

Human Research Protection Program Policies & Procedures

Human Subject Research in the Future

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Background:

The Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board (IRB). Certain HHS Agencies permit Certification of IRB Approval to be deferred until just prior to funding. Additionally, for research applications and proposals that lack definite plans for the involvement of human subjects, the IRB must have in place mechanisms to ensure that any research supported under the award receives IRB review and approval prior to the involvement of human subjects.

Scope:

This P&P covers human subject research that requires “just-in-time” or “future human subjects” review.

Definitions:

Future Human Subjects Research – Research applications and proposals for funding lacking definite plans for the involvement of human subjects either because the specific human subject activities have not yet been fully developed, or because human subject research was not anticipated at the time of the application. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

Just-in-Time Process - A feature is used by NIH for applications meeting established review criteria. In general this feature becomes available for applications that fall within a certain percentile or priority score ranges and have a high likelihood of being funded.

Policy:

- I. “Just in Time” review (JIT)
 - A. The IRB must review the application or proposal for HHS funding to ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.
 - B. The IRB should ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) reviewed and approved by the IRB. Any discrepancies must be resolved prior to the involvement of human subjects.

- C. The application or proposal need not be reviewed by the IRBs at non-awardee institutions participating in the research. However, appropriately redacted copies of funded applications or proposals should be made available to IRBs at participating institutions if requested.

II. "Future Human Subjects" Review (FHS)

- A. The FHS application or proposal need not be reviewed by the IRB prior to an award.
- B. The IRB must ensure that any FHS research supported under the award receives IRB review and approval prior to the involvement of human subjects.
- C. Except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.
- D. Certain types of awards (e.g., program project and center grants) support multiple projects involving numerous investigators. Research that is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research must be reviewed and approved by an IRB.

NOTE - A certification must then be submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

Process

I. "Just in Time" review (JIT)

- A. When a research receives a JIT notice, the IRB must conduct a standard IRB review in order to satisfy the Federal Requirements for IRB review and potential release of federal dollars.
- B. The IRB must review the actual application or proposal for HHS support.
- C. A designated IRB member may document that the proposed research is consistent with any relevant protocol(s) submitted to, or previously approved by, the IRB.
- D. The designated IRB reviewers must have access to the entire application or proposal (exclusive of appendices) because information related to the protection of human subjects sometimes appears only in seemingly peripheral sections.
- E. A copy of the HHS application or proposal should be retained among IRB records.

II. "Future Human Subjects" review (FHS)

- A. When a researcher has a project that meets the definition of FHS, they may submit an FHS application in the eIRB for IRB review and approval.
- B. A memo will be created by the IRB assuring compliance with human subjects protections for the future human activities, prior to the initiation of the work.

Authority

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

Link to OHRP Guidance: <http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>