Committee for the Protection of Human Subjects at Dartmouth College

CPHS reviews for another entity

To be attached to IRB Reliance Agreement

Responsibilities and Communications Plan

This document describes the activities of the Committee for the Protection of Human Subjects at Dartmouth College (CPHS) when the CPHS agrees to act as the reviewing institutional review board (IRB) for another entity. Also described in this document are CPHS expectations of the entity relying on review by the CPHS and of the principal investigator. The activities of the CPHS will only occur after the institutional officials of both Dartmouth College and the entity relying on CPHS review (Relying Entity) have executed an IRB Authorization Agreement.

The administrative office for the CPHS shall:

1. Upon request, notify the designated person at the Relying Entity of the following CPHS findings and actions:
   a. Determination on initial review;
   b. Determination on each continuing review;
   c. Determination resulting from review of study amendments;
   d. Determination of serious or continuing noncompliance;
   e. Suspension of the research;
   f. Termination of the research;
   g. Study termination by the investigator, sponsor, or funding agency;
   h. Other information relevant to the appropriate conduct of the research.

2. Notify the designated person at the Relying Entity of reported unanticipated problems involving risks to human subjects or others that result in a CPHS action to modify a study, but not other adverse events;

3. Notify Relying Entity of known serious or unresolved complaints from subjects or others about the conduct of a study;

4. Notify the Relying Entity of other information relevant to the conduct of each study.

5. Respond promptly to communications from the Relying Entity or its IRB;

6. Notify the Relying Entity of any suspension or restriction of the authority of the CPHS to review research involving human subjects.

The Relying Entity shall:

1. Comply and cooperate with the determinations of the CPHS;

2. If a Federalwide Assurance (FWA) is required, obtain and maintain it;

3. Notify the CPHS promptly of any known instances of noncompliance with the study protocol, as well as applicable regulatory or ethical standards;

4. Notify CPHS promptly of known termination of the research by the investigator, sponsor, funding agency, or by the Relying Entity;

5. Notify CPHS promptly of any known complaints from subjects or others about the conduct of the study;

6. Respond promptly to communications from the CPHS;

7. Notify the CPHS promptly of any restriction or suspension of the activities of an investigator conducting research covered by the agreement between the parties, if any;

8. Assure that the local facilities are adequate for the conduct of the research;
9. Assure the local investigator is appropriately qualified to conduct the proposed research;
10. It is important to ensure objectivity in the design, conduct, and reporting of research. The Rellying Entity is responsible for ensuring the project is being conducted in an unbiased manner. If there are concerns or questions, the Rellying Entity should notify the Reviewing Entity.
11. Keep current the information about the person designated to receive CPHS communications;
12. Arrange for appropriate human research training for personnel involved in the conduct of that research;
13. Maintain compliance with applicable law and institutional policies regarding human research;
14. Maintain research documentation in compliance with applicable requirements;
15. Notify the CPHS if its IRB, provided one exists, rejects the review of the CPHS and performs its own review.

The Relying Entity Investigator/s shall:
1. Comply with the determinations of the CPHS;
2. Notify the CPHS if the role of principal or site investigator is transferred to another person;
3. Comply with human subjects training requirements for all study personnel;
4. Respond promptly to communications from the CPHS;
5. Maintain research documentation in compliance with applicable requirements;
6. It is important to ensure objectivity in the design, conduct, and reporting of research. The site investigator is responsible for ensuring the project is being conducted in an unbiased manner. If there are concerns or questions, the site investigator is responsible to communicate with the Rellying Entity.

Additionally, the Dartmouth Investigator shall work with the external investigator/s and:
1. Send to the CPHS appropriate documentation of changes to the approved study protocol, plan, or consent form before initiating the changes in practice and wait for CPHS approval, unless changes are necessary to eliminate apparent immediate hazards to human subjects;
2. Send to the CPHS appropriate documents for continuing review in a timely fashion prior to the lapse of the previous CPHS approval;
3. Promptly report to the CPHS any serious and unexpected adverse events and unanticipated problems involving risks to subjects using CPHS reporting forms;
4. Promptly report to the CPHS any serious or unresolved complaints from subjects or others about the conduct of the study and protocol deviations;
5. Notify the CPHS of changes in funding;
7. Notify the CPHS about the termination of each study.

Applicable regulations:
45 C.F.R. Part 46
21 C.F.R. Parts 50, 56, 312, 812, and others as applicable