Human Subjects Research at DARPA

Lisa Mattocks
STO ADPM/HSR Action Officer

Industry Day

Definition of Human Subjects Research in the DoD

The term "human subjects research" (HSR) can be applied to research efforts that meet EITHER of the following criteria outlined in the Common Rule:

1) Any research involving an INTERVENTION or an INTERACTION with a living person that would not be occurring but for this research
   - Intervention: physical procedures by which data is gathered (for example, blood sampling) or manipulation of the subject or the subject's environment performed for research purposes.
   - Interaction: communication or interpersonal contact between investigator and subject.
2) Any research in which the principal investigator (PI) conducting research obtains IDENTIFIABLE PRIVATE INFORMATION.
   - Identifiable private information: information about a behavior that:

     (i) occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and (ii) information which has been provided for specific purposes by an individual and the individual can reasonably expect will not be made public. Identifiable information includes but is not limited to names, addresses, medical record numbers, social security numbers and video recordings.

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

HSR approval Process

- Principal Investigator submits protocol to local IRB for review and approval
- HSR package is then submitted for HQ level 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***
  - Recruiting Materials
  - Biosketches/CVs
  - Training Certifications
- DOD HQ reviews entire package
  - May go back to PI with comments/recommendations/changes
- Once DOD gives approval, HSR research can begin
- Note that protected populations (i.e. military, pregnant women, etc) have special regulations that need to be followed.

Note – HQ approval can take anywhere from 3-6 months. Do not delay in starting this process!

Review of the Protocol

All DARPA human subjects research protocols must go through two reviews

1st review

Local Level (local IRB)

2nd review

DoD Level (Headquarters Review)

Helpful Hints/FAQs

- **If possible, submit an IRB approval letter and/or a Draft HSR Protocol with proposal.** Especially, in cases where humans are involved and you don't know that the work is really HSR. Having an IRB already look at it will help you and DARPA in moving forward faster.
- **If you do not have an internal IRB, you have one of three options**
  - Hire a commercial IRB
  - 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
- **If you have a contract involving subcontractors who are conducting HSR; they will also need to obtain human use approval.** Any performer including subcontractors must receive HSR approval through the local IRB and the DoD headquarters 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 headquarters level review for approval and concurrence.

Points of Contact

Government HSR and ASR Action Officer

Lisa Mattocks

Lisa.Mattocks@darpa.mil

571-218-4424

HSR POC

Sahar Zafar

Sahar.Zafar.ctr@darpa.mil

703-362-3438