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 (IAA): 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.

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.

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.

4.4. The researcher must list all non-UGA collaborators and provide their site affiliation information, if any, along with all requested contact information.

4.4.1. Proof of completion of Collaborative Institutional Training Initiative training or an equivalent training from the external site must be provided.

4.4.2. For non-exempt research, a completed and signed Individual Investigator Agreement must be submitted if the non-UGA collaborator is not affiliated with an institution or is affiliated with an institution that does not have an active Federal Wide Assurance.

4.5. The researcher is responsible for factoring extra time needed for external IRB reviews or agreements, and/or site authorizations when planning the research study timeline.

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.

5.2.1. If the external site is engaged and the submission indicates that the external site has an FWA and an associated IRB that will review the research, the IRB will confirm that all collaborators are listed and have proof of completion of appropriate IRB training.

5.2.2. If the external site is engaged and the submission indicates that the external site has an FWA and an associated IRB which requests reliance on UGA IRB, the IRB staff will contact the external IRB to determine responsibility for drafting the IRB Authorization Agreement. See Policy and Procedure: Reliance on an External IRB.

5.2.3. The UGA IRB will use the OHRP template for IRB Authorization Agreements available at http://www.hhs.gov/ohrp/assurances/forms/index.html

5.2.4. The signatory official on agreements for studies with federal funding or support will be the Institutional Official. The signatory official on agreements for studies without any federal funding or support will be the HSO Director or IRB Chair.

5.2.5. If the external site is not engaged, the IRB will determine if site authorization is required for approval according to this policy.
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.

5.5. IRB Staff will document information pertaining to determinations that the requirements of this policy have been met in the review history for non-committee reviews and, for research reviewed by committee, in the meeting minutes by recording the motion to approve.

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
   7.2. Policy and Procedure: Engagement Determination
   7.3. Policy and Procedure: Reliance on an External IRB