Washington University in St. Louis

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PROCEDURE MANUAL FOR COMMUNITY PARTNERS ENGAGED IN RESEARCH

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SECTION I

DEFINITON OF A COMMUNITY PARTNER

An individual community partner is employed or volunteering at a community organization and/or an individual that is self-employed, in private practice or is otherwise involved at a community site where research is being conducted by a Washington University (WU) investigator. The individual community partner becomes "engaged" when he or she interacts or intervenes with human subjects or their private, identifiable information. Further examples of engagement and the necessary educational requirements follow in Section III of this document. Normally, individual community partners are not affiliated with an academic institution and/or are not under the auspices of another Institutional Review Board (IRB).

All Washington University faculty, staff and students that participate in research studies are considered to fall under the Washington University Human Subjects Education policy and therefore are not governed under the Community Partner Manual.

DEFINTION OF ENGAGEMENT

The Office of Human Research Protections'(OHRP) Guidance on Engagement of Institutions in Human Subjects Research, October 26, 2008, states: "In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for research."

HRPO APPROVALS AND CONTINUING EDUCATION

Final approval to interact or intervene with participants or obtain identifiable private information, including protected health information (PHI) for a given study will be held until the appropriate education is delivered to all named engaged community partners at the time of submission. Addition of subsequently engaged community partners will be handled through the revision/amendment process and necessary education will be verified for those individuals at that time.
If, in the future, Washington University requires continuing education for those engaged in human subjects research, the same will be true for any community partners participating in research at the time.

ASSURANCE REQUIREMENTS

When engaging in community research, one must be aware that besides proper education for participating community partners, other approvals and/or documents may be necessary. When community sites are engaged in non-exempt research they are required to obtain a Federalwide Assurance (FWA) and make the Washington University the IRB of Record, or when only a limited number of individuals at the site will be engaged in the research, those individuals may enter into an Individual Investigator Agreement with Washington University. The final determination regarding which contractual agreement is most appropriate will be made in conjunction with the engaged site and/or engaged individual(s), WU HRPO, and WU legal counsel.

TRANSFERABILITY OF EDUCATIONAL TRAINING

The community partner will receive a Completion Certificate. If that community partner goes on to conduct research in another study at the same level, he/she will not be required to complete additional modules. However, if the community partner goes on to conduct research in another study at another level of engagement, he/she/they will be required to complete the additional modules only.

Example: Ms. Jones is working with PI Smith and is required to take Level 2 of the Community Partner Education. Ms. Jones completes this training and is credited. PI Apple subsequently asks Ms. Jones to work on his study and to consent his participants. Ms. Jones now needs to complete Community Partner Education at Level 4. Ms. Jones still gets credit for the modules completed under Level 2 and only needs to complete the additional modules.

INVESTIGATOR'S AND HRPO'S RESPONSIBILITIES

Responsibility	**PI or PD will:**	**HRPO will:**	**HSR QA/QI**
1. Identify which community partners are participating in their research and the role of each of the individuals.	**X**		
2. Ensure that each community partner obtains the necessary education. This may include identifying and paying a "qualified trainer" to deliver the information.	**X**		
3. Report all participating community partners to the HRPO via a HRPO submission.	**X**		

4. Based on information contained with the Community Partner Manual, make an initial assessment as to the Level of Education for each community partner using guidance provided within each grouping listed in Section III.	**X**		
5. The Human Subject Research QA/QI Program may monitor for appropriateness of education provided to community partners.			**X**
6. Verify the appropriate level of education for each community partner.		**X**	

ACCEPTABLE MODES OF DELIVERY

Training may be completed using one of the following methodologies:

1. On-line. Follow WU Vice Chancellor For Research Quick Guide directions. Access CITI through HRPO Education.

2. A hard copy of the approved training material given to the individuals to complete off-line. Send the completed quiz that includes the individual's name, date and signature, including the HRPO number of the study (ies), to HRPO. Note: Individuals using this option will not get credit for module completion in the CITI database. Any subsequent activity by the community partner in the CITI database will be treated as though no human subjects education modules have been completed in the past.

