

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

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### 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 human subjects research.
- By regulation, institutions who are engaged in human subjects research must have an OHRP approved Federal Wide Assurance and certify IRB review and approval to HHS (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/file-a-new-fwa/index.html>)
- 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.**
- Guidance Document available for review here: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

*In summary, this means that the Small Business who is the recipient of the SBIR/ STTR grant must apply for and be granted a Federal Wide Assurance AND obtain IRB approval for their role as the prime awardee of the grant. Washington University's Federal Wide Assurance and IRB approval of the research conducted by their faculty, staff and students DO NOT extend to the small business and thus DOES NOT fulfill the requirement set by the terms of the award.*

### Section 2: Obtaining a Federal Wide 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.
- 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 assurance application process must be conducted online by the small business. 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 Washington University IRB. There are a number of independent IRBs that can be named.
- The small business can apply for an FWA here: <https://ohrp.cit.nih.gov/efile/>
- The FWA must be renewed every 5 years.

*In summary, the small business will need to apply for and obtain their own Federal Wide Assurance naming the IRB other than the Washington University IRB as they will not be the IRB reviewing the largest part of the business's research.*

### **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.
- Washington University IRB acts as the IRB for the small business awardee of SBIR/ STTR on a case by case basis for Phase I SBIR/ STTR grants.
- There is a fee associated with Washington University acting as the IRB for the small business.
- Please contact Washington University Human Research Protection Office PRIOR to grant submission to obtain confirmation that they are able to act as the IRB for the small business and to obtain budgeting information.
- Washington University does not have a mechanism that allows them to act as the IRB for the small business for Phase II SBIR/ STTR grants.
- While a single IRB must review the protocol for both the small business and the Washington University researchers, the Washington University IRB CANNOT act as the IRB for Phase II SBIR/ STTR research.

*In summary, Washington University may be able to act as the single IRB for Phase I but cannot for Phase II. Costs associated with IRB review should be considered during the grant submission phase.*

### **IRB Submission Information**

- If the Washington University IRB is going to be acting as the IRB for the study, Washington University and the small business must enter into an IRB Authorization or Reliance agreement.
- An IRB Authorization or Reliance agreement is an agreement between the small business and Washington University that allows Washington University IRB to act as the IRB for the small business 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 WU HRPO office.
- The Washington University PI should contact HRPO when they are preparing their IRB submission to begin the agreement process.
- This agreement must be kept on file at Washington University and the small business and made available upon request to federal regulatory agencies.
- If Washington University researchers are going to request to rely on another IRB for review of their part of the research, they will need to submit an administrative application in myIRB in

order to obtain confirmation that Washington University is agreeable to relying on the particular chosen IRB.

- Washington University may have to enter in to an IRB Authorization or IRB Reliance agreement with the chosen IRB if one does not already exist.
- Currently, Washington University may also use 2 Independent (Commercial) IRBs- Western IRB (WIRB) and Advarra with agreement from, and appropriate submission of application to HRPO.

*In summary, written legal agreements are needed for Washington University to act as the IRB for the small business and for Washington University to rely on another IRB.*