1. PURPOSE
   1. This policy establishes the states and transitions of studies.
2. POLICY
   1. A submission is a packet of materials submitted to the IRB.
   2. The following are allowable submissions:
      1. Initial
      2. Continuing
      3. Modification
      4. New Information
   3. A study consists of one or more submissions.
      1. A study may have the following states:

|  |  |
| --- | --- |
| State | Meaning |
| Submitted | * An initial submission creates a new study with the state of “Submitted.” |
| Determined Not Human Research | * Study is not human research * No HRPP oversight is required. |
| Determined Human Research Not Engaged | * Study is human research * No HRPP oversight is required. |
| Approved | * Study is human research * HRPP oversight required * Prior review determined that the study could proceed |
| Suspended | * Study is human research * HRPP oversight required * Prior review determined that the study could proceed * More recent review instituted a Suspension of IRB Approval |
| Terminated | * Study is human research * HRPP oversight required * Prior review determined that the study could proceed * More recent review instituted a Termination of IRB Approval |
| Expired | * Study is human research * HRPP oversight required * Prior review determined that the study could proceed * Approval period passed without continuing review |
| Closed | * Study was human research * HRPP oversight was required * Prior review determined that the study could proceed * Study meets criteria for closure |
| Transferred | * Study is human research * HRPP oversight is required * Study was transferred to the oversight of another IRB |

* + 1. A study may change between non-human research and human research states. For example, a study might initially be determined to be not human research and with a modification become human research.
  1. Review actions on a submission are:

|  |  |
| --- | --- |
| Action | Meaning |
| Not Human Research | * The activity does not meet the organizational definition of Human Research.) |
| Human Research Not Engaged | * The activity meets the organizational definition of Human Research but the site is not engaged |
| Approve | * See “SOP: Committee Review Conduct (HRP-106)” |
| Conditionally Approve | * See “SOP: Committee Review Conduct (HRP-106)” |
| Defer | * See “SOP: Committee Review Conduct (HRP-106)” |
| Disapprove | * See “SOP: Committee Review Conduct (HRP-106)” |
| Suspend | * See “SOP: Committee Review Conduct (HRP-106)” |
| Lift Suspension | * See “SOP: Committee Review Conduct (HRP-106)” |
| Terminate | * See “SOP: Committee Review Conduct (HRP-106)” |

* 1. Administrative actions on a study are:

|  |  |
| --- | --- |
| Action | Meaning |
| Expire | * Approval period passed without continuing review |
| Close | * Study meets criteria for closure |
| Transfer | * Study is transferred to the oversight of another IRB |

* 1. Table 1 lists the relationship between the study’s initial state prior to a submission, the IRB or administrative action, and the study’s state after the action.
  2. Table 2 lists the allowable submissions based on the study’s state prior to a submission.

1. REFERENCES
   1. None
   2. Table 1: States and transitions

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table shows new state of activity after action on submission or new information | | Previous State of the Study | | | | | | | | |
| Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Closed | Transferred |
| IRB Action | Not Human Research | Submitted | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research | Determined Not Human Research |
| Human Research Not Engaged | Determined Not Human Research | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged | Human Research Not Engaged |
| Approve | Determined Human Research Not Engaged | Approved | Approved | Approved | Suspended | Approved | Approved | Approved | Approved |
| Conditionally Determine Not Human Research | Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Submitted | Submitted |
| Conditionally Determine Human Research Not Engaged | Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Submitted | Submitted |
| Conditionally Approve | Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Submitted | Submitted |
| Defer | Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Submitted | Submitted |
| Disapprove | Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Submitted | Submitted |
| Suspend | - | - | - | Suspended | - | - | - | - |  |
| Lift Suspension | - | - | - | - | Approved | - | - | - |  |
| Terminate | - | - | - | Terminated | Terminated | - | - | - |  |
| Admin Action | Expire | - | - | - | Expired | Expired | - | - | - |  |
| Close | - | - | - | Closed | Closed | - | - | - |  |
| Transfer | - | - | - | Transferred | - | - | - | - |  |

* 1. Table 2: Allowable submissions

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table shows allowable submissions  X= allowed | | State of the Study | | | | | | | |
| Submitted | Determined Not Human Research | Determined Human Research Not Engaged | Approved | Suspended | Terminated | Expired | Closed |
| Submission Type | Initial | X |  |  |  |  |  |  |  |
| Continuing |  |  |  |  |  |  |  |  |
| Modification |  |  |  | X | X |  | X |  |
| New Information |  | X | X | X | X | X |  | X |