

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.1
Policy Title: Institutional Review Board (IRB) – Submission of Materials

Purpose

The purpose of this policy is to describe when review and approval by the IRB is required because of the institution’s engagement in research activities.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Clinical Investigation Research	Generalizable Knowledge Systematic Investigation	Human Subject
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Policy

Principal Investigators (PIs) must submit material to the IRB for review and approval **prior** to initiating any research activity that meets either the DHHS definition of research involving human subjects or the FDA definition of clinical investigation involving human subjects. Ancillary reviews that are also required to secure final approval from the IRB are built into the IRB submission process as noted on the submission checklists for initial and continuing review. The checklists may be revised as necessary.

PIs may request a specific type of review but the Chair* makes the final determination of the type of review required and if applicable the appropriate approval category.

When continuing review is a requirement, PIs must submit material to request continuing review and approval for non-exempt human subject research prior to the end of the day through which approval is valid. For studies requiring review by the convened board, submissions must be received by posted deadlines. For expedited continuations PI's should submit 30 days prior to the expiration date. Continuing review is also required for studies that have been suspended, in whole or in part.

IRB approval must also be obtained **prior** to implementing modification to previously approved research, except when necessary to eliminate apparent immediate hazards to subjects. For addendums / modifications issued by sponsors, inclusive of cooperative groups, the PI must submit the material for review by the IRB within 90 days of receipt.

An investigator must make a submission to the IRB for review and approval of human subject research projects when:

- UConn Health employees, students, or agents intervene with living individuals by performing invasive or non-invasive procedures for research purposes;
- UConn Health employees, students or agents intervene with living individuals by manipulating the environment for research purposes;
- UConn Health employees, students or agents interact with living individuals for research purposes;
- UConn Health employees, students or agents obtain the informed consent of human subjects for the research
- UConn Health employees, students or agents obtain, receive, or possess identifiable private information or identifiable biospecimens for research purposes;

- UConn Health employees, students or agents obtain, receive, or possess private information that is individually identifiable for the purposes of maintaining statistical centers for multi-site collaborative research;
- UConn Health employees, students or agents maintain operations center or coordinating centers for multi-site collaborative research; or
- UConn Health receives an award through a grant, contract, or cooperative agreement directly from HHS for non-exempt human subject research, even where all activities involving human subjects are carried out by employees or agents of another institution. award to conduct human subject research.
- UConn Health employees, students or agents release individually identifiable private information, or permit investigators to obtain individually identifiable private information, without the subjects explicit written permission;

The PI is responsible for submitting complete forms and required supporting documentation.

The IRB staff and/or reviewer reserve the right to return any submission that is incomplete or that contains out-dated forms.

*Reference to Chair throughout this document means Chair, Vice Chair, or designated experienced IRB member.

Procedure

General Submissions:

The PI completes and submits the relevant form and supporting documentation as indicated on the applicable checklist or instructional document.

The IRB staff and reviewers will follow standard procedures for assigning submissions, conducting reviews and for communicating outcomes to the PI according the exempt, expedited or full board requirements.

Immediate Changes to Secure Subject Safety:

- When changes are necessary to eliminate apparent immediate hazards to the subjects the changes may be implemented prior to approval but must be reported by the PI to the IRB using the problem report form, and when applicable to the FDA, within 5 business days.
- The problem report form is to be accompanied by any other document affected by or related to the change that was instituted.
- The convened IRB will determine whether the change was consistent with ensuring the subject's continued welfare and will also determine whether the event requires reporting as an unanticipated problem, or serious or continuing non-compliance if the change is found to be inconsistent with ensuring the welfare of the subject.

Related Policies

2009-001.0 - Reporting Unanticipated Problems to the Institutional Review Board

2011-009.2 – Institutional Review Board - Exemptions

2011-009.3 – Institutional Review Board – Expedited Reviews

2011-009.5 – Institutional Review Board - Review by Convened Board

Basis

45 CFR 46.103(4)

21 CFR 56.108(a)

Guidance on Engagement of Institutions in Human Subject Research
(<http://www.hhs.gov/ohrp/policy/engage08.html>)

Document Attributes

Date Created: 4/26/2017

Replaced Version: 8/20/2013

Reviewed and Approved By:

Signed Richard H. Simon

1 May 2017

Richard Simon, MD
Director Human Subjects Protection Office

Date