already enrolled becomes a Ward during the course of the study.</p>		
<p>III. Medical Chart Reviews with high likelihood minors may be Wards of State.</p>	<p>Submit to WU IRB stating Wards are one population.</p>	<p>Submit to CD Research Committee with WU IRB Approval (consent may be waived by IRB).</p>
<p>IV. Emergent or Life- threatening situation that involves a Ward and the Ward will <b><u>be treated with an investigational drug or device.</u></b></p>	<p>Follow procedures on HRPO website:  <a href="https://sites.wustl.edu/hrpo/guidance-3/single-patient-treatment/">https://sites.wustl.edu/hrpo/guidance-3/single-patient-treatment/</a></p>	<p>CD local office approval is necessary. Contacts for the local office can be found at: <a href="http://dss.mo.gov/cd/office/">http://dss.mo.gov/cd/office/</a>. See below for the CD letter explaining the CD procedure.</p> <p>For after hours and weekends, call the hotline at 573-751-3448.</p>

### **Additional Information for Review of Categories I-III**

For research that falls into Categories I-III in the table above, the following steps need to occur prior to inviting a Ward of State to consider enrolling in research study:

1. Submit a New or Modification application via the myIRB system for the study in which the Ward(s) will be enrolled.

# Vulnerable Populations

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2. Obtain IRB approval for the project/modification.
  - a. *Carefully* review the IRB meeting minutes available in the myIRB system which may contain conditions of approval or additional procedures required related to enrollment of wards of the state. For example, if the IRB determines that the study falls into particular risk classifications under the federal regulations, the approval may require that an advocate be appointed for each Ward of State to be enrolled in the study. This individual would need to be someone independent of the research team and independent of the person(s) determined by the Missouri Department of Social Services to be the person(s) providing consent for enrollment. (Further information about risk classification of studies involving children is provided in the Regulations section of this document below.)
  - b. The IRB approval letter and approved consent document (if applicable) will be available via the myIRB system once the study is approved by the IRB.
3. After IRB approval, submit an application to the Missouri Department of Social Services, Children's Division.
  - a. Complete the application available at:  
<https://dss.mo.gov/cd/info/forms/pdf/886-4454s.pdf>
  - b. Include with your application to the Children's Division:
    - i. WU IRB approval letter (available in the myIRB system)
    - ii. A copy of your WU IRB approved and stamped Informed Consent Document (available in the myIRB system)
    - iii. Children's Division cover letter
  - c. Send the application via e-mail to: [CD.ResearchCommittee@dss.mo.gov](mailto:CD.ResearchCommittee@dss.mo.gov)  
or send via postal mail to:  
Children's Division Research Committee  
PO Box 88  
Jefferson City, MO 65103

# Vulnerable Populations

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4. Obtain concept approval to enroll Wards of State from the Missouri Children's Division Research Committee.
5. Obtain CD local office approval for each individual Ward of the State you wish to enroll in the research study.
  - a. *Carefully* review any conditions of approval provided in the approval documents from the Children's Division. Depending on the specific circumstances of the study, the Children's Division may require, for example, that other members of the Family Support Team be consulted and/or required to give consent for enrollment of a Ward. (This will need to be done on a child by child basis.)
  - b. If there are any conditions of approval from the Children's Division, submit a Modification via the myIRB system to update your approved protocol to reflect these additional requirements.
  - c. A listing of the Authorized Representatives of the Missouri Children's Division is available at: <https://dss.mo.gov/cd/office/>

## **Regulations**

### Food and Drug Administration (FDA) Regulations:

21 CFR 50.24: Exception from Informed Consent Requirements for Emergency Research

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24>

21CFR 50.55: Wards

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.55>

21CFR 50.56: Additional Safeguards for Children in Clinical Investigations

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.56>

### Health and Human Services (HHS) Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>

# Vulnerable Populations

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## Definitions

**“Authorized Representatives” of the Missouri Children’s Division:** are those individuals designated by the Children’s Division from time to time authorized to sign a research consent form to enroll a Ward of State in a human subjects research study. The ward’s case manager is considered an Authorized Representative.

**“Advocate”** defined in 45 CFR 46.409 is interpreted to mean an individual who works for the welfare of the child such as a Guardian ad litem.

**“Assent”** means a child's affirmative agreement to participate in research.

Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402 and 21 CFR 50.3 (n))

**“Child” under Missouri State law:** for purposes of the foster care system is defined as any person under the age of 17 years of age and any person over seventeen but not yet 18 alleged to have committed a status offense (RSMo 211.021(2) and RSMo 211.031.1(2)) or any person under the retained jurisdiction of the juvenile courts until age of 24 years of age (RSMo 211.041)

**“Children”** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46.402(a)); 21 CFR 50.3 (o))

**“Family Support Team (FST):”** includes those caring for or involved in the care and welfare of the child such as the Biological Parents, Adoptive Family, Case Manager, Case Worker, Foster Parents, Guardian ad Litem, Guardian, Juvenile Office/Officer, Judge and representatives from the Missouri Children’s Division.

