1.0 Purpose:

1.1 To describe the Hartford HealthCare Institutional Review Board (HRPP IRB) process for notifying Principal Investigators (PIs) of a study's impending continuation report due date.

2.0 Definitions:

2.1 N/A

3.0 Procedure:

3.1 The responsibility for submitting timely requests for continuation (progress reports) will be communicated to the investigator at the time of notification of approval of the research project.

3.2 **As a courtesy**, notifications that Requests for Continuation (Progress Reports) are coming due will be emailed to the PI and "Primary contact" as designated on the initial Research Application.

3.3 The first reminder is emailed three (3) months prior to the expiration of the previous approval period. The second reminder is emailed two (2) months prior to expiration of the previous approval period.

3.4 Reports are due two (2) months prior to approval expiration to ensure that the Full Board reviews are conducted in a timely manner so as to avoid a lapse in approval. Exceptions to this schedule are made when the approval period is considerably shorter than one year.

3.5 In addition to the notification memo, blank templates of the "Request for Continuation (Progress Report)" and "IRB Closure Report" are attached for the investigator's convenience.

3.6 The notification reminder memo provides the PI with the Previous Approval date, Approval Valid through date and the Suspension date. The memo also includes a "Current List of Active Study Personnel on Record in the Research Database," as well as if the personnel have completed the required CITI training.

3.7 If the investigator does not submit the requested progress information in sufficient time for review prior to expiration of the previous approval period, or if a project does not receive final approval for continuation before the approval period expires, the project will be suspended until approved, and may be closed if this does not occur. No work may be done on a suspended project until approval is received, except as necessary to prevent risk to the subjects.

3.8 If a project is suspended, the investigator will be notified by e-mail that no further activity will be allowed other than any deemed necessary to prevent harm to subjects previously enrolled.

3.9 Projects for which all clinical and follow-up work has been completed and the use of PHI is completed, or in which no subjects were enrolled may be approved for closure upon request by the PI.

3.10 A project may also be administratively terminated if the PI does not submit a progress report. The PI will receive a suspension letter, and if a progress report is not submitted within two (2) months (60 days) of being suspended, the HRPP has the authority to administratively close the project.

3.11 If a project is closed administratively, the PI will not be allowed to submit any new research projects until he/she has completed the necessary paperwork for the project that was terminated; it may either be a renewal form or a termination form.

4.0 Documentation:

4.1 Each notification email to the PI is documented by data entry within the Research Institute database.

4.2 Archived emails may be retrieved from the Novell GroupWise system as necessary.

5.0 References:

5.1 None

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	CLG	7/1/11	Conversion to new policy template; general expansion of policy