3. Approved training material can be used as a basis for a face-to-face or virtual instruction session given by a qualified trainer.

SECTION II

REQUIREMENTS FOR FACE-TO-FACE and/or VIRTUAL INSTRUCTION and to

QUALIFY AS A TRAINER HOW TO QUALIFY AS A TRAINER

1. Complete either the IRB member biomedical or behavioral track in CITI.

2. Provide either a curriculum vitae or resume outlining your research and training experience to HRPO Education Specialist for approval. You may be asked to conduct a mock presentation for the HRPO Education Specialist.

3. Meet all requirements for a Qualified Trainer as outlined below:

   a) Qualified Trainers will:

   - be familiar with the conduct of research;
   - be knowledgeable about the study(ies) being performed;
   - have a minimum of 6 months experience working in an area of human subjects' research; and
   - have a familiarity with the population he/she will be training.

   b) Qualified Trainers cannot be:

   - subject to **any** sanctions related to human subjects research violations. This includes any issues involving research misconduct where a finding of misconduct is made or there is prohibition from participating in human subjects research;
   - be under investigation by the WU Research Integrity Committee;
   - have a financial conflict of interest with the study(ies) in question; or
   - debarred from receiving federal funds.

TRAINING OPTIONS

More than one trainer may be used in a face-to-face or virtual session. Each trainer must be qualified for the portion of the training he/she is undertaking. Each individual wishing to be a trainer must meet the criteria listed above under "How to Qualify as a Trainer."

TRAINER RESPONSIBILITIES

- Ensures that any engaged community partner receives the appropriate level of education for his/her level of participation in the study

- Ensures that the education for each community partner is documented. Once the individual(s) have completed the training, copies of the Signature Sheet must be sent to HRPO. Training for Groups Level 1 – 4 is valid for the specific HRPO studies listed on the signature sheet only. A sample sign in sheet follows. All fields below are required.

  Sample Signature Sheet:

  Program Title: Human Subjects Education Training

Printed Name	**Signed Name**	**Date**	**Level of Community Partner Education**

- Submits documentation regarding training by email to the HRPO Education Specialist.
- Obtains prior approval for all materials used from the HRPO Education Specialist unless pre-approved materials are being used.

APPROVED MATERIALS

- If materials have not been pre-approved, they must be sent to the HRPO Education Specialist for approval. Materials will be evaluated on the basis of content in relation to the training offered through the CITI program.
- The trainer may utilize any pre-approved training materials offered on the Community Engaged Research webpage (materials still under construction).
- The trainer may elaborate on any pre-approved training materials offered on the Community Engaged Research webpage (materials still under construction). These materials need approval from the HRPO Education Specialist before use.
- Other study appropriate materials developed by the trainer when the information in the CITI modules is not being used as the basis for training. These materials need approval from the HRPO Education Specialist before use.

SECTION III

BIOMEDICAL AND BEHAVIORAL GROUPING EXAMPLES

This is the guidance by which the PI/PD can use to determine which level of education a potential community partner should complete. Each Group is designated by a number, describes the type of activity that the community partner would engage in and is followed by biomedical and behavioral examples.

Group	Examples Biomedical Research	Examples Behavioral Research
Group 1 – (Optional) Non-engaged community partners that the PI feels would benefit from some basic information or background in research or in situations when the community partner is interested in learning more about research.	See examples in the Office of Human Research Protections'(OHRP) Guidance on Engagement of Institutions in Human Subjects Research (2008).	See examples in the Office of Human Research Protections'(OHRP) Guidance on Engagement of Institutions in Human Subjects Research (2008).
Group 2 - Individuals who use, study, analyze, or generate identifiable private information or identifiable biospecimens. (e.g. statistician, research clerk, etc.). These individuals are engaged in the research.	Anyone performing statistical analysis, individuals who may enter private identifiable data into a spreadsheet such as secretary or data entry clerk assigned this function or someone asked to carry a file or otherwise manipulate a research file that contains private identifiable information.	Anyone performing statistical analysis; individuals who may enter private identifiable data into a spreadsheet such as secretary or data entry clerk assigned this function, or someone that may work with a research file that contains private identifiable information.

