Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.15.b
Policy Title: Institutional Review Board –Reliance on External IRB

Purpose

The purpose of this policy is to set forth the mechanism by which the UConn Health IRB may elect to rely upon an external IRB.

Definitions

See policy 2011-007 for definition of Institutional Review Board

Policy

The UConn Health IRB may elect, or may be required, to rely on an external IRB for initial and continuing review and approval of a study. For non-exempt research, in order to do so a written IRB Reliance Agreement must be in place between the relying and reviewing IRB. The agreement must be signed by individuals from each institution with the authority to enter such agreements and must outline the expectations and responsibilities each party will undertake to ensure compliance with the requirements of the Common Rule. When the UConn Health IRB elects to rely on an external IRB the external IRB is referred to as the IRB of Record and it holds the same rights, authority and responsibility as the IRB of UConn Health. The IRB may also need to concur with an external IRB that a project meets criteria for exemption.

When an external IRB is to be utilized, in addition to obtaining the approval of that IRB, before any research activity that engages UConn Health begins, the UConn Health investigator must obtain an official determination from the UConn Health IRB that oversight for the study will be deferred to the external IRB, or that UConn Health IRB concurs that the research meets criteria for exemption. After the initial determination is made, changes to UConn Health study personnel after initial approval will continue to be processed through the local IRB as an administrative change.

When determining whether to rely on an external IRB when the research is conducted at UConn Health, a member of the UConn Health IRB Office will conduct a facilitated review of the study. The facilitated review is done to ensure that that local issues such as training and ancillary approvals have been addressed and that there are no other local issues of concern. The reviewer may require changes prior to agreeing to accept the external IRB as the IRB of Record. This may require that investigators submit a request for modification to the IRB of Record. For research approved by the Hartford Hospital, CCMC or Trinity Health IRB through either expedited review, or deemed to be exempt, when that research engages UConn Health students, residents or fellows, the UConn Health IRB may elect to accept the approval letter of the other site as notification and not require a formal submission in the iRIS system. The HSPP Director/designee, may elect to accept this process for other minimal risk research on a case-by-case basis. The UConn Health IRB reserve the right to require the formal facilitated review process be used.

Facilitated reviews may be conducted by an IRB Chair or designated IRB member, or by IRB support staff as this is an administrative review function not a formal IRB review. Unless prevented by a regulatory mandate for single IRB review, the UConn Health IRB reserves the right to require local review in any circumstance it deems appropriate. If an IRB support person has reviewed the submission and believes local review should be required, consultation with an IRB member will occur before making a final determination. If local review is required, the investigator will be informed and instructed to follow standard submission requirements.

Procedures

The following are general procedures for relying upon an external IRB. The procedures may have to be adjusted to accommodate unique circumstances surrounding an IRB submission and/or requirements of the external IRB.

Requesting Reliance on an External IRB for a New Study (inclusive of UConn Health being added as a new site to an industry sponsored clinical trial or NIH multi-center trial)

The investigator should first consult with staff in the IRB to determine if an IRB Reliance Agreement for the requested IRB of Record is in place.

- If an agreement is not in place a new agreement will be required.
    - The IRB staff (for a study specific agreement) or the HSPP manager (for an umbrella agreement) may need to begin/coordinate discussions with the external IRB to facilitate the establishment of an IRB Reliance Agreement.
        - For minimal risk, non-industry sponsored research, or for research in which the involvement of UConn Health personnel is limited to activity that may qualify for expedited review, the OHRP template may suffice.
        - For other research, the checklist list for elements of an IRB Reliance Agreements will be utilized to ensure the agreement contains all necessary elements.
            - The agreement may be based upon the UConn Health template, or the external site's template, but must address the applicable points denoted in the IRB Reliance Agreement Checklist.
        - The Director of the HSPP at UConn Health is the individual designated to sign such agreements on behalf of UConn Health. In the absence of the Director, others with appropriate signing authority (e.g., the Associate Vice President for Research Integrity and Compliance) may sign.

The investigator is to submit an application to the UConn Health IRB requesting facilitated review. This request may occur prior to, in conjunction with, or after the review by the IRB of Record. If submitted prior to the IRB of Record granting final approval UConn Health may grant a contingent acceptance until all required documents are submitted. The normal process for responding to contingencies is followed. As applicable, at a minimum the protocol, consent form, HIPAA authorization and approval letter from the IRB of Record that also shows the expiration date of approval should be attached to the UConn Health facilitated application. It is strongly encouraged that the application form from the reviewing IRB site be attached as well. Additional requirements pertain to industry sponsored multi-center research and NIH multi-center research.

- for studies that are not industry-sponsored and not NIH multi-center studies (e.g., student research projects, or collaborative research projects involving UConn Health and a nearby facility) the application submission checklist can be used as a guide to determine what additional material to submit. While all elements may not be required for facilitated reviews, the IRB reserves the right to request such material.
    - For research conducted by students, residents and fellows for which IRB Reliance is requested, since the request for facilitated review is an administrative process the student, resident or fellow may submit the facilitated application noting themselves as PI providing that the actual PI of the study is identified in the material being provided.
        - An exception may be made to the need for submission of an application for minimal risk research that engages students, residents or fellows at HH or CCMC that was deemed exempt or approved through expedited review. In such a case the IRB may elect to use the approval letter issued from the other facility to create

the study record in iRIS on behalf of the student, resident or fellow. If done, the IRB person creating the entry will notify the UConn Health personnel engaged in the research and the reviewing IRB that this was done. The IRB reserves the right to require the submission of the application and study documents approved by the other site or original approval letter to ensure the research is minimal risk.

