Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: III.H
Section: IRB Review Procedures
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: February 18, 2004
Revision Dates: June 13, 2013; July 1, 2015; October 1, 2017

Subject: Grant or Umbrella Review

Definitions:
1. Grant Review: A review conducted to assess 45.CFR 46.111 criteria for a specific grant.
2. Umbrella Review: A review, authorized under 45 CFR 46.118, by the sub-Committee or Designee to acknowledge a grant proposal under which any definitive plans for the involvement for human subjects are lacking.

Policy:
It is the policy of the Institutional Review Board (IRB) to review a specific grant in its entirety for the criteria under 45 CFR 46.111 or 45 CFR 46.118.

I. A Grant or Umbrella review may be utilized for IRB approval of a grant where funds will be distributed among multiple sub-studies. A Grant approval does not provide final approval for enrollment of human participants into a particular study; it is simply an approval of a grant proposal in general but does not constitute an approval of the individual research activities and enrollment conducted under the grant.

II. Each sub-study under the grant is to be submitted by the Investigator responsible for the sub-study at the level of review for which it meets criteria for IRB review and approval. The appropriate sections of the grant and/or a protocol will be reviewed and approved with the separate sub-study submissions.

III. Each sub-study is to be conducted in accordance with all applicable HRPP policies and procedures. For each sub-study, the informed consent documents (ICDs) must be submitted with the “Application for Human Research” or a request for a waiver of consent should be submitted according to HRPP policies and procedures.

IV. Grant and/ or Umbrella reviews are subject to annual continuing review. Each sub-study falling under the Grant or Umbrella must be kept current for continuing review approval to be granted.

V. Closure of the Grant or Umbrella review is permitted when the closure report has been submitted to the funding agency.

References
HRPP III.H.1 - Procedure for Grant Review