Human Research Protection Program
UNIVERSITY OF GEORGIA

Guidance on Human Subjects Research Requirements for Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Grant Recipients

Section 1: Institutional (Small Business) Engagement in Human Subjects Research

- The Office of Human Research Protections (OHRP) is the federal office that oversees HHS-conducted or -supported non-exempt research involving human subjects.
- By regulation, institutions engaged in research involving human subjects must have a Federalwide Assurance (FWA) and certify IRB review and approval to HHS.
- OHRP has issued guidance on when institutions are engaged in research
- OHRP has issued guidance stating that institutions are considered engaged in an HHS-conducted or -supported non-exempt human subjects research project when institutions **receive an award** through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research, **even where all activities involving human subjects are carried out by employees or agents of another institution.**
- Federal Guidance for Determining Engagement

In summary, this means that the Small Business that is the recipient of the SBIR/ STTR grant must apply for and be granted a Federalwide Assurance AND obtain IRB approval for their role as the prime awardee of the grant. The University of Georgia's Federalwide Assurance and IRB approval of the research conducted by UGA faculty, staff and students DO NOT automatically extend to the small business.

Section 2: Obtaining a Federalwide Assurance (FWA)

- All institutions engaged in human subjects research that is not exempt from the regulations and is conducted or supported by any HHS agency must be covered by an OHRP-approved assurance of compliance. This is called a Federalwide Assurance (FWA).
- An assurance of compliance is a written document submitted by an institution that is engaged in non-exempt human subjects research conducted or supported by HHS in which an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.
- The small business must complete the assurance application process online. The

assurance application requires that the institution name an IRB.

  - This should be the IRB that reviews the largest percentage of the research conducted by the institution covered under the FWA.
  - This should **NOT** be the UGA IRB. There are many independent IRBs that can be named.

- The small business can apply for an FWA here: https://ohrp.cit.nih.gov/efile/
- Guidance on How to Obtain an FWA.
- The FWA must be renewed every 5 years.
- The assurance process requires the small business to develop and document policies pertaining to IRB review and compliance and other Terms of Assurance.

In summary, the small business will need to apply for and obtain their own Federalwide Assurance naming an IRB other than the UGA IRB.

Pre-Grant Submission Information

- For any grant submitted on or after January 25, 2018 a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. SBIR/STTR grants fall under this requirement.
- Beginning January 20, 2020, for federally funded research any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.
- The University of Georgia IRB will provide IRB review for the small business awardee of SBIR/ STTR on a case by case basis for Phase I SBIR/ STTR grants where the majority of human research activities are conducted by UGA investigators.
- There is a $500 fee associated with University of Georgia IRB providing review for the small business.
- Please contact the UGA Human Subjects Office **PRIOR** to grant submission to obtain confirmation that UGA will provide IRB review for the small business and to obtain budgeting information.

- The University of Georgia IRB will not provide review for the small business (or multiple sites) for Phase II or higher SBIR/ STTR grants where the small business scope of work involves significant engagement in human research activities or where a multi-site protocol is employed. These projects should be submitted to an independent IRB.

In summary, the University of Georgia IRB may provide review for the small business and other collaborators with limited scope of work associated with Phase I grants but may not for Phase II or future phases. Costs associated with IRB review should be considered during the grant submission phase.

IRB Submission Information

- When the University of Georgia IRB provides review for the small business and other collaborators, UGA and the small business/collaborators must negotiate and execute an IRB Authorization or Reliance agreement.
- An IRB Authorization or Reliance agreement is an agreement between the small business and UGA that allows the UGA IRB to provide IRB review for the small business for the specified research and defines the roles and responsibilities of each party.
- This agreement is needed in ADDITION to the sub-award and it is managed by the UGA Human Subjects Office.
- This agreement must be kept on file by the UGA IRB and the small business and made available upon request to federal regulatory agencies.
- If UGA researchers will rely on another (external) IRB for review of their part of the research, they will need to submit a request for External IRB review in the IRB portal in order to obtain confirmation that UGA agrees to rely on the selected IRB.
- The UGA IRB may have to negotiate an IRB Authorization or IRB Reliance agreement with the selected external IRB if one does not already exist.

In summary, written legal agreements are needed for UGA to provide IRB review for the small business or for UGA to rely on another IRB.