



# 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
Pending	<ul style="list-style-type: none"> <li>• An initial submission creates a new study with the state of "Pending."</li> </ul>
Determined Not Human Research	<ul style="list-style-type: none"> <li>• Study is not human research</li> <li>• No HRPP oversight is required.</li> </ul>
Determined Human Research Not Engaged	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• No HRPP oversight is required.</li> </ul>
Approved	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> </ul>
Suspended	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• More recent review instituted a &lt;Suspension of IRB Approval&gt;</li> </ul>
Terminated	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• More recent review instituted a &lt;Termination of IRB Approval&gt;</li> </ul>
Expired	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• Approval period passed without continuing review</li> </ul>
Closed	<ul style="list-style-type: none"> <li>• Study was human research</li> <li>• HRPP oversight was required</li> <li>• Prior review determined that the study could proceed</li> <li>• Study meets criteria for closure</li> </ul>
Transferred	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight is required</li> <li>• Study was transferred to the oversight of another IRB</li> </ul>
Withdrawn	<ul style="list-style-type: none"> <li>• Study was submitted, but withdrawn by investigator</li> <li>• HRPP requested clarifications/revisions from investigator, but none received within 60 days of request</li> </ul>



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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"> <li>The activity does not meet the organizational definition of &lt;Human Research&gt;.)</li> </ul>
Human Research Not Engaged	<ul style="list-style-type: none"> <li>The activity meets the organizational definition of &lt;Human Research&gt; but the site is not engaged</li> </ul>
Approve	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Conditionally Approve	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Defer	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Disapprove	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Suspend	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Lift Suspension	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>
Terminate	<ul style="list-style-type: none"> <li>See "SOP: Committee Review Conduct (HRP-106)"</li> </ul>

2.5. Administrative actions on a study are:

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

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



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3.2. 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	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	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	Human Research Not Engaged	Human Research Not Engaged
	Approve	Approved	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	-	-	-	-	-



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3.3. 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				X	X		X	
	Modification		X	X	X	X	X	X	X
	New Information		X	X	X	X	X	X	X