

# Standard Operating Procedure (SOP)

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|--|---------------------------------------|
| <b>SOP #: 401.125</b>                                      | <b>HRP-125 IRB End Approval Dates</b> |
| <b>Executive Owner: Vice President Research Operations</b> | <b>Effective Date: 6/11/2018</b>      |
|  | <b>Review Date: 09/23/2019</b>        |

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|---------------------------------|---|
| <b>Scope</b>                    | This SOP applies to all <HRPP Personnel> responsible for post IRB review procedures.  |
| <b>Purpose</b>                  | This SOP describes the calculation of the <End Approval Date>.  |
| <b>Qualified Personnel</b>      | The [Organizational Official] carries out these procedures or ensures that others carry them out.   |
| <b>Training</b>                 | Not applicable.   |
| <b>Supplies &amp; Equipment</b> | Not applicable.   |
| <b>Procedure</b>                | <ol style="list-style-type: none"> <li>1. The following research has no &lt;End Approval Date&gt;. However, the date will be captured in the IRB electronic submission system as a means to remind investigators to close studies once completed:             <ol style="list-style-type: none"> <li>1.1. Exempt research</li> <li>1.2. Research that does not require continuing review per “WORKSHEET: Criteria for Approval (HRP-400).”</li> </ol> </li> <li>2. For all other research:             <ol style="list-style-type: none"> <li>2.1. The Action Date is                 <ol style="list-style-type: none"> <li>2.1.1. The date the convened IRB or &lt;Designated Reviewer&gt; made determination to approve the research.; or</li> <li>2.1.2. The date the IRB confirmed that the responsive materials met the requirements of a convened IRB or &lt;Designated Reviewer&gt; determination to conditionally approve the research.</li> </ol> </li> <li>2.2. The Approval Interval is the period of approval granted by the convened IRB or &lt;Designated Reviewer&gt;. (e.g., 1 year, 6 months, 3 months)</li> </ol> </li> <li>3. For initial review, the &lt;End Approval Date&gt; is the Action Date plus the approval interval minus one day.             <ol style="list-style-type: none"> <li>3.1. For example, if the research was approved for one year with an Action Date of April 15, 2020, the &lt;End Approval Date&gt; is April 14, 2021.</li> </ol> </li> <li>4. For continuing review, the new &lt;End Approval Date&gt; is the Action Date plus the approval interval minus one day.             <ol style="list-style-type: none"> <li>4.1. For modifications, the &lt;End Approval Date&gt; is unchanged.</li> </ol> </li> </ol> |
| <b>Definition(s)</b>            | <a href="#">For &lt;Angle Brackets&gt; refer to Policy 400.001 HRP-001 Definitions</a><br><a href="#">For [Square Brackets] refer to Policy 400.003 HRP-003 Designations</a>  |
| <b>Reference(s)</b>             | Electronic Code of Federal Regulation ( <i>e-CFR</i> <sup>TM</sup> ). (June 18, 2015). 21 CFR, §56.109(f): IRB Review of Research. Retrieved from: <a href="#">Click here</a> .   |

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**Related Documents**

Not applicable.

**Keywords**

IRB, institutional review board, IRB member, HRP-125