**“Guardian”** is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402). 21 CFR 50.3 (s) Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes



# Vulnerable Populations

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of these guidelines, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research. Under Missouri State law, “Guardian” is defined as one appointed by the court to have the care and custody of the person of a minor (RSMo 475.010(6)).

**Informed Consent:** The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained. HHS regulations at [45 CFR 46.116](#) and [45 CFR 46.117](#) describe the informed consent requirements. ([OHRP website, 2012](#))

**Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. (21 CFR 50.3 (l) and 45 CFR 46.102)

**“Parent”** is defined as a child's biological or adoptive parent. (45 CFR 46.402(d); 21 CFR 50.3 (p) and RSMo 211.021 (5))

**“Permission”** means the agreement of parent(s) or guardian to the participation of their child or ward in research. (45 CFR 46.402; 21 CFR 50.3 (r))

**Research Application** submitted to the Missouri Division of Family Services should consist of a completed Missouri Department of Social Services Application to Conduct Research/Study, a copy of the WU IRB approval letter, and a copy of the WU IRB approved consent form.

## Task Force

Sarah Fowler-Dixon PhD, WU Human Research Protection Office

James Harrison, Acting Director Missouri Children’s Division

# Vulnerable Populations

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## **Emergent or Life-threatening Situation: CD Procedure**

You have received this letter because Washington University is requesting to treat a child or youth on your caseload (or from your circuit, if you are the on-call worker) with an investigational drug or device. Please note the professionals treating this child consider this to be an emergent or life-threatening situation and believe there are benefits to use this investigational technique.

Such treatment may be allowed under Children's Division policy (see Section 8.3 of the Child Welfare Manual) but will require you to take the following steps:

1. Make an immediate referral of this matter to your supervisor, who should then take it up the chain of command to the level of field support manager or regional director.
2. Share with your supervisors any pertinent information you might have regarding the child's medical history or treatment history that might help them make an informed decision regarding the use of the investigational treatment.

# Vulnerable Populations

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3. The field support manager or regional director will then evaluate the situation and make a determination, based on policy and existing protocols regarding medical treatment of children in the custody of the state. (Note that you may be asked to convene emergency family support team meetings or work with your local court to expedite decisions that might impact the child's safety and well-being. Please follow the directives of your supervisors in regard to this matter.)

The Children's Division and Washington University strive to make the best possible medical and treatment choices to support the welfare of all children, and especially those for whom the state has care and custody. We appreciate your assistance in assuring this matter is handled as expediently as possible.

# Vulnerable Populations

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## **STUDENTS OR EMPLOYEES AS PARTICIPANTS**

### **Purpose**

The involvement of students and employees in research may present special concerns. The federal regulations do not provide explicit protections for these potential participants. This guideline describes special considerations and additional protections that may apply to the review of research including these populations.

### **What Makes Students or Employees Vulnerable?**

Generally, researchers should not enroll their own students or employees as research participants. The federal regulations state “An investigator shall seek informed consent only under circumstances that provide the prospective subject or legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.” (45 CFR 46.116).

The Office for Human Research Protection (OHRP) defines coercion and undue influence as:

- **Coercion** occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance.
- **Undue Influence** occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.

When researchers are also a potential participant’s teacher or supervisor the potential for coercion or undue influence exists.

However, under certain circumstances and with additional protections in place, there may be a justification for the inclusion of such participants.

# Vulnerable Populations

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## Recruitment Considerations

### Student or Employee Status is Incidental to the Research

These individuals are not targeted by the research team for inclusion, but enrolled as part of a larger population. If interested, the researcher will not deny the potential participant an opportunity to take part in the study. In these cases, the students or employees are typically recruited through general announcements or advertisements. Acceptable recruitment techniques may include:

- Public posting of HRPO-approved flyers and advertisements;
- Sending written notices or invitations to individuals who have agreed to receive such solicitations, particularly individuals registered in the Research Participant Registry (formerly, Volunteers for Health Program).

### Research that Targets Students/Employees

Recruitment of these individuals requires justification and implementation of additional protections. The scientific justification for targeting these individuals must be provided as part of the myIRB application. Additional protections will be required to minimize coercion and undue influence. These additional protections may include;

- The use of a third party to recruit participants, including distribution and collection of information/research materials/consent forms.
- Recruitment materials, including the consent form, should explicitly assure participants that their decision to participate or not to participate will have no direct or indirect influence upon their grades, assessments or any other outcomes.
- For students, curtailing of data collection until the teacher/student interaction is complete.

The exact additional protections necessary will be dependent on the research design.

