Human Research Protection Program
UNIVERSITY OF GEORGIA

Engagement Determination

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UGAHRP-008-2	05/24/2021	HSO	HSO Director (HRPP Policy Committee notified)	Page **1** of **3**

1. PURPOSE

1.1. At the University of Georgia (UGA), all ***human subject***s ***research*** activities where a UGA employee or ***agent*** is ***engaged*** come under the purview and oversight of its Human Research Protection Program (HRPP). The UGA Institutional Review Board (IRB) relies on OHRP's Guidance on Engagement of Institutions in Human Subjects Research to determine engagement. The purpose of this ***policy*** is to define the process for determining when a UGA employee or agent is considered engaged in human subjects research.

2. DEFINITIONS

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

2.2. ***Federal-wide Assurance (FWA)***: refers to an assurance of compliance filed with the U.S. Department of Health and Human Services (DHHS). An institution that is engaged in human subjects research that is conducted or supported by any agency of the DHHS must have an assurance of compliance. Through the FWA, an institution commits to DHHS that it will comply with the Policy for the Protection of Human Subjects at 45 CFR part 46.

2.3. ***Agents:*** are employees and individuals who: (1) act on behalf of an institution; (2) exercise institutional authority of responsibility; or (3) perform institutionally designated activities; can include faculty, staff, students, authorized affiliates, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. An "authorized affiliate" is an individual granted research privileges at UGA by a department or college.

3. POLICY

3.1. The University of Georgia (Institution) is engaged when its employees or agents are engaged in a non-***exempt*** research project.

3.2. UGA employees or agents must receive approval or determination from the UGA IRB if any aspect of the research uses UGA resources, facilities, or affiliated populations (e.g., students or employees). This requirement applies whether the research is conducted at times the employee or agent is acting as a UGA-affiliated individual, or at times in other capacities such as, but not limited to the following: nights or weekends, semesters when a student is not currently enrolled in classes, or summer months for a nine-month employee.

3.3. The UGA IRB reviews non-exempt human subject research only when the institution is engaged in the research. The following table describes some scenarios where the activities may constitute engagement and non-engagement of the institution and its employees/agents. Note: These are some common examples and not an all-inclusive list. For additional information regarding engagement, see OHRP Guidance on Research: Coded Private Information or Biological Specimens.

Not-Engaged	Engaged
UGA employees/agents perform commercial or other services for ***investigators*** provided all of the following conditions are met: the services performed do not merit professional recognitions or publication privileges, the services performed are typically performed by the institution for non-research purposes; and UGA employees or agents do not administer any study intervention being tested or evaluated under the protocol.	UGA is the direct (prime) recipient of ***federal funding*** for a research project, even when all activities involving human subjects are performed through subcontract or other arrangements by the employees and/or agents of other institutions.
UGA employees or agents provide potential participants with information about the research but DO NOT obtain ***informed consent***.	UGA employees or agents obtain informed consent from prospective subjects.
UGA permits the use of its facility for intervention and/or interaction with subjects by the non-UGA investigator.	UGA employees or agents interact or intervene with subjects for research purposes.
UGA employees or agents inform prospective participants about the research availability only or provide potential participants with investigator contact information. However, the participant's permission must be obtained for the investigator to contact the participant.	UGA employees or agents distribute information about the research availability and answer questions about the research or engage in protocol-dictated communication about the research.
UGA employees or agents provide coded private information or human biological specimens where the UGA employee or agent is not considered a collaborator in the research.	UGA employees or agents obtain and/or use (analyze) identifiable or coded private information or human biological specimens.

4. PROCEDURES: Researchers

4.1. The researcher submits a complete application for review through the IRB electronic portal. The researcher shall make a preliminary assessment as to the engagement of any member of the study team and list individuals who are engaged according to the above policy as study team members, distinguishing between individuals who are affiliated with UGA and those who are not.

4.2. In the list of UGA study team members, the researcher will indicate which of these individuals will obtain informed consent from prospective participants.

4.3. The researcher will list any ***external sites*** where research will be conducted or from which participants will be recruited.

4.4. As applicable, the researcher shall indicate if the external site listed and/or institutions with oversight responsibility for non-UGA collaborators will conduct an IRB review.

5. PROCEDURES: HRPP Staff

5.1. IRB Staff determines if a submission meets criteria for exempt determination. If the submission meets criteria for exemption, the policy does not apply and this procedure is complete.

5.2. If the research does not meet criteria for exempt determination, the IRB staff applies the policy described in Section 3 to determine institutional engagement.

5.3. The IRB confirms the engagement of study team members by reviewing the description of study procedures and consent process. The *Worksheet: Engagement Determination* can be used as guidance.

5.3.1. 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.

5.3.2. 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 ***modification***s.

5.4. Uncertainty or disagreements about engagement are adjudicated by the IRB Director or designee, in consultation with Office of Research Legal Counsel as needed.

5.5. IRB Staff will document determinations that the requirements of this policy have been met on the review checklist corresponding to the type of review being completed (if non-committee review) or in the meeting minutes by recording the motion to approve.

6. MATERIALS

6.1. Worksheet: Engagement Determination

7. REFERENCES

7.1. DHHS Guidance on Engagement of Institutions in Human Subjects Research
http://www.hhs.gov/ohrp/policy/engage08.html

7.2. OHRP Correspondence - Determining When Institutions Are Engaged in Research
http://www.hhs.gov/ohrp/policy/institutions/ohrp20090113.html

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