Georgia Tech
Office of Research
Integrity Assurance

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 Georgia Institute of Technology's Federalwide Assurance and IRB approval of the research conducted by GT faculty, staff and students **DO NOT** automatically extend to the small business.*

Section 2: Obtaining a Federalwide Assurance (FWA)

- All institutions engaged in non-exempt human subjects research 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 GT IRB.** There are many independent commercial IRBs that can be named. GT IRB cannot serve as the named IRB on the small business FWA application, as it would obligate GT to serve as IRB for ALL research conducted by that small business under their FWA.
- 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 GT IRB.

Pre-Grant Submission Information

Background:

- *For any NIH 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 all federally funded research at any institution located in the United States engaged in cooperative research, the project must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.*

- The Georgia Institute of Technology IRB will provide IRB review for the small business awardee of SBIR/STTR on a **project specific case-by-case basis** for SBIR/STTR grants where the majority of human research activities are conducted by GT investigators.
- Please contact the Georgia Tech Office of Research Integrity Assurance Human Research Protection Program office **PRIOR** to grant submission to obtain confirmation that GT will provide IRB review for the small business and to obtain funding information.

- The Georgia Institute of Technology IRB will not provide review for the small business (or multiple sites) for 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.

Costs associated with independent IRB review should be considered during the grant submission phase.

IRB Submission Information

- When the Georgia Institute of Technology IRB provides review for the small business and other collaborators, Gt and the small business/collaborators must negotiate and execute an IRB Authorization Agreement (Reliance Agreement).

- An IRB Authorization Agreement is an agreement between the small business and GT that allows the GT 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 GT Office of Research Integrity Assurance.

- This agreement must be kept on file by the GT IRB and the small business and made available upon request to federal regulatory agencies.

- If GT researchers will rely on another (external) IRB for review of their part of the research, they will need to submit a request in IRBWISE in order to obtain confirmation that GT agrees to rely on the selected IRB.

    - Guidance on how to submit for external reliance.

- The GT IRB may have to negotiate an IRB Authorization Agreement (Reliance Agreement) with the selected external IRB if one does not already exist.

In summary, written agreements are needed for GT to provide IRB review for the small business or for GT to rely on another IRB. These agreements are executed by the Georgia Institute of Technology Institutional Official and cannot be entered into by the PI.