# Vulnerable Populations

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## **Informed Consent Considerations**

Because of the power imbalance in relationships between students and teachers in the formal education context, or between employees and their supervisors in the context of employment, it may be difficult or impossible to ensure that students who are potential participants in a researcher/teacher's class, or employees in the researcher/supervisor's employment are in a position to give consent freely, without fear of potential or actual reprisal.

Additional protections to minimize coercion and undue influence may include;

- For students, allowing the researcher to describe the research study and what participation includes; however, not seeking informed consent until the course has concluded.
- For students, allowing the researcher to describe the research study and what participation includes; however, asking a third party to distribute and collect consent forms and holding them until grades are posted.
- For employees, allowing consent discussions to occur between the potential participant and a member of the study team to whom they do not report.

## **Confidentiality Considerations**

Loss of a student or employee's confidentiality may be the most significant risk if a researcher/teacher, or researcher/employer gains access to private information regarding the student or employee that might conceivably effect the subjects' grading, evaluation or good standing. The research must make every effort to avoid any breach of confidentiality, by use of anonymous, or coded information whenever possible, and the participants should be so informed.

# Vulnerable Populations

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Should it not be possible to anonymize or use coded research data, participants must be assured that their confidentiality will be maintained to the greatest extent possible, and that the divulgence of private information to the teacher or employer will occur, but will have no impact upon students' grades, employees working conditions or rewards, or any other form of favorable or unfavorable consequence.

Reasons for inability to anonymize or code research information should be provided as part of the myIRB application.

# Privacy and Confidentiality

## **OFFICE OF INFORMATION SECURITY - IRB SECURITY REVIEWS**

### **Key Concepts**

- The IRB has a responsibility to consider privacy and confidentiality as part of the review process.
- The Office of Information Security performs an IRB Security Review to provide expert recommendations on the use of devices, tools and services, as well as data flows and storage, with an emphasis on the use of identifiable data.
- There are regulations and institutional policies that may impact the research plan for data collection, transfer or storage.

### **Tips**

- ✓ The Office of Information Security provides a chart of common platforms, tools, and resources used for research purposes and their associated requirements. The chart documents whether use of the electronic platform/tool/resource/vendor is permissible and if so, whether an IRB Security Review is required. This chart is available on the Office of Information Security website under Resources: [Research Application Chart](#)
- ✓ It is ideal to obtain your IRB Security Review from the Office of Information Security prior to submitting to the IRB. IRB review cannot proceed until this assessment is complete.  
<https://informationsecurity.wustl.edu/services/irb-security-review/>

### **Why is the IRB Security Review Required?**

The role of the IRB is to safeguard the rights and welfare of research participants. The IRB achieves this by ensuring that each human subjects research study submitted for review is compliant with all applicable human subjects regulations,



# Privacy and Confidentiality

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including the criteria for approval (45 CFR 46.111/21 CFR 56.111). One criterion requires the IRB to ensure that, “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”

Furthermore, the IRB must ensure that risks to individuals being recruited for, or participating in human subjects research, are minimized. Where the storage or transmission of electronic research data poses a risk of harm, the IRB is obligated to ensure that the risk is minimized and participants are not exposed to unnecessary risk.

Lastly, the IRB also serves as the Privacy Board when research involves the creation, access, and/or use of protected health information (PHI). In this role, the IRB must ensure that the research study complies not only with the HIPAA Privacy Rule, but also the HIPAA Security Rule. The HIPAA Security Rule establishes strict requirements for how electronic PHI may be stored and transmitted.

The IRB relies on the Office of Information Security review to provide a risk assessment and recommendation on the use of devices, tools and services, as well as data flows and storage. This information supplements the IRB review process.

## **How does the IRB Security Review Occur?**

The IRB Security Review will focus on what data is being obtained and how it is being used in a given research study. The same review standards and process is used regardless of whether the PI is affiliated with the School of Medicine or the Danforth campus.

To initiate the IRB Security Review process, the research team must complete the IRB Security Review form available on the Office of Information Security’s website: <https://informationsecurity.wustl.edu/services/irb-security-review/>

# Privacy and Confidentiality

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The form requires a WUSTL email address. BJH and SLCH study team members who do not have a WUSTL email address will need to send their name and email address to [infosec@wustl.edu](mailto:infosec@wustl.edu). The Office of Information Security staff will initiate the form and assign it to the BJH or SLCH team member for completion.

BJH and SLCH have their own Information Security Office through BJC. When a research study involves both WU and BJH/SLCH data, the research team will submit to the WU Office of Information Security as directed above. The WU Office of Information Security personnel will then initiate a co-review with their BJC counterparts.

If the study involves only BJH/SLCH data, the research team must initiate the review through BJC ServiceNow. That can be done by visiting the following website: <https://bjcprod.service-now.com/sp?id=landing>

Once completed, the report must be provided to the IRB as part of the myIRB submission.

