

Program for the Protection of Human Subjects

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INVESTIGATOR INFORMATION SHEET

COMPARATIVE REVIEW

Purpose

The purpose of this information sheet is to explain the procedures to verify that the information provided for IRB review and approval is internally consistent with grant applications or proposals.

Background

To avoid instances in which human subject research described in an application for HHS support differs significantly from the IRB-approved protocol that is claimed by an investigator to constitute the research in the application, 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). The Program for Protection of Human Subjects applies these standards to all research regardless of funding source (not solely to HHS-supported research). The IRB's review should ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

When Does this Apply?

The two most common scenarios that require the submission of **HRP-215-FORM – Comparative Review** to the PPHS are:

- 1. Research has been approved pending notice of award (NOA).** Once research has been reviewed and approved by the IRB, the expectation is that the research will be conducted as approved by the IRB. There are situations in which the grant application or proposal changes over the course of the peer review process so that at the time of funding the research approved by the IRB is no longer identical to the research that has been funded. Prior to generating final IRB approval for a research study that has received funding, the IRB must conduct a comparative review.
- 2. Additional funding source or change in funding.** When there is a change in funding source for IRB approved research, in order to ensure that the research that is being funded is the same as the research that has been approved by the IRB, the IRB must conduct a comparative review prior to approving the modification to change or add a funding source.

Investigator Responsibilities

It is the responsibility of the Principal Investigator to provide documentation to the IRB that is internally consistent. Any changes to IRB approved research must be submitted using **HRP-213-FORM-Modification of Approved Human Research**.

Changes should not be implemented until IRB approval is received, unless they are necessary to remove apparent immediate hazards from the human subjects.

Relevant Material

HRP-215-FORM- Comparative Review

Reference Documents

45 CFR 46.103(f)

<http://www.hhs.gov/ohrp/policy/aplrev.html> (last accessed 7/26/12)