- for industry sponsored trials or NIH multi-center trials to which UConn Health is being added as a site, the facilitated submission checklist for industry sponsored studies is the applicable checklist to use.
    - The site PI and all key personnel must be designated and sign-off on the submission.
- if a new study-specific IRB Reliance Agreement is being executed, the RS will be responsible for ensuring execution of the document as described in policy 2011-015.a and attaching the document to the study file.

Upon receipt of the material designated IRB staff will assign an IRB number to the submission that reflects that reliance upon an external IRB has been requested as described in the document titled "Coding Scheme for IRB Reliance" and assign the submission to a designated IRB staff person for screening. After screening is complete the submission will be assigned for formal review to an IRB Chair, IRB member, or IRB staff. The IRB reliance agreement will be used as a guide in determining the extent of screening activities. For example, if the agreement stipulates that the relying institution is responsible for verification of training of its personnel, the assigned IRB staff will include that function in the screening process.

- If changes are required prior to acceptance of the external IRB, assigned IRB staff will communicate this to the PI and the routine process for responding to the IRB will be followed.
    - If necessary, the PI will have to submit a modification request to the requested IRB of record to secure approval of the changes.
- If subjects are to be enrolled at UConn Health, the consent form and HIPAA Authorization form are to contain applicable UConn Health language.

The assigned reviewer will make the determination as to whether to accept the external IRB as the IRB of Record. If the determination is made to accept the external IRB as the IRB of Record, the IRB staff assigned to screen the submission will inform the PI and the IRB of Record in writing using the standard template outcome notification letter and verify that the IRB study number indicates which institution is the IRB of record as detailed in the "Coding Scheme for IRB Reliance" document, revising the number if necessary. If a determination is made that local IRB review is required, the IRB staff assigned to screen the submission will inform the PI in writing and revise the IRB number to remove reference to the external IRB.

For a study specific reliance agreement IRB staff assigned to screen the submission is to enter the details of the study and the IRB of record on the HSPP IRB Reliance tracking log.

If the determination is made to accept the external IRB as the IRB of Record, from that point forward, with the exception of reporting changes in study personnel, the investigator only deals with the IRB of Record for the review of continuations, modifications, unanticipated problems and non-compliance.

Requesting Reliance on an External IRB to Add UConn Health as Collaborating Site to an Existing Study

If UConn Health personnel are being added as collaborators to a previously approved study at another facility (e.g., a neighboring facility that provides research opportunities to UConn Health students), and that study did not previously engage UConn Health in the research, in addition to the steps of ensuring that an IRB Reliance Agreement is established, the following steps should be taken:

- A request for modification should first be submitted to the IRB of the other institution to add the UConn Health personnel.
    - The modification should make it clear that a request will be made to UConn Health for reliance upon the other institution as the IRB of Record.
- Once approval has been obtained, an application is to be made in the iRIS system at UConn Health to request facilitated review. The application should include, but not necessarily be limited to; the approved modification, a copy of the currently approved protocol and, as applicable, consent form and HPAA form. The documentation should also include the date through which the study is approved.
- The UConn Health IRB will conduct the review as noted above.
    - UConn Health personnel being added must be in compliance with UConn Health human subject training requirements.
    - UConn Health personnel must also submit the SFI project disclosure form if applicable.
    - UConn Health personnel cannot engage in the research until the review process at UConn Health has been completed.
- An IRB staff member will assign a study number as noted above.

Requesting Reliance on an IRB that is not AAHRPP Accredited

When the IRB of Record is not AAHRPP-accredited, the UConn Health IRB will:

- Require assurance from the non-accredited IRB that it will conduct its review in accordance with ethical standards, applicable laws and regulations and that it will report any regulatory violations or investigations of the reviewing IRB by regulatory agencies, such as OHRP, the FDA or regulatory agencies in other countries (e.g., through use of UConn Health IRB Authorization Agreement).
- Request results of any audits/inspections of the IRB by regulatory agencies (e.g., OHRP, FDA).
- For **greater than minimal risk** research**,** the assigned RS or IRB staff will obtain relevant policies and procedures of the reviewing IRB and a copy of the relevant portion of the minutes of the meeting where the study was reviewed to ensure the review and approval of the study is consistent with applicable ethical standards and regulations.

The UConn Health IRB, when allowable, may elect to forgo reliance on a non-accredited IRB or require additional steps to ensure adherence to applicable ethical standards and regulatory requirements.

Changes in Personnel after UConn Health has Deferred Oversight to an External IRB
When deferring IRB oversight, changes to study personnel must be approved by the IRB of Record in accordance with that IRB's policies and procedures. Changes to UConn Health study personnel are also to be processed through the local IRB as a request for an administrative change through the iRIS system.

Related Policies

2011-009.1 - Institutional Review Board (IRB) – Submission of Materials
2011-009.15.a – IRB Reliance – UConn Health as the IRB of Record
2011-023.0 0 - Educational Requirements

Basis

45 CFR 46.114

Document Attributes

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Reviewed and Approved By:

Richard H. Simon *11/01/2023*

Richard H. Simon, MD **Date**
Director, Human Subjects Protection Program