International Research

Biomedical Prep Work Checklist – Prior to Creating IRB Application

	Things to think about…	Yes	No	N/A
1.	You may contact Cindy Brantmeier for consultation and advice while completing this checklist prior to IRB submission cbrantme@wustl.edu. For assistance preparing your IRB submission, or for questions about IRB requirements, contact an International Research HRPO Partner: Erin Higgs (ehiggs@wustl.edu) or Mitchell Saulisbury-Robertson (saulism@wustl.edu) Useful links include: • Human Research Protection Office (HRPO) website: https://hrpo.wustl.edu/ ◦ HRPO International Research Guidance: https://sites.wustl.edu/hrpo/international-research-2/international-guidance/ • HRPO Research Guide (for general information): http://online.fliphtml5.com/ikcz/ifub/#p=1 • myIRB research application program: https://myirb.wusm.wustl.edu/	☐	☐	☐
2.	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:: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html • 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. • If you have funding associated with your project, you must adhere to the requirements of the funding agency.	☐	☐	☐
3.	If local IRB or Ethical Committee review **IS** required: • Identify the processes needed to obtain the review. • Have you obtained the appropriate documentation (Letter of Approval)? WU IRB approval cannot be granted until documentation is provided to the IRB. ◦ 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. • Approval documentation should be uploaded into the "Misc." attachments section of your myIRB submission form prior to submitting the form to the IRB.	☐	☐	☐
4.	If a country **DOES NOTE** require local IRB or ethical committee review: • Identify the appropriate Regulatory Official or individual who can provide you with documentation that local IRB or ethics review is not required OR documentation of what the local requirements for conduct of human subjects research are ◦ 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. • 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. • 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": https://sites.wustl.edu/hrpo/international-research-2/international-guidance/	☐	☐	☐
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.	☐	☐	☐

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6.	Are specific international site permissions required? • 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? ○ 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. • Once received, do you have documentation of the permission(s)?	☐	☐	☐
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.	☐	☐	☐
8.	Do you want to compensate your research participants? • If yes, are there any local laws or regulations that prevent you from doing this? • What is a culturally appropriate way to compensate them or offer extra credit?	☐	☐	☐
9.	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? • If yes, briefly describe their role in myIRB 1.3 of your myIRB application. • 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: 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. There may be exceptions if the research is exempt. For more information see: 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	☐	☐	☐
10.	Are there country-specific laws or regulations about data collection and/or data transportation? • Are there any country-specific laws or regulations about storing consent forms, research data/documentation and/or any identifiable data? • Have you reviewed WU's guidance on electronic storage of research documents? https://research.wustl.edu/electronic-storage-research-study-documents/ • For studies in the European Union, the General Data Protection Regulation (GDPR) applies: https://ec.europa.eu/info/law/law-topic/data-protection_en • 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. ○ Please note, the local definition for what is considered "identifiable" may differ from one place to another.	☐	☐	☐
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: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html	☐	☐	☐
12.	Is your consent process culturally appropriate? • Consider discussing the consent process with your informed local partner. • Contact your WU International Research HRPO Partner for advice and guidance on different consent processes that may be used. • Build in flexibility	☐	☐	☐

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13.	Have you built in flexibility into your research protocol? • For example, if you plan to interview participants in several places and not just a single location, be sure to describe all options. • 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.	☐	☐	☐

14.	If you are student, have you identified your WU Faculty Sponsor?
	• Please review the following with your Faculty Sponsor:
	  ○ 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.
	  ○ This can cause delays if you or your Faculty Sponsor has not completed this training.
	  ○ 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.
	  ○ 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.
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15.	Have you thought about your research documentation?
	• 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.
	• 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.
	• Research documentation should be ALCOAC:
	  ○ **A**ttributable – can you tell who wrote or performed the study procedure or observation?
	  ○ **L**egible – can you read it, are all pages present etc.?
	  ○ **C**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.
	  ○ **O**riginal – and if not an original, an exact certified copy of the original. A ***certified copy*** is a copy of original information that has been **verified**, as indicated by a **dated signature**, as an exact copy, having all of the same attributes and information as the original.
	  ○ **A**ccurate – real representation of fact. The consent should precisely reflect the event
	  ○ **C**omplete – Research documentation should be completed to the fullest extent and should explain any discrepancies, missing, and/or incomplete data.
	  ▪ Always remember…If it's not documented, then it did not happen.
	• 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: https://research.wustl.edu/topics/human-subjects-research/
	• Contact the Human Research Quality Assurance Program for additional resources or research documentation support. HRQA@wustl.edu or +1 314-747-5525
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	Things to think about…	Yes	No	N/A
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?	☐	☐	☐
17.	Additional Considerations to think about: • Does the trial need to be registered at clinicaltrails.gov? ○ https://research.wustl.edu/clinical-trials-registration-guideline/ • Are there regulations regarding the import of pharmaceuticals and/or medical devices? • Are there regulations regarding the export of biomedical samples (especially potentially infectious material)? • Are there any specific regulations regarding the use of local laboratories to perform clinical lab testing? • Are there any specific regulations regarding use of diagnostic imaging?	☐	☐	☒
18.	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. • Refer to the HRPO Research Guide for information on how to write the Key Information section: https://sites.wustl.edu/hrpo/guidance-3/research-guide/. • Key Information templates are available on the attachments page of your draft myIRB application.	☐	☐	
19.	Is your research federally funded by one of the Public Health Services Agencies (PHS)? If so, describe the protections of the Certificate of Confidentiality (COC) in the consent form. ○ The template language is found in the consent templates available on the attachments page of your draft myIRB application. ○ The use of a document separate from the consent form is also an option. Contact your International Research HRPO Partner: Erin Higgs (ehiggs@wustl.edu) or Mitchell Saulisbury-Robertson (saulism@wustl.edu) to obtain a copy of the COC separate document. ○ For more information on the applicability of a COC to your study see: https://research.wustl.edu/cocs/			