# eIRB States

The current 'State' of a project indicates its status in the review process or its review outcome.

| State | Definition | Who can make changes in this state? | eIRB Form in which this state may appear | | | | |
|---|---|---|---|---|---|---|---|
| | | | Study | Amendment | Remote Site Documentation | Continuing Review | Reportable Event |
| Acknowledged | The submission is an External IRB Review and the study, amendment, continuing review or reportable event that has been acknowledged by the local IRB.<br><br>Reportable events for all types of studies have acknowledgment states.<br><br>**This is an "end state".** | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff<br><br>*Acknowledged studies can be edited through an amendment. Acknowledged Amendments, Continuing Reviews and Reportable Events cannot be edited.* | ☑ | ☑ | | ☑ | ☑ |
| Approved | Submission is approved by IRB. **This is an "end state".** | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff<br><br>*Approved studies can be edited only through new requests (amendment, continuing review or status change).* | ☑ | ☑ | ☑ | ☑ | |

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| Assigned to IRB Meeting | The submission is included on the agenda of an upcoming scheduled meeting. The planned review/meeting date has been set. | IRB staff | ☑ | ☑ | | ☑ | ☑ |
| Awaiting Correspondence | A decision has been made on the submission. The IRB Office will issue correspondence releasing this decision. | IRB Staff | ☑ | ☑ | ☑ | ☑ | ☑ |
| Awaiting Meeting Assignment | The submission meets criteria for full board review and is pending addition to the agenda of an upcoming scheduled meeting. | IRB staff | | | | | ☑ |
| Changes Required for External IRB Review | OBSOLETE for new studies after 10/18/2017 - The External IRB Review study has been reviewed by the local (i.e., institution's) IRB and changes to the study are required. | PI<br>Study Coordinator | ☑ | | | | |
| Changes Required per Department | The Department Reviewer has reviewed the submission and requires changes before the study routes to IRB for review. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |

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|---|---|---|---|---|---|---|---|
| Changes Required per Exempt Reviewer | The “Exempt Reviewer” has reviewed the submission and requires changes before the submission is approved. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Changes Required per IRB | The submission has been reviewed by IRB and changes to the study are required. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | ☑ | ☑ | ☑ | |
| Changes Required per IRB Staff | The IRB Staff has reviewed the submission and requires that changes be made before the study is passed on to IRB for review. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | ☑ | ☑ | ☑ | ☑ |
| Changes Required per Lead Site | The Remote Site Documentation (RSD)/Reportable Event/Continuing Review application has been reviewed by the Lead site and changes are required of the remote site before submission to IRB<br>*Applies to Single IRB studies where the HSSC IRB serves as the single IRB for a multi-site study* | Lead Site Study Staff<br>Remote Site Study Staff | | | ☑ | ☑ | ☑ |
| Changes Required per Mentor | The Mentor has reviewed the submission and requires changes before the study routes to Departments or IRB for review. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |

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| | | | **eIRB Form in which this state may appear** | | | | |
| Changes Required per Not Human Subject Research Reviewer | The Not Human Subject Research reviewer has reviewed the submission and requires changes before the submission is considered for concurrence as Not Human Subject Research. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Changes Required per Pre-Meeting Reviewer | The pre-meeting reviewer has reviewed the submission and requires that changes be made before the study is passed on to IRB for review. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Changes Required per Reviewer | The "Expedited Reviewer", "Facilitated Reviewer" or "NCI CIRB Reviewer" has reviewed the submission and requires changes before the submission is approved. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | ☑ | ☑ | ☑ | |
| Committee Member Review | The Reportable Event submission has been received and is pending review by the IRB Committee Member who has been assigned the review. | IRB staff<br>IRB Chair<br>IRB Committee Member(s) | | | | | ☑ |
| Completed | The study is permanently completed, as indicated through a continuing review submission. **This is an "end state".** | No one | ☑ | | | | |

