Human Research Protection Program
UNIVERSITY OF GEORGIA

Use of External Sites in Research

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-009-1	9/20/2018	HSO	IRB	Page **1** of **4**

1. PURPOSE

1.1. When the University of Georgia (UGA) is engaged in ***human research activities*** conducted at an external site, UGA Institutional Review Board (IRB) has the responsibility to ensure appropriate approval and oversight of the research activities. This includes multi-site studies and studies involving sites external to UGA. This document describes the ***policy*** and procedures for researchers who will conduct research at sites other than UGA and for research that involves researchers who are affiliated with an institution that does not have a ***federal-wide assurance*** and/or an associated IRB.

2. DEFINITIONS

2.1. ***Engagement in human subjects research***: when an institution's employees or agents intervene or interact with living individuals for research purposes; or obtain individually identifiable private information for research purposes.

2.2. ***External Site:*** a site or location, not owned by or under the direct authority of UGA, where the investigator would not normally have privileges to conduct any human research activity.

2.3. ***Individual Investigator Agreement (IIA):*** a written agreement between UGA and a collaborating external investigator who is engaged in non-exempt research but not acting as an employee or agent of any institution or as an employee or agent of a non-assured institution that does not routinely conduct human subjects research.

2.4. ***Institution:*** any public or private entity or agency, which includes but is not limited to federal, state, and other agencies.

2.5. ***Researcher:*** a principal investigator or an individual authorized by the principal investigator and approved by the IRB as a member of the study team, such as a co-investigator, research assistant, or coordinator.

2.6. ***Letter of Authorization (LOA)***: any written record from an External Site providing authorization, approval or permission for the researcher to engage in research activities at that site; this can be an e-mail, letter, or site-specific standard form (sometimes known as Letter of Support).

2.7. ***Affiliation:*** an individual's relationship to a site through employment, enrollment, membership, or other similar means.

3. POLICY

3.1. External sites engaged in human subjects research must seek review and approval or ***exemption determination*** from an IRB or Ethics Board if there is one associated with the site. Federal guidance allows reliance on an IRB external to the institution. See *Policy and Procedure: Engagement Determination* and *Policy and Procedure: Reliance on an External IRB*.

3.2. External sites not engaged in research may need to provide a letter of authorization to the reviewing IRB.

3.3. UGA researchers must follow the policies of the external site for obtaining authorization. Some external sites have policies that grant authority to permit research only if the site's IRB has approved the research.

3.4. Letters of authorization must be provided to the IRB for all research conducted in or outside of the United States where the research and/or site involves one or more of the following (this is not intended to be an all-inclusive list):

3.4.1. the external site is a school or academic organization (e.g., K-12 Public and Private Schools, Universities, and Colleges), the target population are its own ***students***, and/or the research activities are conducted at the site during academic or school-affiliated extra-curricular activities;

3.4.2. the external site is a medical service provider or facility, the target population are its own patients, and the population is targeted because of its affiliation with the site;

3.4.3. the external site is a workplace, the target population are its own employees, the research activities are conducted at the site during work hours or using company resources, and the population is targeted because of its affiliation with the site.

3.4.4. the external site provides services of any kind and the target population are the recipients/clients of these services (e.g., a non-profit organization, counseling agency/center, support groups, and Non-Governmental Organizations (NGOs);

3.4.5. the external site is an organization or association which provides access to its membership;

3.4.6. data collection involves records or information owned by the external site and/or covered by another federal regulation, state, or local law (e.g., ***FERPA*** or ***HIPAA***);

3.5. The IRB may require a letter of authorization for non-exempt research if the targeted population affiliated with the site is considered ***vulnerable*** or if research procedures are expected to cause disruption of normal activities at the site.

3.6. The IRB will not require a letter of authorization for Exempt research involving external sites that do not fall into one of the categories listed in Section 3.4 unless the site has known policies requiring such authorization to conduct research.

3.7. The IRB will not require a letter of authorization for research where information is obtained from a public directory or public website. However, use of public directories or websites to post ***recruitment materials*** must follow the site's policies and guidelines.

3.8. The IRB may waive the requirement to provide a letter of authorization based on the following considerations: the method of initial contact, the potential influence of the person providing

authorization over the ***autonomy*** of the targeted ***participants***, the level of risks associated with the study, and whether the person granting site authorization is also a potential participant.

3.9. The written documentation permitting the research must clearly identify the person/s with authority to provide such authorization, and summarize the ***research procedures*** and any involvement of the external site; where applicable, assure institutional compliance with any State, Federal, or local laws that may apply to the conduct of the research. IRB-provided templates can be used to draft a letter seeking signature to be sent to the site.

3.10. If the research involves multiple external sites that require a letter of authorization, at least one letter of authorization must be provided to the IRB before the research will be approved or exempt determination provided.

3.11. The IRB may require a letter of written authorization prior to the IRB review.

3.12. UGA researchers are responsible for retaining documentation of site authorization or external IRB approval in their research record.

3.13. When an agent of the external site, who is not affiliated with UGA, will be ***engaged*** in non-exempt research, the IRB will require execution of an ***Individual Investigator Agreement (IIA)***.

4. PROCEDURES: Researchers

4.1. The ***Principal Investigator*** or any member of the research team must complete the submission form through the IRB's electronic application system. The Principal Investigator is responsible for submission of the form to the IRB.

4.2. The researcher must identify any external sites where prompted in the submission form and provide all requested contact information.

4.3. When applicable, the researcher must contact each existing external site to request a letter of authorization. When letter becomes available, it must be uploaded where prompted in the submission form. See *School Site Authorization Template* or *External Site Authorization Template*.

5. PROCEDURES: Institutional Review Board

5.1. The IRB will review the submission to determine if the research activities will be conducted at an external site(s).

5.2. If external sites are involved, the IRB will determine if the site is engaged in research. To determine if engaged, see *WORKSHEET: Engagement Determination* and *Policy and Procedure: Engagement Determination*.

5.3. For ***non-committee reviews***, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence, if needed.

5.4. For committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required ***modifications***.

6. **MATERIALS**
   6.1. Individual Investigator Agreement template, http://www.hhs.gov/ohrp/assurances/forms/iiabasicpage.html
   6.2. WORKSHEET: Engagement Determination
   6.3. External Site Authorization Template
   6.4. School Site Authorization Template

7. REFERENCES
   7.1. Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement, http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html
   7.2. Policy and Procedure: Engagement Determination

Revision History:
12/11/2015: REV0 New Document
9/20/2018: REV1