DARPA-Funded Research Involving Human Subjects

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

Definition of "Human Subject" and HSR

Human Subject

An investigator (whether professional or student) obtains information from a living individual through **EITHER**:

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 (HSR)

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 human subjects as defined on this page is considered HSR.

Federal and DoD Policies

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

DARPA Inst. 66 (DI-66)

Developed to implement the guidelines set forth by policies below and applies to all DARPA-funded HSR.

32 CFR 219, DoDI 3216.02, 10 USC 980, DFARS Clause 252.235-7004

DOW-specific policies that implement the Common Rule, require informed consent, and enforce compliance through contracts.

COMMON RULE (45 CFR 46)

The foundational regulation for all federally-funded human subjects research.

HSR approval 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.*****

1. Principal Investigator submits protocol to local IRB for review and approval
2. HSR package is then submitted for DoD headquarter review and approval
3. DoD review authority, reviews the entire package[1]
4. Once DoD HRPO approval is obtained, HSR research can begin

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)

HSR package should include:

- Includes local IRB approval letter
- Federal Wide Assurance (of institution performing research)
- Informed Consent Document*
- Recruiting Materials
- Biosketches/CVs
- Training Certifications

***Make sure informed consent document includes statement that the research is being funded by DoD and thus the DoD has access to the data**

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

[1] May go back to PI with comments/recommendations/changes

Helpful Hints

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.

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.

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

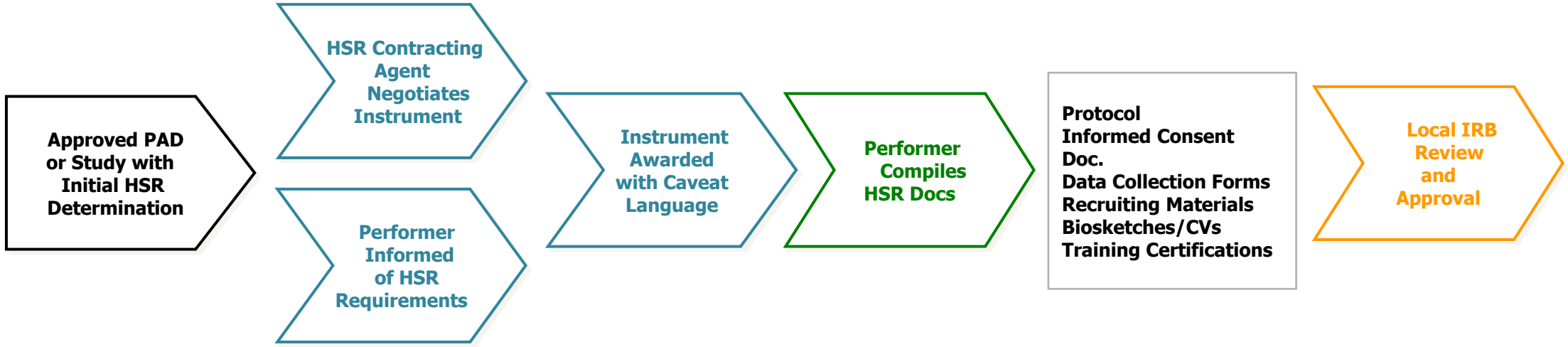
If work involves collaboration with other performers, considering using their IRB

Commercial IRB statistics:

Average Turnaround Time	Average Cost	DARPA's Contribution
• Unconditional approval and/or decision documents returned within 1-2 weeks from the local IRB.	• 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.

Review: Complete HSR Approval Process

LOCAL IRB REVIEW



ADMIN REVIEW (DoD HRPO)

*including local IRB approval letter

Responsibilities:

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

*Please give 1-3 months for the complete process

Questions?

SBIR·STTR

POWERED BY INNOVATORS
MOVING TECHNOLOGY FORWARD

Please contact the Small Business Programs Office at:

(703) 526-4170

sbir@darpa.mil