Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.3
Policy Title: Institutional Review Board (IRB) – Expedited Reviews

Purpose

The purpose of this policy is to describe circumstances under which an IRB reviewer may determine that a human subject research study qualifies for initial or continuing approval under one or more of the federally recognized expedited categories, or one or more expedited categories that may be developed by the institution for non-federally funded non-FDA regulated minimal risk research. This policy also sets forth circumstances when modifications to a previously approved study may be reviewed by the expedited procedure.

Definitions

See policy 2011-007.0 for the definitions of the following terms:

Member, experienced	Modification, Minor	Suspension
Termination	Test Article	-Prisoner

Policy

Regardless of funding source, the categories of research for which expedited review may be used for initial and/or continuing review are those that have been published in the Federal Register. The institution may also develop and publish categories of research for which expedited review may apply for non-federally funded or non-FDA regulated minimal risk research. The expedited categories for continuing review of research previously approved by the convened IRB are not applicable to initial reviews, and UConn Health does not utilize the provision that expedited continuing review may occur for a study previously reviewed by the convened board where no subjects have been enrolled and no additional risks have been identified.

FDA regulated research that involves the use of investigational articles cannot be approved through the expedited review process unless the remaining activity for the study is limited to long-term follow-up or data analysis.

For all types of submissions (e.g. initial, continuation, modifications) unless otherwise specified by the IRB, responses to contingences for approval may be reviewed by any experienced member of the IRB or experienced IRB/HSPP support staff for purposes of issuing the final approval.

For all expedited submissions, the reviewer may approve an expedited project, require modifications to secure approval, or refer the submission to the full board for review. The reviewer may not deny approval.

<u>Initial Review by Expedited Procedures:</u>
Only an experienced scientific member of the IRB can conduct the initial review of a study for which the PI has requested expedited review. The Chair of a panel is the default reviewer, but the review may be assigned to any qualified member. In efforts to minimize the time to approval by reducing the number of times a submission is returned to the study team for correction, the screening function and formal review process may be incorporated into a primary reviewer system whereby the officially assigned

reviewer and IRB staff person* review the submission concurrently. If continuing review is required projects will be approved for no more than 365 days. If continuing review is not required projects will be approved for either the expected duration of the project, or one year from the date of final approval, whichever is longer.

Expedited Review of Modifications, Problem Reports and Responses to Contingencies:
An experienced scientific member will review clinical modifications that qualify for expedited review (e.g. addition of blood draws). The Chair of a panel is the default reviewer but such tasks may be assigned to other qualified members.

Any member of the IRB may review and approve administrative modifications.

An IRB Chair or Vice Chair will review Problem Reports Forms to determine if the reported issue needs to be referred to the full board, or if it is a minor issue that does not represents serious or continuing non-compliance or an unanticipated problem involving risk to subjects or others.

The reviewer will determine whether a request for modification meets the definition of minor modification to previously approved research and therefore the eligibility criteria for expedited review. Studies involving vulnerable populations may request approval of modification through the expedited process. A request for modification through the expedited review and approval process cannot include procedures whose inclusion would make the research ineligible for initial review using the expedited procedures (e.g. addition of an investigational drug).

Study closures are most often reviewed as expedited modifications. Requests for closure should be submitted at the time the next continuation application is due or within 30 days after the completion of all study activity involving the use of private identifiable information or biospecimens, whichever comes first.

Continuing Review by Expedited Procedures:

Continuing review is currently required on at least an annual basis for federally funded / supported research and FDA regulated research.

Unless specifically required otherwise by the IRB continuing review is not required for the following:

- non-FDA regulated and non-federally funded/supported studies that were initially approved under an expedited category;
- non-FDA regulated and non-federally funded/supported studies or that now qualify for expedited status (e.g. remaining activity is limited to blood draws within expedited limits),
    - investigators should submit an expedited request for modification to the IRB to request eligibility for expedited status when a study reaches the point where the remaining activity is limited to activity that would qualify for expedited review.

Should the FDA or Federal regulation be revised to adopt a policy whereby expedited continuing approval is not required UConn Health will apply this same standard to such research.

