Where to submit documents for NCER

The process of human subjects research approvals for grants (including fellowships) within NCER actually begins quite early: the very development of the call for proposals involves conversations about whether or not human subjects research is likely for a particular focus area. As a result, the NCER Human Subjects Official (HSO) is involved at key stages of the RFA development process. The first flow chart attached below identifies appropriate stages for HSO involvement beginning with the RFA concept meeting.

In addition, a table and flow chart of the approval process for the human subjects research part of your grant or fellowship are provided. They are as follows:

- Approval Process Table This table contains information on the types of human subjects research that might be conducted and the individuals responsible for approving those studies depending on the nature of the proposed research.

- Approval Process Flow-Chart: This graphic display was developed as a visual representation of the steps in the Approval Process Table.

Any questions about this process, or about the research you are (thinking about) conducting should be directed to:

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Acting Human Subjects Official
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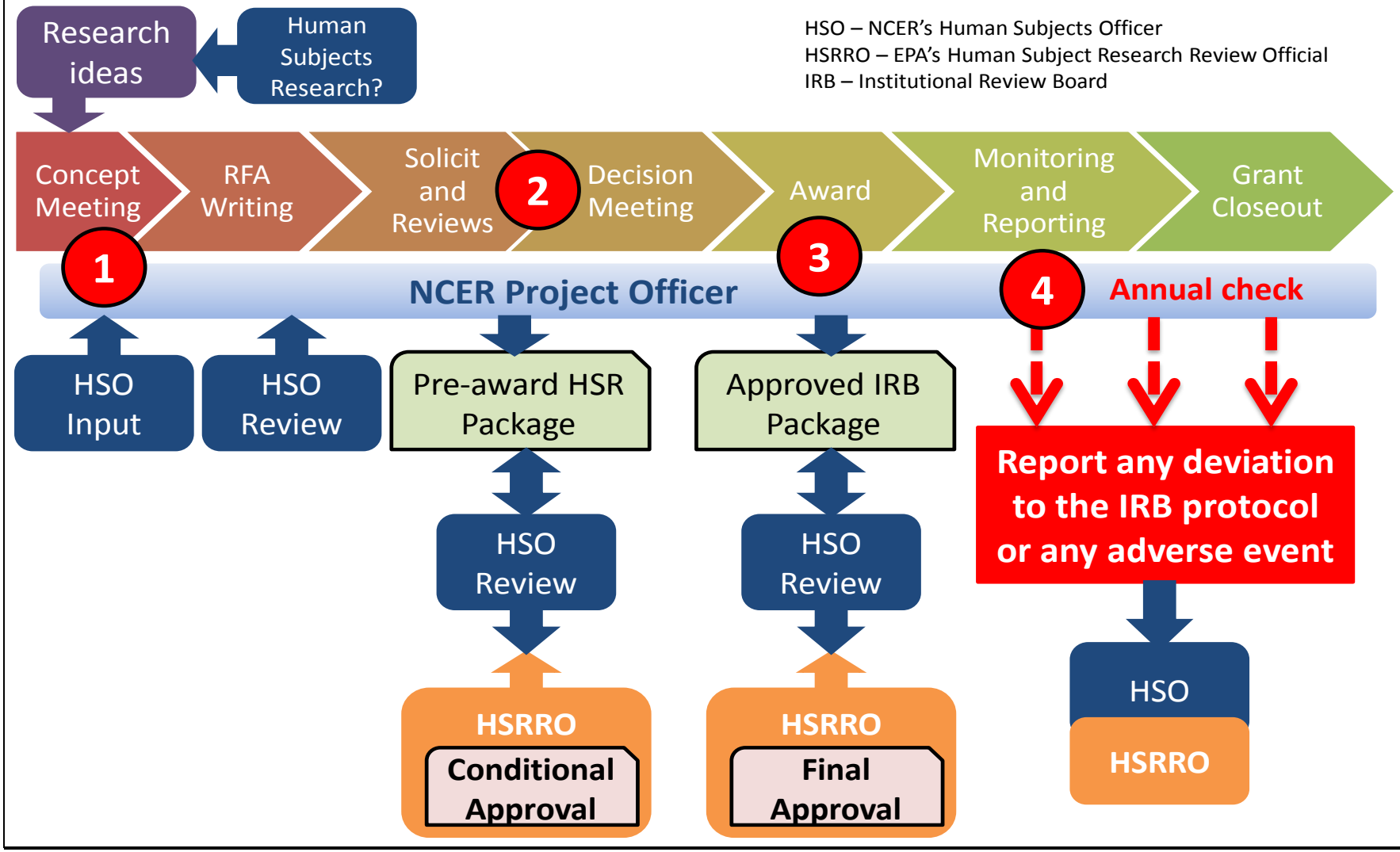
703-347-8080

Human Subjects Review for NCER grants



Who should review/approve human studies in NCER?									
	Research Scenario								
	Interventional Human Study		Observational Human Study		Database study with no interaction	Exempt HSR (b)	Not HSR	Changes to approved study	
	Conditional Approval (a)	Final Approval	Conditional Approval (a)	Final Approval				Minor	Substantive (c)(d)
PI	X	X	X	X	X	X	X	X	X
IRB		X		X	X	X		X	X
HSO	X	X	X	X	X	X	X	X	X
HSRRO	X	X	X	X	X	X			X

Footnotes:

a. Conditional Approval may be provided to grant applications in accordance with 40 CFR 26.118. However, no work with human subjects can begin until the study has IRB approval and final approval from the EPA HSRRO.
b. HSR = Human Subjects Research as defined in 40 CFR 26.101.
c. Substantive changes as defined in on EPA Human Subjects Research Intranet site.
d. **Adverse Events** significant enough for a subject to be removed from study, or that results in an **Unanticipated Problem Involving Risks to Subjects or Others** (UPRISO) as defined by the IRB of record should also be submitted through the Substantive Study Change pathway. Otherwise, We expect investigators to follow the definitions and reporting timeframes for adverse events and unanticipated problems of the IRB of record for their project

Human Subjects Review for NCER (grants and fellowships)

Final approval for studies involving human subjects, database studies, and substantive changes in approved studies

Conditional Approval of studies involving human subjects

Minor changes to approved studies; studies that do not qualify as human subjects research

Not human subjects research