Drexel University Human Research Protection

Procedure for Obtaining a Letter of Reliance (Assurance)

The Office for Human Research Protections (OHRP) has made an allowance for the Institutional Review Board (IRB) of one institution to act on behalf of the relying institution's IRB via an IRB Authorization Agreement. The DU IRB refers to this Authorization Agreement as a "Letter of Reliance". The intent of the agreement is to help minimize or reduce the burdens of review and redundancy in work load when two or more institutions will act together on the same protocol.

When a DU investigator seeks to work collaboratively with another institution, we ask that the following procedures be taken into consideration. Please note that the Letter of Reliance can only be executed with an institution which holds a valid Federal Wide Assurance number (FWA) that is not expired.

The process of finalizing the DU IRB Letter of Reliance is executed by a representative from DU Human Research Protection (HRP) with the other institution's IRB or their Office of Research Compliance.

There are two primary examples of how the process of securing a Letter of Reliance may apply to a DU investigator.

Example 1: DU IRB is the IRB of record if the research is conducted at DU facilities which include DU patients or patient records, students or employees. In this example the other institution will rely on the DU IRB when collaborating with DU faculty.
Example 2: the other institution's IRB will be the IRB of record if the research will be conducted on their property, with their patients or patient records, or with their students or employees.

Please note that the DU IRB will always reserve the right of determining whether or not an agreement will be executed, as well as the right to review a proposal in addition to, and independent of any other institution's IRB.

1. Selecting the IRB of record.
    a. <u>Research conducted at DU facilities</u>, with its faculty, staff, students, patients or their patient's records, requires that the DU IRB will be the IRB of record, and will review the proposal independently of another institution's IRB. The DU IRB will be responsible for oversight of the related compliance activities and reporting requirements in accordance with both OHRP and FDA guidelines, (Should this be the case follow directions in #3 below).
    b. <u>Research conducted at another institution</u>, (regarding the examples cited above in 1a), will require the other institution to be responsible for the IRB review, related compliance activities and reporting requirements in accordance with both OHRP and FDA guidelines (Should this be the case follow directions in #4 below).

2. Once the Principal Investigator (PI)* has determined where the research will primarily take place, and who will be involved, the PI must contact their IRB and/or

compliance office, as well as the IRB and/or compliance office of the other institution to confirm that such an agreement is acceptable to both IRBs/institutions.

3. <u>If the DU IRB will be the IRB of record</u>, the DU PI must provide the following documentation to the IRB:
    a. A complete application in accordance with the appropriate directions and IRB policies as they relate to the specific category of research;
    b. If research activities will be conducted exclusively at DU and will involve non-DU research personnel, then documentation must be submitted that all personnel conducting research activities have completed DU IRB specific training, inclusive of CITI human subjects research protection training;
        I. Investigative team members without a DU affiliation, that are affiliated with an institution that has not filed for a Federal Wide Assurance (FWA) with OHRP will be required to complete and sign an "Unaffiliated Investigator Agreement";
        II. If the proposal involves use or access to Protected Health Information (PHI), any unaffiliated personnel must also complete the Business Associate Agreement. (Both agreements are available from the DU IRB coordinator)
    c. The contact information for the other institution's IRB/Office of Research Compliance, inclusive of their FWA number, Chair/administrator name, address, phone, fax, and email);
    d. During the DU IRB review process, the IRB coordinator will contact the other institution directly to confirm their agreement with the terms of an official reliance between the institutions;
    e. Once the DU PI receives a letter of approval from the DU IRB it is expected that the PI will provide a copy of all official IRB communications and approval documents with the relying institution's IRB.
    f. Please note: PI's requesting a "Letter of Reliance" on behalf of a protocol that already has DU IRB approval, will follow the directions above and also submit a modification request to the IRB by use of form HRP-213 "Modification of Approved Human Research."

4. <u>If the other institution will be the IRB of record</u>, the DU PI needs to provide the following documentation to the DU IRB:
    a. A cover letter from the DU PI stating the request for a reliance agreement including a description of the role the DU PI or student/ key personnel will play in the research study at the other institution. This letter should be on official letterhead and signed by the PI and include the name and signature of the student/key personnel.
    b. The contact information of the individual at the other IRB/institution who will handle the reliance on their end, as well as their FWA number.
    c. A copy of the final letter of approval, the final approved consent form(s), application, advertisements, and any other documents approved by the other institution's IRB that are in support of the research proposal;
    d. The final documentation of approval must indicate the names of the DU personnel participating in the research;

e. The DU PI will remain in contact with the DU IRB by providing a copy of all official communications and documents submitted to the other institution's IRB as long as the protocol remains active. Examples of communications are adverse event reports, continuing reviews/renewals, final reports, amendments to protocols, protocol violations and deviations.
f. It is the PI of record responsibility to remain in contact with the reviewing IRB and to follow any and all directions and procedures they require; this may include additional institution specific training or security clearances.
g. It is strongly recommended that the PI of record maintains open lines of communication with the IRB of record to help assure compliant conduct of research.

5. Once the Letter of Reliance has been finalized the DU PI will receive official notice from the DU IRB that they may initiate their protocol. The DU IRB coordinator will email to the PI's attention the DU IRB approval letter and a copy of the final executed Letter of Reliance. A hard copy of each document will also be mailed to the PI.

*Please note DU IRB guidelines will only faculty and staff members to serve as PI. Students, medical research residents, fellows, and post-doctoral fellows are always co-investigators. When submitting your proposal or letter of request for a "Letter of Reliance" to the DU IRB on behalf of a student project, the student will be noted as co-investigator or as key personnel and all documents regarding the study will be addressed from and in the name of the PI. The student will also be listed as noted above.

Any additional questions may be addressed by calling a representative from Human Research Protection at 215-255-7857.