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| Contingencies Pending | The submission has been reviewed by the full board and contingencies have been issued. The PI must meet these contingencies and resubmit. Approval will be issued if the contingencies are met. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | ☑ | | ☑ | ☑ |
| Conversion Changes Requested by IRB Staff | The converted study application has been reviewed by the IRB Office. The IRB office requests changes to the submission before the conversion is approved. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Correspondence Review | Correspondence drafted by the IRB office is being reviewed by the IRB Chair for his/her approval before being released. | IRB staff<br>IRB Chair<br>IRB Committee Member(s) | ☑ | ☑ | ☑ | ☑ | |
| Department Review | The study has been submitted, it is now awaiting Department Review review to advance to IRB. | Department Reviewer (i.e., SRHS CRC) | ☑ | | | | |
| Designated Reviewer Contingency Review | The PI's response to contingencies has been submitted to IRB and is under review. | IRB staff | ☑ | ☑ | | ☑ | ☑ |
| Disapproved | The Submission did not receive IRB Approval.<br>**This is an "end state".** | No one | ☑ | ☑ | | ☑ | |

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| | | | header: **eIRB Form in which this state may appear** | | | | |
| Exempt Approved | The submission qualified for exemption and has been approved as such. **This is an "end state".** | *The study can be edited through new amendment requests by:*<br>PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Expired | The dates of approval have lapsed. The study is no longer IRB-approved. | IRB Staff | ☑ | | | | |
| Expired - Continuation in Progress | The dates of approval have lapsed but a Continuing Review has been submitted. The study is not currently IRB-approved. | IRB Staff | ☑ | | | | |
| External IRB Review | OBSOLETE for new studies after 10/18/2017 - An IRB staff member has received a study request for consideration of review by an external IRB. They may (1) accept the request, (2) return the application to the submitter requiring changes or (3) render the study not eligible for review by an external IRB. | IRB Staff | ☑ | | | | |

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| External IRB Review Archive | OBSOLETE for new studies after 10/18/2017 - The IRB has rendered the study acceptable for external IRB review. **This is an "end" state**. | New documents can be uploaded and comments logged on the study by: IRB Staff PI Designated Study Staff | ☑ | | | | |
| In Exempt Review | The IRB staff has made the assignment to an IRB Member who has been designated as the "Exempt Reviewer". The submission is now pending the review of this individual. This reviewer may (1) make a motion for approval or may (2) require changes to the submission. | Designated "Exempt Reviewer" (an IRB Committee Member) | ☑ | | | | |
| In Exempt Review Awaiting Correspondence | The "Exempt Reviewer" has completed review of the submission. The decision letter must now be drafted by the IRB office. | IRB staff | ☑ | | | | |
| In External IRB Review | OBSOLETE for new studies after 10/18/2017 - The IRB staff has opted to forward this study to a designated reviewer for concurrence as an External IRB study. The submission is now pending the review of this individual. | Designated Reviewer | ☑ | | | | |

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| In Not Human Subject Research Review | The IRB staff has opted to forward this study to a designated reviewer for concurrence as Not Human Subjects research. The submission is now pending the review of this individual. | Designated Reviewer (an IRB Committee Member) IRB Staff | ☑ | | | | |
| In Not Human Subject Research Review Awaiting Correspondence | The Not Human Subject Research reviewer has completed review of the submission. The decision letter must now be drafted by the IRB office. | IRB Staff | ☑ | | | | |
| In Pre-Meeting Review | The IRB staff has forwarded this study for review. | Designated Reviewer | ☑ | | | | |
| In Pre-Meeting Review Awaiting Correspondence | The designated pre-meeting reviewer has requested changes before scheduling it for an IRB meeting | PI Co-Investigator(s) Study Coordinator Designated Study Staff Designated Reviewer | ☑ | | | | |

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| | | | Study | Amendment | Remote Site Documentation | Continuing Review | Reportable Event |
| In Review | The IRB staff has made the assignment to an IRB Member who has been designated as the "Expedited Reviewer", "Facilitated Reviewer" (OBSOLETE for new studies after 10/18/2017), "NCI CIRB Reviewer" (OBSOLETE for new studies after 10/18/2017) or "External IRB Reviewer". The submission is now pending the review of this individual. This reviewer may (1) make a motion for approval or may (2) require changes to the submission. | Designated "Expedited Reviewer" or "Facilitated Reviewer" (an IRB Committee Member) | ☑ | ☑ | ☑ | ☑ | |
| In Review Awaiting Correspondence | The "Expedited Reviewer", "Facilitated Reviewer" (OBSOLETE for new studies after 10/18/2017), "NCI CIRB Reviewer" (OBSOLETE for new studies after 10/18/2017) or "External IRB Reviewer" has completed review of the submission. The decision letter must now be drafted by the IRB office. | IRB staff | ☑ | ☑ | ☑ | ☑ | ☑ |
| IRB Assignment | The study has been submitted and is waiting for an IRB staff member to accept it for pre-review. | IRB staff | ☑ | | | | |
| IRB Chair Correspondence Review | The correspondence drafted by the IRB office is being reviewed by the IRB Chair for his/her approval before being released. | IRB Chair | ☑ | ☑ | ☑ | ☑ | ☑ |