## **When is an IRB Security Review Required?**

The requirement for an IRB Security Review is triggered by the use of tools and services, as well as proposed data flows, with an emphasis on the use of identifiable sensitive data (this includes, but is not limited to Protected Health Information and Missouri Personally Identifiable Information). Obtaining an IRB Security Review for the use of a product, process, or vendor for one research study does not negate the need for subsequent security reviews. The product, vendor or process is reviewed within the context of each research study.

With each research study, variables pertinent to the security review may change. As a result, that may impact the security assessment. Security parameters in place for products and vendors change over time, ownership of products and vendors change over time, and the terms of service may be updated or revised. All of these factors may impact the security assessment.

# Privacy and Confidentiality

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For more information about Missouri PII, visit the Office of Information Security's website: <https://informationsecurity.wustl.edu/items/missouri-personally-identifiable-information-pii/>

A full listing of identifiers for PHI can be found here: <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>

The Office of Information Security provides a chart of common platforms, tools, and resources used for research purposes and their associated requirements. The chart documents whether use of the electronic platform/tool/resource/vendor is permissible and if so, whether an IRB Security Review is required. This chart is available on the Office of Information Security website under Resources: [Research Application Chart](#)

## **Electronic Devices**

Storage of research data on mobile devices will require a security review. Mobile devices include phones, tablets, wearable technology, such as Fitbits or smart watches.

The Office of Information Security will ensure that the appropriate security settings are in place. This is especially important for the collection of PHI, as the HIPAA Security Rule requires encryption of electronic PHI that is not stored behind a secure firewall.

## **IRB Review**

The Office of Information Security does not provide a research team approval or disapproval of their research plans. Their review provides a risk assessment for the IRB's consideration.

# Privacy and Confidentiality

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The IRB will review the information provided in the security review in determining whether a proposed research study satisfies the criteria for approval (45 CFR 46.111/21 CFR 56.111).

# Sharing Research Data

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## **Key Concepts**

- Funders of research and journals commonly require the sharing of research data in order to facilitate scientific discovery and assist in the replication of study results.
- The consent form must include information that adequately informs the research participant about the potential to share their data.
- For studies that fall under the NIH data sharing policies, there are IRB considerations when developing a data management and sharing plan.

## **Sharing research data**

There are several circumstances under which a researcher will want to share data. This could be based on requirements from the funder of the research project or journals that publish articles about the research. Another example is when a researcher wants to share data with a collaborator to use for their own research purposes. With any request to share data, the IRB and investigators must consider what human subjects requirements apply. Most importantly, the participants must be adequately informed about the plans for sharing to enable them to make an informed decision.

## **Consent forms**

In order to adequately inform a participant about plans to share their data, the consent should include a description of what will be shared, for what purpose and with whom. The WU IRB consent template has standard language available that will cover this information, along with other considerations such as property rights, FDA implications and commercial benefit on behalf of the participant.

Requests to share data obtained without consent will be carefully evaluated to determine if a waiver of consent can be granted or if the individuals must be

# Sharing Research Data

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consented for this activity. As a general course, it is rare to approve sharing of data without obtaining consent.

## **NIH sharing requirements**

The NIH Data Management and Sharing Policy that went into effect on January 25th, 2023 requires most NIH grants to include a data management and sharing (DMS) plan.

The IRB's primary role in the NIH DMS policy is to ensure participants are adequately informed about the plan for sharing data. While the IRB will not accept the project for review until the Just-In-Time notice has been received, the development of the consent form or any restrictions on use of existing data should be considered at the time of grant submission.

The consent form must be consistent with the DMS plan. This will be evaluated at the time of IRB submission. This may include the submission of a new project or submission of a modification. A modification form will be used when a new NIH funding source with a DMS plan is being added to an existing study or when a DMS plan is added to a grant at the time of competitive renewal.

In the consent form, it is not necessary to include the level of detail on sharing that is found in the DMS plan. The WU IRB consent template includes language that can be used to describe the plans for sharing. If the consent language is not consistent with the DMS plan, it may be necessary to re-consent the research participants or revise the DMS plan. Revision of the DMS plan will require NIH approval.

When considering if your information is de-identified, in addition to the standard identifiers, be sure to consider research with rare populations. In some cases it may be difficult or impossible to share data that truly cannot identify the research participants.

# Sharing Research Data

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It is expected that consent to share data will be obtained from the participant. The ability to share data that is collected under a waiver of consent is very limited.

- Data collected under a waiver of consent cannot be shared in an open access database.
- Identifiable data cannot be shared in a controlled access database without explicit consent.
- In certain limited circumstances, deidentified data may be shared in a controlled access database. The IRB will consider these requests on a case by case basis.
- Consistent with the NIH Genomic Data Sharing policy, it is expected that consent will be obtained when sharing genomic data regardless of the identifiability of the data.

If any of the following are part of the DMS plan, you should consult with the IRB prior to submitting your application to NIH.

- Data will be shared in an open access database.
- Data will be shared with direct or indirect identifiers.
- Consent was not obtained for use and sharing of the data.

