DARPA-Funded Research Involving Human Subjects

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

Definition and Regulations

HUMAN SUBJECTS RESEARCH (HSR) aka HUMAN USE

These protocols apply to all research that meets either of the following criteria:

1) Any research involving an INTERVENTION or an INTERACTION with a living person that would not be occurring under usual circumstances.
2) Any research involving data/information/specimens collected originally from people (broadcast video, web-use logs, surveys, etc.) in which the identity of the subject is known, or the identity may be readily ascertained from the information.

REGULATIONS

- The Common Rule

  Title 32, Code of Federal Regulations (CFR) Part 219, "Protection of Human Subjects," current edition
  http://www.dtic.mil/biosys/downloads/32cfr219.pdf

- DoD Instruction 3216.02

  Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
  http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

Suggested Best Practices

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 the awarded performer does not have an IRB, recommend:
1) Teaming with an institution who has an IRB or
2) Using a commercial IRB (see website: http://www.circare.org/info/commercialirb.htm)

Commercial IRB Statistics

- Average Turnaround Time: Unconditional approval and/or decision documents returned in a week 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.

HSR Review Information

In addition to a local IRB approval, a headquarters-level (DoD-level) human subjects regulatory review and approval is required for all research conducted or supported by the DoD.

- The Service component (Army, Navy, Air Force) responsible for managing the award can provide further guidance regarding headquarters-level approvals.
- Confirmation of a current Federal Wide Assurance (FWA), Institutional Review Board (IRB) Approval, and appropriate human subjects protection training provided by the performers is required before headquarters-level approval can be issued.

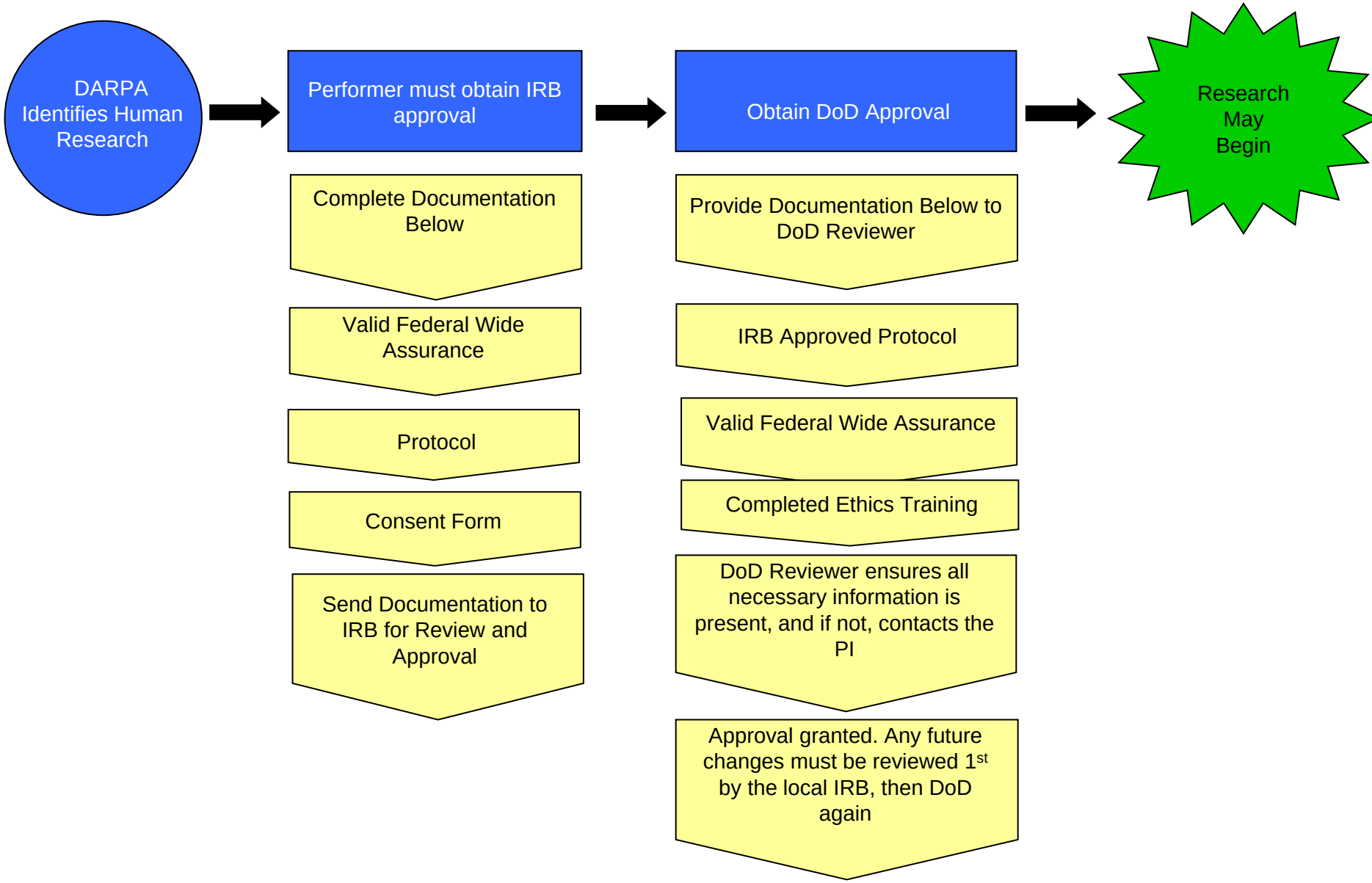
Federal Wide Assurance (FWA) Requirement

- Any performer engaged in HSR must hold a valid FWA through the Department of Health and Human Services. See website: http://www.hhs.gov/ohrp.
- The IRB conducting the review must be named on the Institution's Assurance.