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| | | | *eIRB Form in which this state may appear* | | | | |
| IRB Conversion Review | The converted study application has been submitted, it is now waiting for the IRB Office to review the submission and issue approval or request changes. | IRB staff | ☑ | | | | |
| IRB Staff Contingency Review | The contingencies have been submitted by the PI. The IRB staff is reviewing these contingencies to see if they have been met. | IRB staff | ☑ | ☑ | | ☑ | ☑ |
| IRB Staff Reliance Activation Review | The request for more information to activate an External IRB Review study has been submitted by the study team. The IRB staff is reviewing the information to see if all requirements are met. | IRB staff | ☑ | | | | |
| IRB Staff Review | An IRB staff member has accepted and is reviewing the submission. They may (1) pass the submission on for full board review, expedited, or exempt review or they may (2) return the application to the submitter requiring changes. | IRB staff | ☑ | ☑ | ☑ | ☑ | ☑ |
| Lead Site Review | The Remote Site Documentation (RSD)/Reportable Event/Continuing Review application has been submitted by the remote site to the Lead investigative site for review prior to IRB submission. *Applies to Single IRB studies where the HSSC IRB serves as the single IRB for a multi-site study* | Lead Site Study Staff | | | ☑ | ☑ | ☑ |

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| Meeting Complete Awaiting Correspondence | The IRB has completed review of the submission at a full board meeting. The decision letter must now be drafted by the IRB office. | IRB Staff | ☑ | ☑ | | ☑ | ☑ |
| Mentor Review | The study has been submitted, it is now waiting for the Mentor to review the submission and issue approval or request changes. | Mentor | ☑ | | | | |
| Not Human Subjects Research | The study has been reviewed and an assessment made that it is Not Human Subjects Research. **This is an "end state".** | No one | ☑ | | | | |
| Not Ready for Review | The study has been returned to an editable state after IRB determines it cannot be considered in its current condition because it is unclear or is missing large components. | PI Co-Investigator(s) Study Coordinator Designated Study Staff | ☑ | | | | |
| Overdue Study Status | The recorded dates of approval on an External IRB Review study have lapsed. | PI Co-Investigator(s) Study Coordinator Designated Study Staff | ☑ | | | | |
| Pre Submission | The study (or Amendment, Continuing Review, Status Change or Reportable Event) has not yet been submitted for review. | PI Co-Investigator(s) Study Coordinator Designated Study Staff | ☑ | ☑ | ☑ | ☑ | ☑ |

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| Received Not Reportable | The Reportable Event submission has been received but it does not meet criteria for review. **This is an "end state".** | No one | | | | | ☑ |
| Reliance Acknowledged, Pending Activation | The local IRB has acknowledged reliance on an External IRB, however the study requires additional information and/or External IRB review that must be submitted by the study team for the local IRB to activate study enrollment. | PI<br>Co-Investigator(s)<br>Study Coordinator<br>Designated Study Staff | ☑ | | | | |
| Suspended | The study approval has been suspended. | IRB Staff | ☑ | | | | ☑ |
| Template | The submission has been copied as a template (non-editable copy) of another project. | No one | ☑ | | | | |
| Terminated | The Study has been terminated. **This is an "end state" documented by the IRB.** | No one | ☑ | | | | |
| Transferred | The study was previously under the local IRB's purview and has been transferred to an external IRB. **This is an "end state".** | No one | ☑ | | | | |

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| | | | Study | Amendment | Remote Site Documentation | Continuing Review | Reportable Event |
| Withdrawn | The submission (Study, Amendment, Continuing Review, Status Change or Reportable Event) has been withdrawn. **This is an "end state".** | No one | ☑ | ☑ | ☑ | ☑ | ☑ |