For more information about the NIH Data Management and Sharing Policy, refer to the resources available at the Bernard Becker Medical Library <https://beckerdms.wustl.edu> and <https://beckerdms.wustl.edu/resources/human-participant-data-considerations>. General resources for the Danforth campus are available through the University Libraries

<https://library.wustl.edu/research-support/data-services> and <https://libguides.wustl.edu/datamanagement>.

## **Genomic sharing**

Per the NIH Genomic Data Sharing policy, researchers generating large-scale human and non-human genomic data, as well as other –omic datasets, are expected to share data as well as specimens or cell lines for which consent was obtained for future research purposes. In addition, some journals have similar requirements to share genomic data. For more information, refer to the section of this guidance document titled, “Guidance on Consent for Genomic Data Sharing for Researchers”.

# Reportable Events

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## **INVESTIGATOR REPORTING REQUIREMENTS**

### **Key Concepts**

- Researchers are responsible for knowing and following the IRB's reporting requirements.
- When researchers rely on an IRB other than the WU IRB, they are responsible for knowing and following the reporting requirements of the reviewing IRB.
- The reporting requirements for the WU IRB are found within the WU IRB Policy and Procedures, [section X](#).

### **Tip**

The following two charts collate information researchers need to know about what events are reportable, how they are to be reported, and the timeframe for reporting. These charts are available in the Guidance section of the HRPO website.

- [How to report events in myIRB when the WU IRB or the NCI CIRB is the IRB of Record](#)
- [How to report events in myIRB when the WU IRB or the NCI CIRB is NOT the IRB of Record](#)



# Reportable Events

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## **What must be reported?**

### Unanticipated Problems involving risks to participants or others

To be promptly reportable, these events must be all three of the following criteria:

- Are unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the study-related documents, such as the IRB-approved research study and informed consent document; and (b) the characteristics of the subject population being studied; and
- Are related or possibly related to participation in the research; and
- Suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

### Non-compliance

Noncompliance is defined as follows:

- Failure to follow any applicable regulation or institutional policies that govern human subjects research or failure to follow the determinations of the IRB.
- Noncompliance may occur due to lack of knowledge or due to deliberate choice to ignore regulations, institutional policies, or determinations of the IRB.

# Reportable Events

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## Changes initiated without IRB approval to alleviate an immediate hazard

In the conduct of research, there may be occasion where a researcher must deviate from the IRB approved plan in order to prevent an immediate hazard to a research participant.

All such changes must be reported to the IRB. If the change was initiated due to an unanticipated problem, also report as a REF-Unanticipated Problem. If the change was initiated due to non-compliance, report as a REF-Noncompliance.

## New Information

New information is any information received by a research team that may impact the willingness of participants to participate or continue participation in the research study. New information is to be submitted to the IRB as a modification.

## **PI Responsibilities**

### Monitoring

Researchers are responsible for monitoring their studies throughout the year for adherence to the IRB approved protocol. The purpose of this monitoring is to identify major deviations and to look for trends in minor deviations that may indicate a systemic issue in how the study is being conducted that could potentially negatively impact the rights, safety, or welfare of participants or the study's ability to produce scientifically valid results.

Researchers are responsible for making the initial determination as to whether an event is promptly reportable to the IRB.

# Reportable Events

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## Reporting

Researchers are responsible for ensuring reportable events are submitted to the IRB within stated timeframes.

Events that result in the death of a research participant, at a site overseen by the WU IRB, must be reported within 1 working day.

All other reportable events must be submitted to the IRB within 10 working days.

## Reliance on another IRB

When WU/BJH/SLCH researchers rely on another IRB they are responsible to know what events must be reported to the reviewing IRB, how those events are to be submitted to the reviewing IRB, as well as the time frame for reporting.

These investigators must also follow the WU sIRB reporting requirements found in the WU Policy for use of a single IRB (SIRB) in multi-site research studies and the SIRB Research Guide which outlines what events must be reported to the WU IRB.

# Reportable Events

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## **DEVIATIONS IN APPROVED RESEARCH**

### **Key Concepts**

**It is the responsibility of the Principal Investigator to determine whether an unapproved deviation is major or minor and to ensure proper reporting to the appropriate IRB. When making the determination of whether the unapproved deviation is major or minor, the Principal Investigator should consider whether the deviation negatively affected any of the following:**

- The rights, safety or welfare of the subject
- The scientific validity of the study (the ability to draw conclusions from the study data)
- Please be aware that outside of the IRB reporting requirements you may be subject to other reporting requirements with the sponsor or FDA.

### **Definitions**

#### **Deviation**

Any alteration or modification to the IRB-approved research without prospective IRB approval. The term research encompasses all IRB-approved materials and documents including the detailed protocol, myIRB application, consent form, recruitment materials, questionnaires/data collection forms, and any other information relating to the research study.