Group	Examples Biomedical Research	Examples Behavioral Research
Group 3 - Individuals who will interact with participants for research purposes but will not play an active role in the consent process. These individuals are engaged in the research. Examples of individuals who would fall into this category would be persons hired as part of the research team to act as an agent of the PI/PD or to conduct some component of the research study on behalf of the PI/PD.	Someone that might enter the treatment room to perform a procedure on behalf of the research team. This is beyond or in addition to their normal daily functions and therefore would constitute performance for research purposes.	Licensed Clinical Social Workers or Licensed Counselors hired to work on a research study to facilitate focus groups with victims of physical abuse on behalf of the PI. The LCSW or counselor is appropriately trained and qualified to lead the discussion, but has not had formal education in issues involving human research.

Group	Examples Biomedical Research	Examples Behavioral Research
Group 4 - Individuals who will have an active role in the consent process or answer specific questions related to the study. These individuals are engaged in the research. Examples of individuals who would be included in this group include those that assist with or perform the consent process, individuals who provide an explanation of the research prior to the participant agreeing to participate or those that answer specific procedural questions about the study or follow-up procedures and those individuals put in the position of possibly having to answer research related questions (i.e. individuals who hand the consent document to the participant to read).	Individuals who would be included in this group include those that assist with or perform the consent process, individuals who provide an explanation of the research prior to the participant agreeing to participate or those that answer specific procedural questions about the study or follow-up procedures and those individuals put in the position of possibly having to answer research related questions (i.e. individuals who hand the consent document to the participant to read). This includes modified and/or abbreviated consent processes.	Licensed Therapists (LT) that provide research counseling services to parents and juveniles who have attempted suicide. The LTs inform the clients about the study, answer questions about the research, and otherwise act as authorities of the research. The LTs have no other role in research activities.
Group 5 - Individuals becoming employed by WU, one of its affiliates or wishing to be a collaborator on a research study. Training for Group 5 must take place on-line. See directions at the WU Office of the Vice Chancellor for Research. These individuals are engaged in the research. You will need to contact the HRPO Education Specialist for a non-WU employee number.	A community physician wishes to assist with a research study. She will consent the participants and conduct procedures to collect research data. In addition, she expects to be listed as a co-author on all publications	An individual completing a Ph.D. in clinical Psychology at Stanford University accepts a post-doctoral appointment at Washington University and is added to a research study by her mentor at WU in June, just prior to the post-doc's July 1 appointment at WU.

SECTION IV

MODULES REQUIRED BY EDUCATIONAL GROUPING (note: Some modules are only available in one CITI track.)

This section describes the educational groups correlating to the appropriate CITI modules. As described in Section I Acceptable Modes of Delivery, the content of the modules may be delivered using a variety of modalities.

REQUIRED BEHAVIORAL MODULES							
GROUP	History & Ethical Principles	Defining Research with HS	Regs. and Social and Behavioral Sciences	Privacy & Confidentiality	Assessing Risk in SBR	Informed Consent	Internet Research
Group 1	X						
Group 2	X	X	X	X			
Group 3	X	X	X	X	X		
Group 4	X	X	X	X	X	X	
Group 5	X	X	X	X	X	X	X

REQUIRED BIOMEDICAL MODULES								
GROUP	History & Ethical Principles	Basic IRB Regs. & Review	Informed Consent	Privacy & Confidentiality	Social and Behavioral Research for Biomedical Researchers	Records – Based Research	Genetic Research	Protected Populations
Group 1	X							
Group 2	X	X		X		X		
Group 3	X	X		X				X
Group 4	X	X	X	X				X
Group 5	X	X	X	X	X	X	X	X