Institutional Review Board (IRB) Requirements

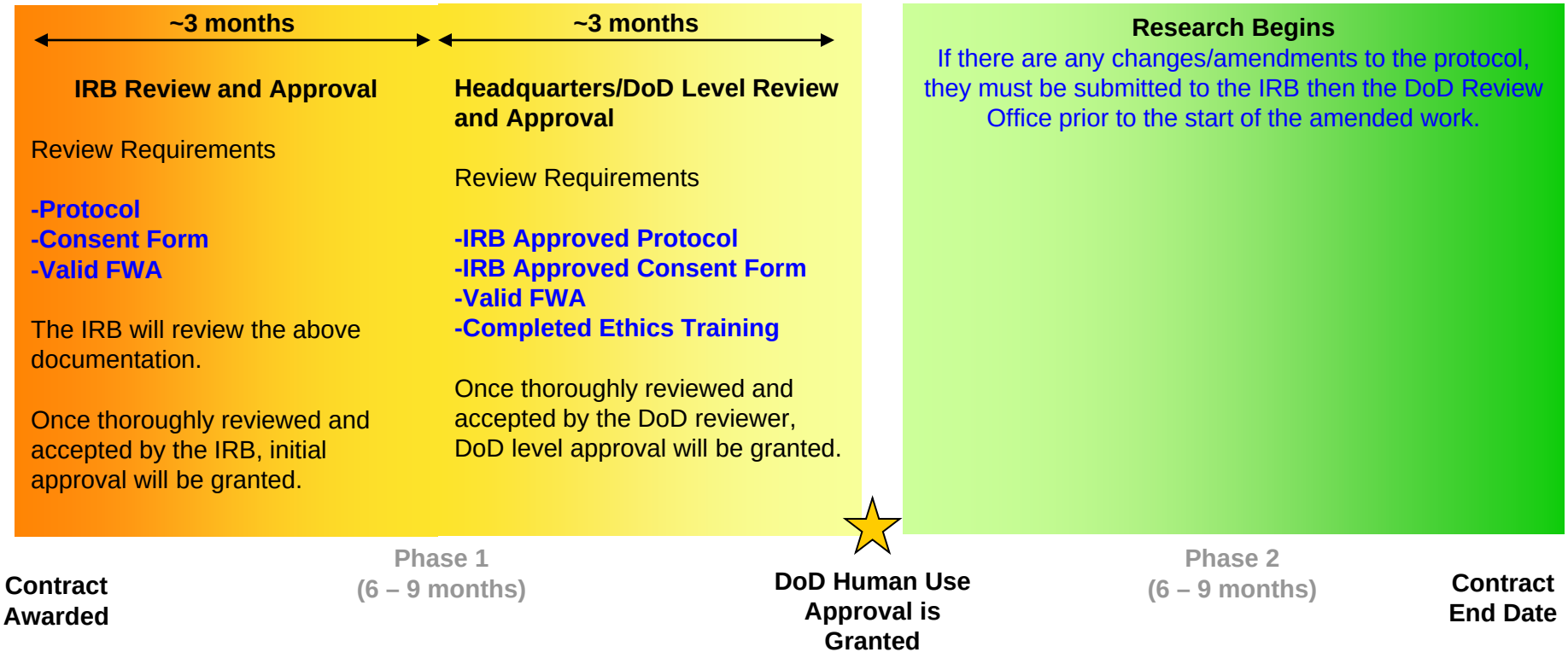
- The protocol, separate from the proposal, must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment, consent process, data collection, and analysis.
- The consent form, if applicable to the research, must comply with the Common Rule (32 CFR 219).

Approval Process



The Approval Process and Timeline

PI must submit/complete all items in blue



****Note: Absolutely NO money can be used on human research and testing until DoD approval is granted.**

****Plan for 6-9 months for approval process.**

Definitions

- **Assurance** – A formal written document issued by a federal department ensuring compliance with necessary regulations governing human subject research and describing those proceedings through which compliance will be achieved. Example: Federal Wide Assurance (FWA) through DHHS
- **Common Rule** – The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is 32 CFR 219.
- **DARPA Agent** – DARPA executes its programs through the Military Departments and other US Government agencies, called Agents, and, where appropriate, demonstrates technical feasibility and defense utility in joint experiments and demonstrations with these Agents. DARPA Agents perform functions such as award and administration of contracts, oversight of technical efforts, and various support functions. In addition, they may actively participate in the development of technology as well as transition opportunities.
- **Informed Consent** – The legally effective written permission and agreement of the human subject or the human subject's legally authorized representative prior to that individual's participation in human subject research. The document should be signed after the individual has been made aware of all foreseeable risks and benefits of participation.
- **Institutional Review Board (IRB)** – A committee designated by an institution to review, approve, and conduct periodic monitoring of research involving human subjects. IRBs assume oversight responsibility for protecting the rights of human subjects.
- **Protocol** – A comprehensive, detailed and specific plan of action for execution of human subjects research. A protocol may include, but is not limited to: objectives, research design, population, recruitment process, data collection, and analyses.

Questions?

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