

Trustees of Dartmouth College
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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**Reporting Protocol Deviations
&
Requesting Exceptions to Approved Eligibility Criteria**

The Committee for the Protection of Human Subjects (CPHS) works cooperatively with researchers to protect the rights and welfare of research participants, as well as to protect the scientific integrity of the data produced by human research projects. In order for research activities to be conducted ethically, they should produce complete, accurate, and reliable scientific data in return for the contributions of the people who volunteer to participate in them.

All researchers should use the following procedures for reporting protocol deviations to assist CPHS efforts to achieve appropriate human subject protections. For clinical trials, investigators should use the procedure described below for requesting eligibility exceptions.

Protocol Deviations:

In general, changes in approved research activities may not be initiated without prior CPHS review and approval, except when necessary to eliminate apparent immediate hazards to research participants. See 45 C.F.R. 46.103(b)(4) or 21 C.F.R 56.108(a).

It is the responsibility of the principal investigator to determine whether a protocol deviation may affect the rights or welfare of research participants and should be reported to the CPHS. Protocol deviations should be evaluated for safety implications, violations of participant rights, dignitary harms, and compromise of the scientific integrity of the study. Please note that an investigator may report a protocol deviation prospectively or retrospectively depending on the circumstances prompting the change from previously approved research activities.

Protocol deviations are changes in CPHS approved research activities that:

Have not received prior CPHS approval and should be within the control of the research team, including the sponsor and its contracted agents, e.g., contract research organization, central laboratory, drug distribution facility;

And

May affect the rights and welfare of research participants;

Or

May affect the scientific integrity of the study data.

These changes in CPHS approved research activities should be promptly reported to the CPHS using the protocol deviation reporting form available on the CPHS web site at <http://www.Dartmouth.edu/~CPHS/tosubmit/forms> .

The CPHS reviews protocol deviations to determine whether they may:

- 1) require CPHS action to modify or suspend previously approved research activities;
- 2) involve serious or continuing noncompliance;
- 3) represent an unanticipated problem involving risks to research participants or others; and
- 4) invoke CPHS reporting obligations to the Office of Human Research Protection (OHRP) or institutional officials.

Eligibility Exceptions:

Potential research participants who do not satisfy all of the eligibility criteria specified in the protocol currently approved by the CPHS may not be enrolled in the study. An investigator may request CPHS approval for an exception to the eligibility criteria to enroll a particular individual. The CPHS expects such requests to occur rarely. Repeated requests for eligibility exceptions suggest the investigator should revise the protocol to reflect more appropriate eligibility criteria for the study consistent with research participant safety and preserving the scientific integrity of the data.

The procedure for requesting eligibility exception is to complete the “Eligibility Exception Request” form that is available on the CPHS web site at <http://www.Dartmouth.edu/~CPHS/tosubmit/forms> .

If an exception has been made to eligibility criteria without prior CPHS approval, it should be reported as a protocol deviation.