

# Standard Operating Procedure (SOP)

<b>SOP #: 401.134</b>	<b>HRP-134 Designated Exempt Reviewers</b>
<b>Executive Owner: Vice President Research Operations</b>	<b>Effective Date: 7/15/2015</b>
	<b>Review Date: 09/23/2019</b>

<b>Scope</b>	This SOP applies to the [IRB Executive Chair] and HRPP staff.
<b>Purpose</b>	This procedure establishes the process to designate or remove individuals from the list of IRB members who can review and approve exempt <Human Research>. This procedure begins when [IRB Executive Chair] considers adding or removing an individual designated to review and approve exempt <Human Research>. This procedure ends when the [IRB Executive Chair] notifies HRPP staff of a new individual designated to review and approve exempt <Human Research> or the removal of a previously designated individual.
<b>Qualified Personnel</b>	The [IRB Executive Chair] carries out these procedures. IRB staff maintain a list of individuals designated to review and approve exempt <Human Research> and the category of exemption each individual is authorized to grant.
<b>Training</b>	Not applicable.
<b>Supplies &amp; Equipment</b>	Not applicable.
<b>Procedure</b>	<ol style="list-style-type: none"> <li>1. