Establishing Reliance Agreements Between the Chamberlain University IRB and External IRBs

Procedure Number:  S-IRB01

Effective Date:  March 1, 2018

Department of Origin:  Chamberlain University Institutional Review Board (IRB)

Procedure Approved By:  Carla Sanderson, Provost

Purpose:  This procedure details the process for establishing an agreement (IRB Reliance Agreement) between the Chamberlain University IRB and external IRBs. The nature of such agreements are to allow one IRB (either the Chamberlain University IRB or an external IRB) to assume primary responsibility for reviewing and approving a proposed human subjects research study for which multiple IRB jurisdictions are involved, and for routine oversight of approved non-exempt studies as described in 45 CFR Part 46. The IRB assuming primary responsibility is known as the reviewing IRB, while other IRBs are known as the relying IRBs.

Areas of Responsibility:  Chair, Chamberlain University Institutional Review Board  Provost, Chamberlain University

Procedure Details:

1. In the absence of a reliance agreements, the Chamberlain University IRB maintains authority to review, approve, and monitor human subjects research studies under its jurisdiction as described in the Chamberlain University IRB Handbook and supported by 45 CFR Part 46.

2. The principal investigator (PI) of a proposed human subjects research study must initiate the request for a reliance agreement by completing and submitting required forms to the Chamberlain University IRB.

3. If the PI wishes to have the Chamberlain University IRB serve as the reviewing IRB (the IRB who assumes primary responsibility for review and oversight), the PI must submit a “Request for Chamberlain University IRB to serve as the Reviewing IRB” form. The form must be signed (approved) by the external IRB prior to submission to the Chamberlain University IRB. A unique reliance agreement must be requested for each external IRB; therefore, a separate form must be completed and signed by each external IRB involved in the proposed reliance agreement. The form must be submitted either at the time the Chamberlain University IRB is conducting an initial review of the proposed study or after approval for the proposed study has been provided by the Chamberlain University IRB. (The latter scenario may occur if a request for an additional study site is sought.)

4. If the PI wishes to have the Chamberlain University serve as the relying IRB (the IRB who defers to another IRB for primary review and oversight), the PI must submit a “Request for Chamberlain University IRB to serve as the Relying IRB” form. The form must be submitted to the Chamberlain University IRB prior to any request of Chamberlain to conduct a usual initial review of the proposed study. (Once the Chamberlain University IRB has granted approval of a non-exempt study under its jurisdiction, it may not cede approval and study monitoring to an external IRB.)
5. Any desired change in the verbiage of the non-modifiable fields of the reliance agreement request forms must be reviewed by the Adtalem Global Education legal department prior to review and consideration by the Chamberlain University IRB.

6. Reliance agreement requests require approval by majority vote of the full Chamberlain University IRB. Votes may be obtained asynchronously through electronic means or during a regularly scheduled meeting of the Chamberlain University IRB.

7. Reliance agreement forms must be signed by designated authorities from each IRB before they can be enacted. If either IRB declines to enter into a reliance agreement, usual procedures and requirements of each IRB will be maintained.

8. A reliance agreement request form signed by designated authorities from both IRBs constitutes the official reliance agreement.

9. The reliance agreement remains active until the study is officially closed by the reviewing IRB.

10. Requests for a reliance agreement that are provided on forms from another institution will require review by the Adtalem Global Education legal department prior to review and consideration by the Chamberlain University IRB.

11. PIs are required to provide all IRBs involved in reliance agreements copies of official reports to and actions from the reviewing IRB.

12. If an external IRB who is serving as the reviewing IRB decides to terminate the reliance agreement for any reason, the PI must ensure that the external reviewing IRB notifies the Chamberlain University IRB immediately so that a transition plan can be developed. The Chamberlain University IRB is not bound to approve any future study-related activities that were previously approved by the external reviewing IRB.

References:
Code of Federal Regulations: TITLE 45 PUBLIC WELFARE Department of Health and Human Services PART 46 PROTECTION OF HUMAN SUBJECTS

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