When continuing review is required, unless otherwise noted, the approval period for studies approved through expedited review will be for one year from the date the final content review is completed. This may sometimes result in a shorter review cycle if there are administrative issues that must be addressed before final IRB approval is released. Content review is inclusive of reviewing responses to contingencies for approval when such contingencies require a change to a study related document. In such cases the content review is considered completed when the required changes to study related documents have been approved (e.g. change to protocol or change to consent as contingency for approval). For example, if a study were reviewed on October 7, 2016 and the IRB required a change to a consent and that an investigator complete required training before approval could be granted, if the revised consent was reviewed and approved on October 8, but the investigator did not complete required training until October 10, 2016, the final approval date would be October 10, but the review cycle would be based on the date the content review was completed so the study would be valid through October 7, 2017. Anniversary dates are not retained for expedited studies. Approval is valid through the expiration date (also known as the valid through date) noted in the approval letter. For example an expedited study given final IRB approval (either initially or for continuing review) on October 8, 2016 would be approved as valid through October 7, 2017, meaning that research is approved to be conducted on October 7, 2017, but will no longer be approved on October 8, 2017 and may not be conducted on or after that date without final continuing approval by the IRB. Continuing review and final approval for expedited studies must be obtained prior to the end of the day through which IRB approval is granted in order to avoid a lapse in approval

Reviewer Form:
The expedited reviewer form must be completed by the reviewer to document that the criteria for approval have been met. The reviewer form becomes part of the IRB study record. If the reviewer determines that continuing review is required for a study that meets expedited criteria that would not otherwise require continuing review the reviewer should document the reason for the requirement.

Agenda Listing:
For informational purposes, all submissions approved through the expedited review process are presented on the agenda of the next regularly scheduled meeting of the original reviewing panel for which the submission deadline has not passed. Any member may request that a submission approved through expedited review require full board review. The board will vote and a majority vote of the members present will decide the issue. Decisions made at full board meeting will supersede any decisions made through the expedited review process. Should the full board vote to deny approval previously granted, the withdrawal of approval is considered a termination of approval.

*The IRB staff person may also be an IRB member but is not required to be.

Procedure

Submission by PI:
A Principal Investigator (PI) may request expedited review and approval of a research study by indicating the level of review requested within the electronic submission form (e.g. the application, request for continuing, or request for modification form). The PI must also provide all of the other material requested on the IRB application checklist as applicable to the study.

Assignment to Regulatory Specialist*:
The IRB Administrator will assign expedited submissions to a Regulatory Specialist (RS).

- For new studies, the RS assignment is generally determined by alternating the assignment of new submissions among the RS for each panel.
- For previously approved research, preference will be to assign the submission to the RS of the Panel that granted the initial approval, however assignment of submissions may be alternated among the RSs to more evenly distribute assignments.

*The RS may also be a member of the IRB.

Screening:
The RS will screen all submission for completeness and may request that the PI provide additional documents, clarifications, or make corrections. Such requests for information will be made through the electronic submission system by setting the study status to initial screening, assigning a review process of returned for corrections, and checking the submission complete box. The RS will screen response and may repeat this process if necessary. In efforts to reduce processing time, this screening function may be incorporated into the formal review process. The RS will determine whether to use a separate screening function (e.g. several documents are missing from the submission such that a thorough review cannot be completed), or to incorporate the screening function into the formal review process by using a primary reviewer system or forwarding concerns to the reviewer.

Assignment for Review:
Once a submission is determined to be of sufficient quality for review, the RS will assign the reviewer(s) per policy. The assigned reviewer will receive an automatic notification of the assignment.

Conducting the Review:
All reviewers will be provided with all of the material relevant to the submission as well as the corresponding reviewer form. The reviewer form addresses the regulatory criteria for approval and the reviewer must document on the form that the criteria are met.

