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 for 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 to rely on an external IRB for review and approval of a study. In such an event, the external IRB, referred to as the IRB of Record, holds the same rights, authority and responsibility as the IRB of UConn Health. The UConn Health IRB reserves the right to require local review in any circumstance it deems appropriate, and if required the PI will follow standard submission requirements.

When an external IRB is utilized, 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 and must also obtain approval from that IRB.

When determining whether to rely on an external IRB, a member of the UConn Health IRB, most often the IRB Chair, will conduct a facilitated review of the initial submission that will be required to be made to the UConn Health IRB. The facilitated review is done to ensure that the study is acceptable to UConn Health. 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.

In all cases for which UConn Health accepts the review of an external IRB, a written IRB Reliance Agreement must be in place between the two institutions that outlines the expectations and obligations of each party. At a minimum, such agreements will contain the elements noted in the template agreement form provided by the Office for Human Research Protections (OHRP) (http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf)

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.

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)

The Principal Investigator (PI) should first consult with an IRB Regulatory Specialist 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 and the OHRP template may serve as the basis for the agreement.

The PI is to submit an application request to the UConn Health IRB requesting facilitated review.

- as applicable, the submission should incorporate documents already approved by the IRB of Record and relevant correspondence from the IRB of Record regarding the approval of the study

- the application submission checklist should be used as a guide to determine submission requirements.
    - for industry sponsored trial to which UConn Health is being added as a site, the full board submission checklist is the applicable checklist to use.
- if a new IRB Reliance Agreement is being executed, the submission should incorporate that document as well and the RS will be responsible for processing the document as described in policy 2011-015.a

An IRB Regulatory Specialist will screen the material and, assign it for formal review.

- If changes are required prior to acceptance of the external IRB, the Regulatory Specialist 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. Once the determination is made to accept the review the Regulatory Specialist will:

- inform the PI and the IRB of Record in writing
- ensure that the IRB study number indicates which institution is the IRB of record as follows:
    - H##-###-# .....Hartford Hospital is IRB of Record
    - C##-###-# .....CT Children's Medical Center is the IRB of Record
    - Q##-###-# .....Quorum IRB is the IRB of Record*
    - S##-###-# .....UConn Storrs is the IRB of Record
    - SF##-###-# .....Saint Francis is the IRB of Record
    - O##-###-# .....Other institution, with details filed on the IRB Reliance tracking log
    - U##-###-#.....Schulman IRB is the IRB of Record*
    - W##-###-#.....WCG/WIRB is the IRB of Record*
    - NCI##-###-#.....NCI Central IRB is the IRB of Record

For a study specific reliance agreement the Regulatory Specialist is to enter the details of the study and the IRB of record on the IRB Reliance tracking log on the shared HSPP x drive.

If the determination is made to accept the external IRB as the IRB of Record, from that point forward the PI 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 Ad 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 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, survey tools etc. 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 as required for all routine IRB submissions.
    - 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.

*utilized for industry sponsored clinical trials

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: **Signed Richard Simon** **Date:** **8/15/2016**
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