Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.15.a
Policy Title: Institutional Review Board –Reliance on UConn Health as IRB of Record

Purpose

The purpose of this policy is to set for the mechanism by which the UConn Health IRB may elect to act as the IRB for another institution.

Definitions

See policy 2011-007 for definition of Institutional Review Board

Policy

The UConn Health IRB may agree to act as the IRB of Record for another institution. In such cases the UConn Health IRB will hold the same rights, authority and responsibility as the IRB for the other institution, should one exist.

Before a UConn Health employee, student, or agent can begin a research activity that engages another institution in research, that institution must have accepted UConn Health as the IRB of Record.

When acting as the IRB for another institution:

- Standard UConn Health submission requirements pertain
- At the time of initial approval, personnel from the other institution must provide proof of training in human subject protections completed within the past three years and as applicable make disclosures regarding significant financial interests in the research.
    - The UConn Health IRB reserves the right to require additional training of those personnel.
    - The UConn Health IRB reserves the right to add requirements to manage a conflict should one exist.

In all cases for which UConn Health agrees to act as the IRB of Record for another institution, a written IRB Reliance Agreement must be in place between the institutions that outlines the expectations and responsibilities each party will undertake to ensure compliance with the requirements of the Common Rule. For study specific agreements related to minimal risk research the template provided by the Office for Human Research Protections (OHRP) may be utilized. Otherwise, the agreement should address the applicable points denoted in the IRB Reliance Agreement Checklist.

Procedures

Execution of Written Agreements:

A designated IRB Regulatory Specialist (RS) within the HSPP will oversee processing of IRB Reliance Agreements that are study specific. The UConn Health or SMART IRB template agreement may serve as the basis for such agreements. The RS will ensure that the following occurs:

- Signatures from appropriate officials at each institution are obtained.
    - At UConn Health the Director of the HSPP is the individual designated to sign such agreements however other individuals who have the authority to commit the institution to

a binding agreement (e.g., the Associate Vice President for Research Integrity and Compliance) may sign if the Director is unavailable.

- Final approval for a study is not released until the agreement has been fully executed.
- Details of the agreement are logged on the IRB Reliance tracking log on the shared HSPP drive
- A copy of the agreement is uploaded to the electronic file
- A copy of the agreement is placed in the IRB Reliance Agreements binder.

The HSPP Manager will oversee the processing of blanket IRB Reliance Agreements, ensuring that signatures from appropriate officials at each institution have been obtained and that a copy is placed in the IRB Reliance Agreements binder.

Requesting that UConn Health Act as the IRB of Record

The following are general procedures for requesting that UConn Health act as the IRB of Record. The procedures may have to be adjusted to accommodate unique circumstances surrounding an IRB submission.

Principal Investigators are encouraged to contact an IRB RS to inquire about the possibility of UConn Health acting as the IRB of record prior to submitting a request.

- The RS will advise the PI as to whether a blanket agreement already exists, the relying institution(s) is(are) part of the SMART IRB Initiative, or whether a study specific agreement would likely be accepted.

When a research study involves collaboration with another institution that may rely upon the UConn Health IRB, the Principal Investigator is to identify that institution in the IRB application and describe the role that the institution will have in the research (e.g., enrollment of subjects, data analysis, performance of procedures etc.). The PI is also to indicate in the application that UConn Health is the requested IRB of record.

Obtaining approval at UConn Health indicates UConn Health's willingness to act as the IRB of Record. The PI must also obtain confirmation from the other institution's IRB that it will accept UConn Health as the IRB of Record. The PI will have to comply with requirements of that IRB when making this request (e.g., the other institution may agree to accept UConn Health forms or may require that the PI complete their forms).

The IRB of the other institution will conduct a review and determine whether to accept UConn Health as the IRB of Record or to require an independent review by their IRB.

- If the other IRB requests changes prior to accepting UConn Health as the IRB of record the PI must submit a request for modification to the UConn Health IRB to address the changes requested from the other IRB. Once the modification is approved it would then be provided to the other IRB for final determination of acceptance.
- If UConn Health is accepted as the IRB of record, the other IRB should issue a statement to that effect to the UConn Health IRB and the PI.
    - From this point forward, the PI will only deal with the UConn Health IRB and the UConn Health IRB will keep the other IRB apprised of continuing reviews, modifications, other

events related to the study (e.g., unanticipated problems, serious or continuing non-compliance, and lapses in study approval).

- The UConn Health IRB RS is responsible for ensuring that a letter that indicates the institution for which UConn Health is acting as the IRB of record is incorporated into the IRB number as described in the document titled "Coding Scheme for IRB Reliance."

The project cannot start at the other site until UConn Health has approved the project **and** the other IRB has provided documentation that they have accepted UConn Health as the IRB of record.

If independent IRB review is required, the PI must also follow directions/requirements of the other institutions IRB and continue to fulfill requirements of both IRBs independently.

Once the research is approved, the addition of an investigative site may be considered a minor modification when the new site will follow the currently approved protocol. Requests to add research sites which will follow a new or different protocol will require review as a separate study or protocol.

Related Policies

2011-009.1 – Institutional Review Board – Submission of Materials
2011-009.15.b – Institutional Review Board – Reliance on External IRB
2011-023.0 0 - Educational Requirements

Basis

45 CFR 46.114

Document Attributes

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Reviewed and Approved By:

Richard H. Simon **11/1/2023**

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