#### **Minor Deviation**

A minor or administrative deviation is one that does not have the potential to negatively impact the rights, safety, or welfare of participants or others or the scientific validity of the study.

# Reportable Events

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## Major Deviation

A major deviation is one that does have the potential to negatively impact the rights, safety, or welfare of participants or others or the scientific validity of the study.

## **Report What and When**

### Major deviations

Must be reported to the IRB within 10 working days of the occurrence of the event or notification to the Principal Investigator of the event. The only exception to this timeframe is a major deviation that results in the death of a WU/BJH/SLCH participant. Major deviations resulting in death must be reported within 1 working day of the occurrence of the event or the notification to the Principal Investigator of the event.

Major deviations should be submitted using the Reportable Event Form (REF) application.

If the deviation represents an Unanticipated Problem or was made in response to an Unanticipated Problem, select “An unanticipated problem involving risks to participants or others...” as the REF application type.

If the deviation was not made in response to an Unanticipated Problem, select “Noncompliance” as the REF application type.

### Minor or Administrative Deviations

Researchers are responsible for monitoring their studies throughout the year for adherence to the IRB approved protocol. The purpose of this monitoring is to identify major deviations and to look for trends in minor deviations that may indicate a systemic issue in how the study is being conducted that could potentially negatively impact the rights, safety, or welfare of participants or the study’s ability to produce scientifically valid results.

# Reportable Events

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A series of minor deviations pointing toward a more global issue that could affect the rights, safety or welfare of the participant or affect the validity of the study should be reported as a major deviation.

In all other instances, a summary of minor deviations should be provided to the IRB at the time of continuing review, if the study will require continuing review.

The summary should be included in the continuing review application as part of the description of the overall study progress.

Do not submit a document that simply lists all of the deviations that occurred during the conduct of the study.

An example of an appropriate summary is as follows: “There were a few minor deviations that have occurred which included several out of window visits due to inclement weather or scheduling issues with the participants and 2 participants failed to bring their medication diary to a follow up visit. There were no systemic issues identified with these deviations.”

## **Examples**

The following examples are intended to be a guide to investigators and study team personnel. These lists are not all-inclusive.

### ○ Major Deviations

- Failing to obtain legally effective consent prior to initiating research procedures. This includes failure to obtain signed consent when required.
- Medication errors, such as administering the wrong study drug to a participant or the wrong dose of the right study drug.
- Failing to conduct a study procedure or administer a study assessment that was meant to assess the safety of the individual’s continuation in the study.
- Changes necessary to eliminate apparent immediate hazards to a participant or others.

# Reportable Events

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- Informed consent obtained by someone other than individuals authorized by the IRB to obtain informed consent.
  - Enrollment of a participant who did not meet all inclusion/exclusion criteria.
  - Performing a study procedure that has not been approved by the IRB.
  - Failure to report an Unanticipated Problem to the HRPO and/or sponsor of the study.
  - Study visit conducted outside the required timeframe that, in the opinion of the investigator, may impact the safety of the participant.
  - Failure to follow the IRB-approved safety monitoring plan.
  - Implementation of recruitment procedures that have not been IRB-approved.
  - Execution of an e-consent where the consent content, as approved by the IRB, was not accurately and completely transferred into the e-consent platform (e.g., Redcap).
  - Execution of an e-consent process when this consent process was not approved by the IRB.
  - Changing the e-consent platform used without first obtaining IRB approval of the change.
  - Failure to update the stamp information within an e-consent document to reflect the current approval and expiration dates.
- Minor Deviations
- Receiving completed questionnaires back from participants where items are missing.
  - Completing a study visit outside of the required timeframe when, in the opinion of the investigator, there are no safety implications.

# Reportable Events

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- Use of an expired consent form in which the information contained is not substantively different than the currently approved consent, unless the deviation occurs repeatedly.
- Minimal over-enrollment
- A signed copy of the consent form was not given to the participant.
- Use of a written consent process (wet-ink signature) when the study was approved solely for use of an e-consent process, but the e-consent platform is not functioning.
- Documentation deficiencies in the consent form such as:
  - A missing investigator signature
  - The participant signs the consent form but does not print their name in the signature block.

Note: A participant that does not sign and date the consent form prior to the initiation of research is considered a major deviation.

## **ICH-GCP**

For research conducted under ICH-GCP guidelines, HRPO interprets the reporting requirements outlined in this document to meet the reporting requirements of 4.5.2 which state:

- For research conducted under ICH-GCP guidelines: ICH 4.5.2 states that “an investigator should not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), change of telephone number(s)).



# Continuing Review

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## **Key Concepts**

- HHS and FDA federal regulations that set the requirements for continuing review are no longer harmonized.
- If a continuing review form is not received and approved prior to the next approval due by date, IRB approval to conduct the research will lapse.

## **Tip**

The myIRB system sends automated email reminders to notify research teams that a continuing review application is due. These reminders are courtesies only. It is the PI's responsibility to track Continuing Review requirements.