For initial and continuing review the expedited reviewer form requires the reviewer to document:

- that the research is minimal risk
- that if identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or could be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, there are reasonable and appropriate protections that will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal, and
- risks are reasonable in relation to potential benefits
- informed consent has been appropriately addressed
- subject selection is equitable
- that the research is not classified.
- the approval category

If applicable, for initial review, the reviewer will document on the reviewer form the permissible categories for vulnerable populations and that the required findings for the population to be included in the research have been met. If applicable, the reviewer will document on the reviewer form that criteria for waivers or alterations of consent, or waivers of documentation of consent have been met. The

signature statement when documenting approval for continuation, when continuing review is a requirement, affirms that the reviewer has determined such protections continue to be met.

Reviewers also have access to historical data if necessary to supplement the review.

Communication Back to PI:
After review of the material the reviewer may approve the submission or request revisions before granting approval.

- The RS is automatically notified by the system once the reviewer completes the assignment
  - If revisions are required,
    - the RS returns the submission to the PI with the noted contingences by setting the submission status to Approved Contingent and checking the submission complete box.
      - In efforts to minimize time to approval and the number of times a submission is returned for correction/responses, the RS may revise the documents as necessary. In such an event the contingency for approval would be that the PI review and accept the changes made by the IRB. If not accepted the PI would indicate why and the review process would repeat.
    - the RS will screen the responses. If response are not sufficient the process of returning the submission to the PI for response would repeat. If responses are sufficient, the RS will reassign the submission for review. At this point the review of responses may be assigned to any member of the IRB or HSPP/IRB staff as a scientific, experienced member has already conducted the initial review.
  - If approved, as applicable
    - the RS will enter the approval period for the study
      - if continuing review is required a due date for continuation will be entered
    - will set the submission status, and if applicable study status, to approved
    - will generate and send the final approval letter using the applicable standard template
    - will stamp relevant documents with the IRB electronic stamp
    - will return the submission to the PI by checking the submission complete box

Referral to Full Board:
If the reviewer determines the submission does not qualify for expedited review, or if the reviewer and the investigator cannot agree on the modifications required for approval, the submission will be sent to the convened IRB for review. The expedited reviewer cannot deny approval. The PI will be informed automatically through the electronic submission history tracking that the submission has been placed on a full board agenda.

Informing the Board of Expedited Activity:
After approval has been granted by the reviewer, the RS will add the expedited approval to the informational agenda of the next regularly scheduled board meeting for of the initial reviewer's panel for which the submission deadline has not passed.

- Any member may request that a submission approved through expedited review require full board review. The board will vote and a majority vote of the members present will decide the issue.
    - If the vote is in favor of full board review the Chair will contact the PI, or direct the RS to do so, to withdraw the approval until full board review is conducted. Notification will be done through the study correspondence tab in the electronic system. This is not considered a suspension or termination of approval that is reportable to institutional officials or agency heads.
    - Should the full board vote to negate approval previously granted the withdrawal (i.e. denial) of approval is considered a termination of approval.
        - The RS will inform the Director and Deputy Director of the HSPP (DHSPP) of this decision by copy of the minutes, and
        - The DHSPP will report to institutional officials and, as applicable, regulatory agencies.
            - Letter may be prepared for signature by RS or Deputy Director
        - The PI will be informed by letter prepared by the RS and signed by the IRB Chair. This letter will also instruct the investigator to inform any previously enrolled subjects of the change in approval status.

Related Policies

2009-003 – Imposing and Lifting Suspensions of IRB Approval or Imposing Terminations of IRB Approval
2009-004 – Required Reporting to Institutional Officials and External Agencies
2009-005 – Monitoring of IRB Approved Studies
2011-006.2 – Vulnerable Populations – Prisoners
2011-007.0 – Definitions Applied to Policies
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-009.10 – Institutional Review Board – More Frequent Review

Basis

45 CFR 46
21 CFR 56
Guidance Document: Categories of Research that may be reviewed by the IRB through an expedited Review Procedure (http://www.hhs.gov/ohrp/policy/expedited98.html)

Document Attributes

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Reviewed and Approved By:
Richard H. Simon *5-Feb-18*

Richard Simon, MD **Date**
Director Human Subjects Protection Program