Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.7
Policy Title: Institutional Review Board (IRB) – Assignment of Status Codes

Purpose

The purpose of this policy is to set forth the status codes that the IRB may assign to a study and to define when each code would be used.

Definitions

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

IRB Approval | Noncompliance | Noncompliance, Continuing | Noncompliance, Serious
Unanticipated Problem Involving Risk to Subjects or Others

Policy

The IRB will assign the applicable status codes to each submission and study that it reviews. As described below, the code may reflect the status of the study overall, or the status of a particular submission associated with the study (e.g., a request for modification).

Approved
This status code is assigned when a study is given final IRB approval through the expedited or convened board review process, or through a determination that the research is exempt. Final approval means that any contingencies initially identified have been addressed. This code is also used to reflect approval of requests for continuations and requests for study addendum/ modifications. Other institutional officials cannot approve research if it has not been approved by the IRB.

Approved Contingent
This status code is assigned after formal review by the IRB when minor modifications or confirmation of assumptions are required before final approval will be given. The modifications required for approval must be directives to the investigators and not require the judgment of the IRB to determine if the criteria for approval have been satisfied. This code may also be used to reflect the review outcome for submissions for requests for continuation and modifications and facilitated reviews.

Lapsed
This status code is administratively assigned to a study by the IRB submission system, iRIS, when a study has not received final approval for continuation, or final approval to extend the expected completion date of the study when continuing is not required, prior to the expiration of the current approval period. The status will also be automatically assigned to exempt research for which the expected completion date has passed.

Closure by PI
This status code is assigned by the IRB Regulatory Specialist when an investigator has submitted a request for closure of a study and the IRB (UConn Health or external IRB in the case of reliance) grants the request.

Deferred
This status code is assigned when the board has reviewed a study at a convened meeting and has significant concerns with the protocol, consent document or other relevant material, or requires

substantive clarifications on issues that relate to the regulatory criteria for approval. The principal investigator must respond to each concern in writing and resubmit for review by the same IRB panel. This status may also be assigned to requests for continuation and modifications.

Determined Not Human Subjects
This status code is assigned when the IRB determines that a submission for which IRB approval has been sought does not meet the definition of research involving human subjects or a clinical investigation involving human subjects.

Disapproved
This status code is assigned when the board reviews a study and determines that one or more of the regulatory criteria for approval has not been met and in the board's opinion cannot be satisfied. This status code may also be used for requests for continuations and modifications. This status code can only be assigned by the convened board.

Facilitated Review Accepted/ Declined
The accepted or declined status code is assigned to indicate whether the UConn Health IRB has agreed to rely upon an external IRB for a study. The review may be accepted contingently if the UConn Health IRB requires minor modifications prior to agreeing to defer oversight to an external IRB.

Inactive-Administratively Closed
This status code is assigned by the IRB Administrator to reflect that a study has been administratively closed by the IRB due to failure to request continuing review or to respond to contingencies for continuing approval in a timely manner. The investigator will be notified of studies closed by the IRB. Administrative closures by the IRB are not reportable events. The IRB Administrator will assign this status code to exempt research after the anticipated completion date has passed.

Non-Reportable Event
This status code may be assigned by an expedited reviewer or the convened board to reflect the determination that an event described within an IRB submission, e.g. an issue described on a problem report form, does not constitute serious noncompliance, continuing noncompliance or an unanticipated problem involving risk to subjects or others.

Pending
This status code is assigned by the IRB submission system, iRIS, to new study submissions when material has been received for review but the review has not yet occurred.

Reportable Event
This status code may be assigned by the convened board to reflect the determination that an event described within the IRB submission, e.g. an issue described on a problem report form or in an audit letter, does constitute serious noncompliance, continuing noncompliance and/or an unanticipated problem involving risk to subjects or others. The specific type of event that the issue represents will be noted in the IRB meeting minutes.

Suspension
This status code is assigned to reflect the imposition of a temporary hold on any or all research activity associated with a study, or a permanent stop to some portion of a previously approve research activity. This code may be assigned by the Chair, the convened board or other institutional official designated in

the policy for imposing suspensions. Suspension may ultimately result in termination if the investigator cannot adequately address the concerns of the IRB or other institutional officials.

Tabled
This status code is used in the IRB minutes only when a submission is not reviewed at the meeting for which it was originally scheduled, for example, due to a loss of a quorum. This status code may also be used for requests for continuation and modification.

Termination
This status code is assigned to reflect a permanent withdrawal of study approval that requires all study related activity to cease. This code may be assigned by the convened IRB or other institutional official designated in the suspension policy for reasons such as noncompliance or the occurrence of serious or unexpected risks to subjects.

Withdrawn – Never Approved
This code will be administratively assigned by the IRB staff upon communication from an investigator that final approval for a submission will not be sought.

Procedure

For submissions reviewed by the convened board, the IRB Regulatory Specialist (RS) will enter the status code assigned by the board into the electronic data base.

For expedited and exempt submissions the RS will enter the status code in the electronic system based on documentation received from the reviewer.

The status code assigned will be communicated from the IRB to the investigator in writing using the standard IRB outcome letter.

For suspensions or terminations imposed by other institutional officials the IRB RS will change the status code in the system upon receipt of documentation from the individual imposing the action.

Related Content

2009-001 - Reporting Unanticipated Problems to the Institutional Review Board
2009-002 - Reporting Noncompliance to the Institutional Review Board
2009-003 - Imposing and Lifting Suspensions of IRB Approval or Imposing Terminations of IRB Approval
2011-007.0 – Definitions Applied to Policies
2011-009.2 – Institutional Review Board - Exemptions
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by the Convened Board

Basis

45 CFR 46
21 CFR 56

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Richard H. Simon **6/8/2023**

Richard H. Simon, MD **Date**
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