

POLICY: STATES AND TRANSITIONS

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1. PURPOSE

1.1. This policy establishes the states and transitions of studies.

2. POLICY

2.1. A submission is a packet of materials submitted to the IRB.

2.2. The following are allowable submissions:

- 2.2.1. Initial
- 2.2.2. Continuing
- 2.2.3. Modification
- 2.2.4. New Information

2.3. A study consists of one or more submissions.

2.3.1. A study may have the following states:

State	Meaning
Submitted	<ul style="list-style-type: none"> • An initial submission creates a new study with the state of "Submitted."
Determined Not Human Research	<ul style="list-style-type: none"> • Study is not human research • No HRPP oversight is required.
Determined Human Research Not Engaged	<ul style="list-style-type: none"> • Study is human research • No HRPP oversight is required.
Approved	<ul style="list-style-type: none"> • Study is human research • HRPP oversight required • Prior review determined that the study could proceed
Suspended	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Study is human research • HRPP oversight required • Prior review determined that the study could proceed • Approval period passed without continuing review
Closed	<ul style="list-style-type: none"> • Study was human research • HRPP oversight was required • Prior review determined that the study could proceed • Study meets criteria for closure

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Transferred	<ul style="list-style-type: none"> • Study is human research • HRPP oversight is required • Study was transferred to the oversight of another IRB
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2.3.2. 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.

2.4. Review actions on a submission are:

Action	Meaning
Not Human Research	<ul style="list-style-type: none"> • The activity does not meet the organizational definition of <Human Research>.)
Human Research Not Engaged	<ul style="list-style-type: none"> • The activity meets the organizational definition of <Human Research> but the site is not engaged
Approve	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”
Modifications Required to Secure Approval	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”
Defer	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”
Disapprove	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”
Suspend	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”
Terminate	<ul style="list-style-type: none"> • See “SOP: Committee Review Conduct (CM-106)”

2.5. Administrative actions on a study are:

Action	Meaning
Expire	<ul style="list-style-type: none"> • Approval period passed without continuing review
Close	<ul style="list-style-type: none"> • Study meets criteria for closure
Transfer	<ul style="list-style-type: none"> • Study is transferred to the oversight of another IRB

2.6. 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.

2.7. Table 2 lists the allowable submissions based on the study’s state prior to a submission.

3. REFERENCES

3.1. None