Group	Required CITI Modules – Biomedical	Required CITI Modules - Behavioral
GROUP 1 – (Optional) Non-engaged community partners that the PI feels would benefit from some basic information or background in research or in situations when the community partner is interested in learning more about research.	History and Ethical Principles	History and Ethical Principles
GROUP 2 - Individuals who who use, study, analyze, or generate identifiable private information or identifiable biospecimens but have no contact with the research participants. (e.g. statistician, filing clerk, etc.). These individuals are engaged in the research. Examples of individuals who would fall into Group 2 include anyone performing statistical analysis; individuals who may enter private identifiable data into a spreadsheet such as secretary assigned this function, or someone that may work with a research file that contains private identifiable information.	History and Ethical Principles Basic Institutional Review Board (IRB) Regulations and Review Process Records-Based Research Privacy and Confidentiality -SBR	History and Ethical Principles -SBR Defining Research with Human Subjects –SBR The Regulations and the Social and Behavioral Sciences – SBR Privacy and Confidentiality -SBR
GROUP 3 – Individuals who will interact with participants for research purposes but will not play an active role in the consent process. These individuals are engaged in the research. Examples of individuals who would fall into this category would be persons hired as part of the research team to act as an agent of the PI/PD or to conduct some component of the research study on behalf of the PI/PD.	History and Ethical Principles Basic Institutional Review Board (IRB) Regulations and Review Process Research with Protected Populations –Vulnerable Subjects: An Overview Informed Consent Privacy and Confidentiality -SBR	History and Ethical Principles -SBR Defining Research with Human Subjects –SBR The Regulations and the Social and Behavioral Sciences – SBR Informed Consent - SBR Privacy and Confidentiality –SBR Assessing Risk in Social and Behavioral Sciences - SBR

Group	**Required CITI Modules – Biomedical**	**Required CITI Modules - Behavioral**
GROUP 4 - Individuals who will have an active role in the consent process or answer specific questions related to the study. These individuals are engaged in the research. Examples of individuals who would be included in this group include those that assist with or perform the consent process, individuals who provide an explanation of the research prior to the participant agreeing to participate or those that answer specific procedural questions about the study or follow-up procedures and those individuals put in the position of possibly having to answer research related questions (i.e. individuals who hand the consent document to the participant to read).	History and Ethical Principles Basic Institutional Review Board (IRB) Regulations and Review Process Research with Protected Populations –Vulnerable Subjects: An Overview Informed Consent Privacy and Confidentiality -SBR	History and Ethical Principles -SBR Defining Research with Human Subjects –SBR The Regulations and the Social and Behavioral Sciences – SBR Privacy and Confidentiality –SBR Assessing Risk in Social and Behavioral Sciences – SBR Informed Consent - SBR

Group	Required CITI Modules – Biomedical	Required CITI Modules - Behavioral
GROUP 5 - Individuals becoming employed by WU, one of its affiliates or wishing to be a Principal Investigator/Project Director, co-investigator, or collaborator on a research study. Training for Group 5 must take place on-line. These individuals are engaged in the research. Individuals who fall into this group are treated as any other WU employee or affiliate and must complete the regular WU CITI curriculum as listed in the next two columns. On-line entry and directions to this curriculum can be found on the WU Office of the Vice Chancellor for Research website. You will need to contact the HRPO Education Specialist for a non- WU employee number.	History and Ethical Principles Basic Institutional Review Board (IRB) Regulations and Review Process Research with Protected Populations –Vulnerable Subjects: An Overview Informed Consent Social and Behavioral Research for Biomedical Researchers Genetic Research in Human Populations Records - Based Research Privacy and Confidentiality -SBR	History and Ethical Principles -SBR Defining Research with Human Subjects –SBR The Regulations and the Social and Behavioral Sciences – SBR Privacy and Confidentiality –SBR Assessing Risk in Social and Behavioral Sciences – SBR Informed Consent – SBR Internet Research -SBR

SECTION V

EXPLANATION OF CITI MODULES
This section gives a brief description of the contents of each module.