## **When is Continuing Review by an IRB Required?**

Continuing review is required at least annually for the following study types:

- All **FDA-regulated** projects.
- All non-exempt human subjects research projects that fall under the **Pre-2018 Common Rule**.
- All non-exempt human subjects research projects that fall under the **2018 Common Rule**, unless:
  - The research has progressed to the point that it involves only data analysis or accessing follow-up clinical data or;
  - The research was reviewed and approved as a new study using the expedited review mechanism.

In myIRB, the project summary page for the study, will include whether the study was reviewed under the pre-2018 common rule or the 2018 common rule. Additionally, it will also state whether the study is FDA regulated.

# Continuing Review

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This information is located in the lower left corner of the summary page under the header “federal regulatory oversight.”

## **How Should I Prepare for a Continuing Review Submission?**

The PI or their delegate may submit the continuing review form in myIRB.

To submit a continuing review form, have the following information available, as applicable:

- Current financial disclosure information for all study team members. As part of the continuing review application you will be required to confirm that all financial disclosures in myIRB are still accurate or to make the appropriate updates.
- A summary of significant changes made to the research study since the initial new project review.
- A summary of minor deviations that have occurred (if this is a multisite study provide this information only for your site).
- A summary of adverse events and serious adverse events that did not meet the criteria to be promptly reported to the IRB as unanticipated problems (if this is a multisite study provide this information only for your site).
- If multisite, the total multisite enrollment number.
- The enrollment numbers of your site including current information about where participants are within the study.
- Information pertaining to any complaints received from participants and how those complaints were resolved.
- Summary information pertaining to any events previously submitted on reportable event forms.
- Any progress reports submitted to outside study sponsors that have not previously been submitted to the IRB.
- All data and safety monitoring reports not previously submitted to the IRB.

# Continuing Review

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- Any correspondence with federal agencies.
- Any monitoring reports from entities external to the university.

## Can I Submit a Modification with the Continuing Review Form?

Modifications to the approved research may be submitted at the same time as a continuing review using the combined MOD/CR form. myIRB will not permit you to submit a continuing review application if a modification form is currently under review.

## How Early Should I Submit a Continuing Review Form?

Continuing review forms will be accepted for review when the study has no more than 100 days of IRB approval remaining.

myIRB sends research team contacts automated notices as studies approach their expiration dates. These notices are a courtesy. It is the PI's responsibility to track expiration dates and ensure continuing review forms are submitted.

## What Do I Do After My Continuing Review Form is Approved?

It is the PI's responsibility to review the continuing review approval documents including the IRB approval memo and the IRB meeting minutes (if applicable). These documents may include regulatory determinations that may have changed since the last IRB review (e.g., the parental signature requirements or continuing review interval).

Once a continuing review application is approved make sure to use only the most recent version of any consent forms. The IRB approval stamp on these documents will be updated to reflect the current IRB approval and expiration dates. Outdated documents should no longer be used.

# Continuing Review

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## **What Happens When a Study Expires?**

IRB approval to conduct human subjects research activities ends at midnight on the study's expiration date. If a continuing review form has not been approved by the IRB prior to this date ALL study activities must cease as the study no longer has IRB approval. This includes all research related interventions with participants (including treatment with investigational products), collection of data, as well as data analysis.

## **Requests to Continue Treatment During a Lapse in IRB Approval**

There may be times when it is in the best interest of the participant to continue some research activities during a lapse in IRB approval. The PI must submit an email to the IRB Chair to request to continue treatment if a lapse in IRB approval is anticipated. To be eligible, a continuing review form must be pending with the IRB.

An email requesting permission to continue treatment must be submitted directly to Derek Byers, the Executive Chair of the IRB at [dbyers@wustl.edu](mailto:dbyers@wustl.edu). The email must include the following information:

- When the lapse started (is anticipated to start) and when review and approval of the continuing review form by the IRB is anticipated.
- A very brief summary of the study protocol.
- What interventions and/or study procedures need to be done during the lapse.
- Why it is in the participant's best interest to have these done.
- The number of participants that are active in the study

# Continuing Review

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- Of the active participants, how many will receive interventions and/or study procedures (including continued administration of a study drug or any other treatment intervention or follow up procedures).

If the request to continue treatment is approved, the IRB Executive Chair will acknowledge and approve the request by email. At that time, treatment may continue while the continuing review form is pending.

## **What Happens if a Continuing Review Form is not Submitted?**

If a continuing review form is not submitted for IRB review, IRB approval to conduct human subjects research activities ends at midnight on the study's expiration date (i.e., the next approval due by date). Extensions beyond the expiration date will not be granted.

Expired projects without a pending continuing review form are closed by the HRPO office. Once the study is closed by the HRPO, reopening the study will require submission of a new project form. The closed study application cannot be reactivated.

