DARPA-Funded Research Involving Human Subjects

Guidance for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR)

Definition of Human Subjects Research in Federal and DoD Policies

The term "human subject" can be applied to research efforts that meet EITHER of the following criteria:

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens.

Human Subjects Research involves:

- Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens.

Any DARPA-funded research which involves humans as defined on this page MUST be considered HSR.

Federal and DoD Policies

All DARPA-funded HSR, must comply with these policies:

COMMON RULE (45 CFR 46)

32 CFR 219

DoD Instruction 3216.02
10 USC 980

DARPA Inst. 66

The associated DARPA Instruction (DI) **DI-66,** was developed to implement the guidelines set forth in **DoDI 3216.02, which implements, 32 Code of Federal Regulations (CFR) 219** "Protection of Human Subjects"**(a/k/a <u>the DoD's version of the Common Rule</u>).**

HSR approval Process

- Principal Investigator submits protocol to local IRB for review and approval
- HSR package is then submitted for DoD headquarter review and approval
  - Includes local IRB approval letter
  - Federal Wide Assurance (of institution performing research)
  - Informed Consent Document ***Make sure informed consent document includes statement that the research is being funded by DoD and thus the DoD has access to the data***
  - Recruiting Materials
  - Biosketches/CVs
  - Training Certifications
- DoD review authority, reviews the entire package
  - May go back to PI with comments/recommendations/changes
- Once DoD HRPO approval is obtained, HSR research can begin
- Note that protected populations (i.e. military, pregnant women, etc.) have special regulations that need to be followed. This includes such things as command level approval for recruitment of subjects (active duty military)

Note – DoD HRPO review and approval can take anywhere from 1-3 months. Do not delay in starting this process!

*****If the funded activity is Research Not Involving Human Subjects, please reach out to the PM/SETA team, for further guidance before contacting your local IRB.*****

Helpful Hints

Strongly recommend proposing HSR to be conducted during Phase 2; thereby ensuring enough time to prepare and submit human use approval documentation to the Institutional Review Board (IRB) during Phase 1.

- **If possible, submit a Draft Protocol with proposal.** Especially, in cases where the research might be research not involving human subjects, the PM/SETA team can provide a self-assessment submittal document to the performer to complete before creating a submittal to an IRB (Protocol Determination Sheet).

- **If you have a contract involving subcontractors who are conducting HSR; they will also need to obtain HSR approval.** Any performer including subcontractors must receive HSR approval through the local IRB and the DoD HRPO before start of their research.

- **If you make changes to the statement of work, they also need to be approved.** If the changes are to the HSR portion of the work, the revisions will have to go through the local IRB for review, as well as DoD HRPO review for approval and concurrence.

Commercial IRBs

If you do not have an internal IRB, you have one of three options

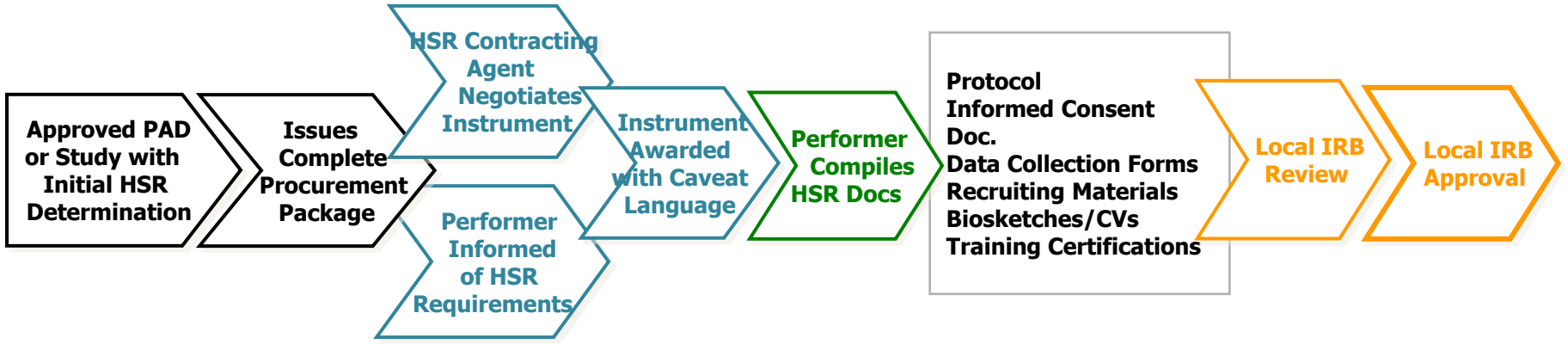
- Hire a commercial IRB (see website: http://www.circare.org/info/commercialirb.htm)
- Work with the Contracting Agent to determine if they have an internal IRB that could assist
- If work involves collaboration with other performers, considering using their IRB

Commercial IRB statistics:

- Average Turnaround Time: Unconditional approval and/or decision documents returned within 1-2 weeks from the local IRB.
- Average Costs: Initial IRB Review $900-$2750; Annual Continuing IRB Reviews for duration of HSR $400-$2750. Additional fees may apply depending on extra research sites, investigators, etc.
- DARPA will pay for the costs of using a commercial IRB if included in the proposed budget.

Complete HSR Approval Process (for non-exempt HSR)

LOCAL IRB REVIEW



ADMIN REVIEW (DoD HRPO)

*including local IRB approval letter

Responsibilities:

DARPA | Local IRB | DoD Reviewer | Performer | HSR Contracting Agent

*Please give 3-6 months for the complete process

Questions?

Please contact the Small Business Support Team at:

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