

COURSE 13, TUTORIAL 1

PART 3

HOW TO ASSURE COMPLIANCE WITH THE FINAL RULE



All SBIR/STTR funding agencies follow the Final Rule to ensure human subject protection in studies. But what exactly does the investigator need to do to ensure compliance with the Final Rule? For the purposes of this tutorial, we will assume that the investigator's SBIR/STTR firm will be doing human research in conjunction with an institution that is capable of carrying out the firm's research protocol. The institution must be registered with the U.S. Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP) and have received a Federalwide Assurance (FWA) number. You will need the FWA registration number for your application.

ROLE OF THE INSTITUTIONAL REVIEW BOARD

Next, the investigator must prepare a research proposal for submission to, and review by, the institution's approved Institutional Review Board (IRB). The IRB can be internal to the institution or an institution approved external IRB. The IRB will be evaluating your proposal for the following:

- » The risks to subjects are minimized as much as possible.
- » The risks to subjects are reasonable in relation to anticipated benefits.
- » The informed consent process is adequate.
- » The research plan makes provisions for the safety of the subjects during the data collection process
- » Provisions are in place to protect the privacy of subjects and maintain confidentiality of data
- » Appropriate safeguards are included within the study to protect the rights and welfare of Federally defined vulnerable subjects (pregnant women, fetuses, children, and prisoners)

IRB VS. AGENCY APPROVAL

The IRB can be internal to the institution or an institution approved external IRB.

The IRB can evaluate the proposal, not approve the proposal or return it to you with suggested changes that will enable approval. You will need IRB approval before funding for the human research can be released to you by the SBIR/STTR funding agency. The IRB will provide you with a Human Subject Assurance number for your application. Agency approval is also required, beyond that of the IRB, to receive SBIR/STTR funding. For example, the NIH uses their peer review process to review the proposal. The Defense Health Agency (DHA) – part of the DoD – uses the U.S. Army's Medical Research and Materiel Command's Human Research Protection Office (HRPO) to evaluate human research proposals for adequate subject protection.



ADDITIONAL AGENCY REQUIREMENTS

Agencies may have other requirements, for example, the NIH also want certification that all key personnel have received human subjects education training. The NIH offers a free tutorial that can be used to fulfill the education requirement. If the human research is a clinical trial, the NIH also requires the submission of a Data Safety Monitoring Plan (DSMP). The DSMP “should address the PI’s plan for ensuring the safety of participants and the validity and integrity of the data for all clinical trials.”

CHOOSING AN INSTITUTION AND IRB

Select your institution and IRB carefully. If your selected institution and/or IRB is found to be non-compliant with the agency’s human research protection regulations, your SBIR/STTR award could be terminated or suspended.

HUMAN SUBJECT TESTING IN PHASE I PROPOSALS

Considering the complexity of human subject research and length of time needed to get the necessary approvals for conducting human research, it is very unlikely that it would be possible to complete a human subject trial given the limited time constraints imposed on SBIR/STTR Phase I projects. It can take 30+ days to receive IRB approval once your project is

scheduled for review. The IRB may have a long queue of proposals to review before yours or it may convene infrequently. For this reason, DoD agencies recommend that human subject testing not be part of any Phase I proposal. Similar language can be found in the Department of Energy’s (DOE) “SBIR/STTR Instructions for Completing a DOE SBIR/STTR Phase I Grant Application”. NASA will not allow human subject testing during a Phase I SBIR/STTR program.

If a firm is considering human subject research in Phase I, the principal investigator (PI) should contact that SBIR office at the agency of interest prior to a solicitation release to determine under what circumstances the research would be allowed.

Due to time constraints, DoD agencies recommend that human subject testing not be part of any Phase I proposal.