Title	Approximate Time	Module Synopsis
History and Ethical Principles	15 – 20 min.	Objectives: Discuss why ethics are necessary when conducting research involving human subjects; describe the major historical events that have influenced how research involving human subjects is conducted; identify problems with past studies that have violated ethical standards; describe the Belmont Principles.
Informed Consent	10 – 15 min.	Objectives: The purpose of this module is to provide a basic understanding of informed consent and the process of obtaining informed consent. By the end of the module you will be able to: ▪ Describe the requirements for complying with informed consent regulations. ▪ Describe the process for obtaining informed consent. ▪ Describe the regulations for waiving informed consent.
Informed Consent -SBR	15 – 20 min.	Module contents: 1. Overview of informed consent 2. Information that must be provided to subjects 3. Waivers of elements of consent 4. Ensuring comprehension of consent information 5. Ensuring free choice 6. Informed consent in exempt research 7. Documentation of informed consent 8. Waivers of documentation of informed consent

Title	**Approximate Time**	**Module Synopsis**
Basic Institutional Review Board (IRB) Regulations and Review Process	25 – 35 min.	The purpose of this module is to provide a basic understanding of the human subject protection regulations that govern the participation of human volunteers in research in the United States. By end of the module you will be able to: Describe the role, authority, and composition of the IRB. List the IRB requirements for conducting research involving human subjects. Describe the types of IRB review. Describe the process of working with the IRB. Identify other regulations and regulatory groups that require compliance based on the type of research being conducted.
The Regulations and the Social and Behavioral Sciences – SBR	20 min.	Module contents: 1. Title 45 CFR 46 2. Contents of the Federal Regulations 3. What must be reviewed? 4. Expedited or full review? 5. Who must review research with human subjects? 6. What questions must be addressed during a review? 7. Reviews throughout the life of a project
Defining Research with Human Subjects –SBR	10 – 15 min.	Module goes through definitions of “research” and “human subject.” Research: systematic investigation; research development, testing and evaluation; contribute to generalizable knowledge Human Subject: living individual; gathering information “about whom;” intervention; interaction; identifiable private information; observing and recording private behavior; private information provided by individuals for specific reasons.

Title	Approximate Time	Module Synopsis
Privacy and Confidentiality –SBR	15 – 20 min.	Module contents: 1. Definitions. 2. Private vs. Public Behavior. 3. Controlling Access to Private Information. 4. Privacy and Research Methods. 5. Confidentiality. 6. State Laws. 7. Certificates of Confidentiality.
Social and Behavioral Research for Biomedical Researchers	15 – 20 min.	This part of the training program will: Characterize social and behavioral research, presenting the most likely and typical risks. Extend the basic concepts of human subjects' protection to these situations for biomedical researchers.
Assessing Risk in Social and Behavioral Sciences – SBR	10 – 15 min.	Module contents: 1. Risks associated with participation in social and behavioral sciences research 2. Assessing risks 3. Balancing risks and potential benefits 4. Minimizing and managing risks 5. Consent Issues
Research with Protected Populations –Vulnerable Subjects: An Overview	10 – 15 min.	Objectives: To provide an understanding of the concept of vulnerability and to discuss some of the characteristics of vulnerability.
Genetic Research in Human	10 – 15 min.	Objectives: Genetics research raises ethical issues that differ in many

Title	Approximate Time	Module Synopsis
Populations		ways from those that arise in other kinds of human subjects' research. The purpose of this module is to understand: • Privacy and confidentiality. • Informed consent. • Risks of harm.
Records - Based Research	15 – 20 min.	Objectives: • Understand concerns about inappropriate access and unauthorized disclosure. • Have procedures in place to protect the confidentiality of the records while in use and of the information collected. • Obtain all required approvals (institutional, state, federal, and international, if applicable) prior to conducting the research.
Internet Research -SBR	20 min.	Module contents: 1. Observing online communications 2. Designing Internet research: the consent process 3. Designing Internet research: Privacy issues 4. Assessing risk 5. Technical issues

References: *OHRP Guidance on Engagement of Institutions in Human Subjects Research,* October 16, 2008.

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