UCONN HEALTH

POLICY NUMBER 2006-02
July 12, 2016

POLICY: SUSPENSION OR TERMINATION OF IRB APPROVAL IMPOSED BY ADMINISTRATIVE OFFICERS (HUMAN SUBJECTS PROTECTION PROGRAM)

PURPOSE: To describe the process by which Administrative Officers (AO) of UConn Health may suspend or terminate research studies previously approved by an Institutional Review Board (IRB).

POLICY STATEMENT:
It is the policy of UConn Health that in addition to the IRB, the AOs identified in Policy 2002-42 (Review and Approval of Research Involving Human Subjects) may suspend or terminate studies previously approved by the IRB. Reasons for imposing a suspension or termination include, but are not limited to, learning of 1) previously unanticipated risks to subjects, 2) findings of serious or continuing non-compliance, or 3) findings from the continuing review or internal monitoring process. Administrative Officers may seek advice from other institutional areas (e.g. legal counsel, risk management, research compliance) in determining whether to impose a suspension or termination of IRB approval. In addition, when imposing a suspension or termination, AOs will give consideration to the impact that the suspension or termination may have on subject safety and/or welfare. Consideration will include, but is not limited to:

- whether participation can be stopped safely;
- whether subjects should be transferred to another physician for clinical care;
- whether subjects can be kept on study under the same PI;
- if kept on study under the same PI, whether additional monitoring is required;
- whether subjects can be kept on study under another PI.

Imposing a Suspension / Termination

1) The person imposing the suspension or termination will inform the Principal Investigator in writing. If immediate action is required the directive may be given verbally to the PI and the letter will follow. Letters to the PI are to be sent within 5 working days of the effective date of suspension or termination. Such letters will include:
    - the effective date of suspension or termination;
    - if notification was initially done verbally the letter will reference the date of verbal notification;
    - the reason for the suspension or termination;
    - for suspension, identification of the research activity, in whole or in part, that must stop;
    - any corrective action or clarification that must occur;
    - if the reason for suspension may bear on the subjects decision to continue participation, a directive that currently enrolled subjects be informed of the suspension;

- for terminations, a directive that all currently enrolled subject be informed of the termination;
- a referral to the IRB standard operating procedures for how to request approval from the IRB to continue any treatment related activity that is in the best interest of the subject,
- notice that failure to comply with the directive to suspend or terminate a study may result in disciplinary action that may include suspension or termination of employment, and
- a direction to the PI that a written response is to be submitted to the person who imposed the suspension/termination and that a copy of the response is to be distributed to the other individuals noted on the initial suspension/termination letter.

2) The individual imposing the suspension or termination is responsible for the preparation and sending of the letter to the investigator and to the following individuals:

   - the AOs identified in policy 2002-42 (Review and Approval of Research Involving Human Subjects) and
   - IRB Chairs and Vice Chair of the reviewing IRB panel

Lifting a Suspension

1) The PI of the suspended study must submit his/her response to the person who imposed the suspension, or directly to the IRB if advised to do so, with a copy to the individuals noted on the original letter of suspension.
2) The person who imposed the suspension is responsible for notifying the IRB Chair in writing when s/he is satisfied that all concerns that led to the suspension have been addressed and to recommend lifting the suspension.
3) The IRB Chair may use the expedited review process to lift the suspension but reserves the right to require full board review. (Only the IRB can lift a suspension)
4) The IRB will send written notification to the PI, with a copy to the individuals noted above, when the suspension is lifted.

Richard Simon (Signed) 8/1/16

Richard Simon, M.D. **Date**
Director Human Subject Protection Program

Jeffrey Seemann (Signed) 8/10/16

Jeffrey Seemann, Ph.D. **Date**
Vice President for Research

New Policy: 1/18/06
Revised: 5/5/06, 8/13/08, 7/12/16