
Yale University Human Research Protection Program

920 PR.6 Use of NICHD IRB for Review and Oversight of Research Involving Yale Investigators

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Overview

This procedure reviews the process for use of Eunice K. Shriver Institute of Child Health and Human Development Institutional Review Board (NICHD IRB) for IRB review and oversight of research involving Yale investigators. Yale maintains a Memorandum of Understanding with NICHD IRB which sets forth understandings, authority and responsibilities of both institutions.

Protocol Transfer

The National Children’s Study has been approved by the Yale IRB, and will be transferred to the NICHD IRB upon execution of the Memorandum of Understanding.

When the transfer has taken place, the Yale protocol (HIC#1006006929) will be closed. A new protocol will be created in the Coeus system, indicating oversight by the NICHD IRB. The NICHD IRB protocol expiration date will be entered into the system.

NICHD Submission Forms

All submissions must use the standardized forms developed by the NICHD IRB. Approval documents from internal scientific committees which are responsible for conducting a thorough review of research protocols **prior** to a Yale IRB submission must be included with the submission. These include the Pediatric Protocol Review Committee (PPRC) and the Yale Cancer Center Protocol Review Committee (PRC), as appropriate. Any Yale IRB determinations regarding management of conflict of interest will be included in the submission to the NICHD IRB.

Complete protocol submission packets will be sent by the Yale PI to NICHD IRB either by a) scanned pdf, b) facsimile, c) next day delivery by a national air courier service, or (c) U.S. mail.

Conflict of Interest

Each Yale research team member who takes part in NICHD research projects must comply with Yale University policy and procedures regarding Disclosures and Management of Personal Interests in Human Research <http://www.yale.edu/hrpp/policies/index.html#COI>.

If the principal investigator, co-investigator, or any other responsible person, or any of their family members (spouse, child, domestic partner) has an incentive or interest, financial or otherwise, that may be viewed as affecting the protection of the human subjects involved in the protocol, the scientific

objectivity of the research or its integrity this must be explained to the Yale IRB with the personnel change request.

Yale will review the conflict and determine a management plan, if needed. Yale will provide the NICHD IRB with the conflict and the management plan as noted above.

Protocol Changes

Yale's agreement with NICHD requires that the Yale IRB ensure that the investigators and other staff conducting the research are appropriately qualified and meet Yale's standards for eligibility to conduct research, have been through an appropriate institutional conflict of interest clearance process, and have had required training in human subjects research protections pursuant to Yale policies. Personnel changes must be submitted to the HIC for verification of training and review of conflict of interest requirements. The changes will be entered into the Coeus system as FYI actions. The PI is then responsible for submission of personnel amendments to NICHD IRB per their procedure.

All non-personnel changes, amendments, or modifications and annual renewal submissions should be sent directly by the principal investigator to the NICHD IRB.

Internal University Scientific Review

Yale University policies require that the following internal scientific committees review protocols prior to IRB review. Thus, documentation of approval from the following committees must be included in the protocol submission packet when appropriate.

- **Pediatric Protocol Review Committee (PPRC):** Reviews all new research conducted at the Yale School of Medicine that involves children with the exception of Pediatric Oncology, which is reviewed by the Protocol Review Committee noted below.
- **Protocol Review Committee (PRC):** Reviews all therapeutic research trials for cancer conducted at Yale.

Investigator Acceptance of NICHD IRB Requirements

Investigators conducting NICHD IRB-approved research studies are required to abide by NICHD IRB requirements and determinations.

Continuing Review

The Yale Principal Investigator must comply with all NICHD IRB requirements for continuing review.

Courtesy renewal reminders will be generated in the Coues system and sent to the Yale PI.

Investigators are required to complete the Yale annual disclosure of external interests related to University responsibilities.

Unanticipated Problem Reporting

The Yale Principal Investigator is required to report protocol-related unanticipated problems involving risks to subjects or others that occur at Yale to the NICHD IRB and to the Yale IRB.

Adverse Event Reporting

Principal Investigators are required to report protocol-related adverse events that occur in a Yale-enrolled subject as defined by HRPP policy to the NICHD IRB and to the Yale IRB within the timeframe set by the NICHD IRB.

Participant Complaints

Participants will be provided contact information for the Principal Investigator and the HRPP to convey any concerns they have about the conduct of research, their participation, or their rights as a research participants. The HRPP will follow up with participant complaints, in consultation with the Principal Investigator and others, as appropriate.

Recordkeeping

The NICHD IRB will retain a comprehensive protocol file. The NICHD IRB will notify the Yale Principal Investigator of its decisions to approve, disapprove, or recommend modification of research studies. The Yale Principal Investigator is responsible for forwarding all NICHD IRB determinations to the Yale IRB. A copy of all correspondence from NICHD IRB regarding each individual protocol will be retained at the Yale IRB office.

Federal Restriction

The HRPP will notify the NICHD IRB immediately of any suspension or restriction from a Federal or state regulator agency or office of Yale’s authorization to review studies. **Contact Information**

For NICHD IRB :

NCS_IRBs@mail.nih.gov, with “NCS IRB Operations Center” in the Subject Line; or via facsimile to 301-480-3111

Website information: http://www.NICHD_IRB.com/

For the Yale IRB:

Jean H. Larson
Education and Community Outreach Manager
Human Research Protection Program
55 College Street
New Haven, CT 06510

Jean.larson@yale.edu

Website information: <http://yale.edu/hrpp/>

Phone: (203) 785-4688

Fax: (203) 785-2847