OSP Roundtable
What Administrators Need to Know about Human Subject Protections: Working with the CPHS

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The Committee for the Protection of Human Subjects (CPHS) at Dartmouth College

= Institutional Review Board (IRB)

For:

Dartmouth College
Dartmouth-Hitchcock Medical Center
Other entities
Topics

- Who We Are
- Purpose of review
- When is Review Needed?
- Levels of Review
- Renewals, Terminations, and Amendments
- Applying for Review
- Education Requirement
- Update- Revised Regulations
- Contact Us
- Questions?
CPhS by the Numbers

- 5 Committees: 3 meet monthly, other 2 meet only as needed.
- 65+ members
- 9 staff
- 3 Full Committee Meetings per month

  Ongoing expedited reviews including new studies, revisions, renewals

- Review Time:
  - Varies depending on level of review needed, response time, other factors
  - Deadline? Let us know!
Purpose of IRB Review

- Protection of the rights and welfare of research participants
- Assure institutional compliance with federal regulations and state law
When is CPHS review needed?

Research?
Research? Regulatory definition

Research means a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge.
Research?  Regulatory definition
  yes
Human subject involved?
Research? Regulatory definition

yes

Human subject involved? Regulatory definition

*Human subject means a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.*
Research? Regulatory definition
  yes
Human subject involved? Regulatory definition
  yes
Exempt from further IRB review?
Research? Regulatory definition

yes

Human subject involved? Regulatory definition

yes

Exempt from further IRB review?

6 regulatory categories of research activities
Research?  Regulatory definition
  yes
Human subject involved?  Regulatory definition
  yes
Exempt from further IRB review?
  6 regulatory categories of research activities
  no
Eligible for expedited review?
Research?  Regulatory definition
  yes
Human subject involved?  Regulatory definition
  yes
Exempt from further IRB review?
  6 regulatory categories of research activities
    yes  no
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Eligible for expedited review?
Minimal risk?  Regulatory definition
  Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Research? Regulatory definition yes

Human subject involved? Regulatory definition yes

Exempt from further IRB review?
   6 regulatory categories of research activities no

Eligible for expedited review?
   Minimal risk? Regulatory definition yes
   9 regulatory categories of research activities
Research? Regulatory definition
  yes
Human subject involved? Regulatory definition
  yes
Exempt from further IRB review?
  6 regulatory categories of research activities
    no
Eligible for expedited review?
  Minimal risk? Regulatory definition
    yes
  9 regulatory categories of research activities
    no
IRB review at a convened meeting
  “full committee review”
Renewals and Terminations

- Interval based on level of risk, but not less than once per year.

- Renewal materials due in CPHS Office in time for renewal to be reviewed before expiration. We send email reminders to PIs and contact people.

Study can be terminated at any time if all study activities including data analysis are complete.
Applying for Review

All Applications should be submitted via IRB Rapport

- Determination of “not human subjects research under the purview of CPHS”
- Exemption
- Other Research Plan/Protocol Templates:
  - Data, Specimens, and Registries Research Plan
  - Minimal Risk Clinical Research Plan
  - Social, Behavioral, Non-Clinical Research Plan
  - Clinical Research Protocol (or Sponsor Protocol)
    - With Protocol Plus document

Questions about how to apply? Contact us!
What needs to be reviewed by CPHS?

- Completed application for review: “study plan”
- Scripts of planned interactions with focus groups and for interviews
- All study instruments- survey, interview scripts, focus group scripts, etc
- Recruitment materials- posters, recruitment letters or emails, etc.
- Plan to obtain permissions from potential participants: documents or scripts containing appropriate information about what participation involves
- Data management plan
- Funding Proposal
Human Subjects Protections
Education Requirement

All investigators and research personnel must complete the education requirement prior to initiating research activities.

Options for completion:

- In-person sessions
- CITI online course
- Completed at previous institution? Send us your certificate

"Refresher Course" needed every 3 years- CITI course available
Update 2017- new regulations published, effective January 2018

Intent of new regulations:

Increase protections for research subjects while facilitating research and reducing administrative and resource burden.

Reflect shifting landscape of research over past two decades.
Update 2017 - new regulations published, effective January 2018

1. Consent Form: new wording requirements, process, public posting
2. Broad consent: new term
3. Limited IRB review: new term
4. Expand Exempt categories (including prospective chart review, benign behavioral interventions)
5. Continuing Review of minimal risk research
6. Single IRB for U.S. based multi-site studies. Flexibility built in. (3 years effective day)
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