



**POLICY: States and Transitions**

| Document No.: | Edition No.: | Effective Date: | Page:       |
|---------------|--------------|-----------------|-------------|
| HRP-050       | 001          | January 2, 2020 | Page 1 of 5 |

**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"> <li>• An initial submission creates a new study with the state of “Submitted.”</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 <b>Suspension of IRB Approval</b></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 <b>Termination of IRB Approval</b></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>                   |



**POLICY: States and Transitions**

| Document No.: | Edition No.: | Effective Date: | Page:       |
|---------------|--------------|-----------------|-------------|
| HRP-050       | 001          | January 2, 2020 | Page 2 of 5 |

|             |  |
|-------------|--|
| 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>   |

- 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.



**POLICY: States and Transitions**

| Document No.: | Edition No.: | Effective Date: | Page:       |
|---------------|--------------|-----------------|-------------|
| HRP-050       | 001          | January 2, 2020 | Page 3 of 5 |

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 <b>Human Research.</b>)</li> </ul>                   |
| Human Research Not Engaged | <ul style="list-style-type: none"> <li>The activity meets the organizational definition of <b>Human Research</b> 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

**POLICY: States and Transitions**

|                      |                     |                        |                    |
|----------------------|---------------------|------------------------|--------------------|
| <b>Document No.:</b> | <b>Edition No.:</b> | <b>Effective Date:</b> | <b>Page:</b>       |
| <b>HRP-050</b>       | <b>001</b>          | <b>July 15, 2019</b>   | <b>Page 4 of 5</b> |

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                          |
| <b>IRB Action</b>   | Not Human Research                                 | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b>         | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> | <b>Determined Not Human Research</b> |
|   | Human Research Not Engaged                         | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>            | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    | <b>Human Research Not Engaged</b>    |
|   | Approve  | <b>Approved</b>                      | <b>Approved</b>                      | <b>Approved</b>                              | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Approved</b>                      | <b>Approved</b>                      | <b>Approved</b>                      | <b>Approved</b>                      |
|   | Conditionally Determine Not Human Research         | <b>Submitted</b>                     | <b>Determined Not Human Research</b> | <b>Determined Human Research Not Engaged</b> | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Terminated</b>                    | <b>Expired</b>                       | <b>Submitted</b>                     | <b>Submitted</b>                     |
|   | Conditionally Determine Human Research Not Engaged | <b>Submitted</b>                     | <b>Determined Not Human Research</b> | <b>Determined Human Research Not Engaged</b> | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Terminated</b>                    | <b>Expired</b>                       | <b>Submitted</b>                     | <b>Submitted</b>                     |
|   | Conditionally Approve                              | <b>Submitted</b>                     | <b>Determined Not Human Research</b> | <b>Determined Human Research Not Engaged</b> | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Terminated</b>                    | <b>Expired</b>                       | <b>Submitted</b>                     | <b>Submitted</b>                     |
|   | Defer  | <b>Submitted</b>                     | <b>Determined Not Human Research</b> | <b>Determined Human Research Not Engaged</b> | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Terminated</b>                    | <b>Expired</b>                       | <b>Submitted</b>                     | <b>Submitted</b>                     |
|   | Disapprove   | <b>Submitted</b>                     | <b>Determined Not Human Research</b> | <b>Determined Human Research Not Engaged</b> | <b>Approved</b>                      | <b>Suspended</b>                     | <b>Terminated</b>                    | <b>Expired</b>                       | <b>Submitted</b>                     | <b>Submitted</b>                     |
|   | Suspend  | -                                    | -                                    | -  | <b>Suspended</b>                     | -                                    | -                                    | -                                    | -                                    | -                                    |
|   | Lift Suspension                                    | -                                    | -                                    | -  | -                                    | <b>Approved</b>                      | -                                    | -                                    | -                                    | -                                    |
|   | Terminate  | -                                    | -                                    | -  | <b>Terminated</b>                    | <b>Terminated</b>                    | -                                    | -                                    | -                                    | -                                    |
| <b>Admin Action</b>   | Expire   | -                                    | -                                    | -  | <b>Expired</b>                       | <b>Expired</b>                       | -                                    | -                                    | -                                    | -                                    |
|   | Close  | -                                    | -                                    | -  | <b>Closed</b>                        | <b>Closed</b>                        | -                                    | -                                    | -                                    | -                                    |



**POLICY: States and Transitions**

| Document No.: | Edition No.: | Effective Date: | Page:       |
|---------------|--------------|-----------------|-------------|
| HRP-050       | 001          | July 15, 2019   | Page 5 of 5 |

|  |          |   |   |   |             |   |   |   |   |  |
|--|----------|---|---|---|-------------|---|---|---|---|--|
|  | Transfer | - | - | - | Transferred | - | - | - | - |  |
|--|----------|---|---|---|-------------|---|---|---|---|--|

3.3. Table 2: Allowable submissions

| Table shows allowable submissions<br>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      |