# Check-In Forms

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## **Key Concepts**

- Studies that do not require continuing review must submit Check-In forms every 3 years (every year for student PIs)
- If the Check-In form is not submitted within the required timeframe, the study will be closed. It is the responsibility of the PI to submit a new application if the study is active.

## **Tip**

The Check-In forms are created automatically by myIRB and can be found in the PI's Draft Forms tab in myIRB.

## **What is a Check-In form?**

Under the 2018 Common Rule regulations, non-FDA regulated studies that are reviewed by the expedited procedure no longer require continuing review. In order to ensure continued compliance and appropriate closure of studies, submission of an administrative Check-In form is required every 3 years (every year if the PI of the study is a student).

## **What studies will be required to complete Check-In forms?**

Check-In forms are required for studies that do not undergo a continuing review by the WU IRB. This includes:

- studies that qualify as exempt
- studies reviewed by expedited procedure that fit the criteria where continuing reviews are not required (i.e. not FDA regulated, research fits expedited review categories and is reviewed under the New Common rule)
- studies overseen by IRBs other than the WU IRB (i.e. studies that submitted a Request to Rely form)

# Check-In Forms

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## **How will I know when I need to complete my Check-In form?**

The myIRB system sends automated email reminders to notify the PI and delegates when this form needs to be completed. The Check-In form should be completed as soon as the reminders are received.

## **What do I need in order to complete my Check-In form?**

To Submit a Check-In form, have the following information available:

- If the study is active or completed
- If the study has enrolled any participants (actual numbers of enrolled participants are not required)
- If there have been any changes in funding or study team financial interests
- If there have been any events that were or should be reported to the IRB (See section X of the IRB policy document for a list of events that are promptly reportable to the IRB).
- If you submit your Check-In form and the study is active and all funding sources, financial interests and reportable events are up to date, the form will be automatically filed and nothing further is needed.
- Otherwise, the form will follow the same workflow as other forms that you submit to HRPO. A HRPO staff person will communicate with you via the standard workflow process in myIRB for additional actions that are required.

The form can be viewed under the form history section found on the project summary page for your study.

# Study Closures

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## **Key Concepts**

- PI's are required to submit closure forms in myIRB at the conclusion or discontinuation of all IRB approved projects.
- A study can be closed and identifiers retained, but the data cannot be analyzed for any purpose. To work with the data a new IRB project must be submitted and approved.
- A study can be closed and analysis of the data continue as long as the research data has been anonymized (no identifiers remain and there is no link to identifiers).
- Unless a new PI is named, a study must be closed in myIRB before the PI leaves the institution.

## **Tips**

- ✓ Once a study is closed, the study cannot be re-opened. To re-open a study a new project must be created.
- ✓ Once a closure form is submitted to the IRB the study is automatically closed.

## **When Should I Close My study?**

All research interventions (e.g. labwork, investigational drug administration, radiology exams) and interactions (e.g. questionnaires, follow up phone calls) with research participants must be completed.

All planned data analyses conducted by WU investigators should be completed, including data analysis required for pending journal publications.

Data cleaning, auditing, and queries from the sponsor/lead site (when applicable) must be completed.



# Study Closures

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## **Prepare For Study Closure**

Review the myIRB application against approved enrollment numbers. If more participants were enrolled than approved by the IRB a modification is required to increase the sample size. A closure form cannot be submitted until enrollment numbers are rectified.

Confirm that all reporting requirements were met as defined by WU IRB policies. If anything needs to be reported to the IRB this should be done with the appropriate form (e.g., MOD or REF) and prior to submitting the closure report.

Review the IRB approved application to determine if identifiers must be destroyed (e.g. if the consent form states that all identifiers will be destroyed at the conclusion of the study).

## **Record Retention**

Per WU IRB policy, records must be kept in their original form or a certified scanned electronic form for at least six years from the completion of the study (submission of the closure form in myIRB).

There may be additional retention requirements from applicable federal or state laws or at the request of the study sponsor/lead site.

## **Closing The Study**

Instructions on how to complete a closure form and where to find the closure form are available on the [HRPO website](#).

After submission of the closure form myIRB will automatically generate an email to all study team members listed as contacts in the Research Team section of the application confirming closure of the study with the IRB.

# Study Closures

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Instructions on how to access documentation of a study's closure are available on the [HRPO website](#).

## **When A PI Leaves The Institution**

Unless a new PI is named, a study must be closed in myIRB before the PI leaves the institution.

Once a PI leaves the institution, their access to myIRB will be terminated. A delegate's access to any studies not transferred to a new PI will be terminated.

However, research team members will still be able to access a read-only version of the study.

## **Expired Studies**

Expired projects that have not been closed by the PI will be administratively closed by HRPO. Closure of the project may occur as early as 24 hours following expiration of the study's IRB approval.

Once the study is closed by the HRPO, reopening the study will require submission of a new project form. The closed study application cannot be reactivated.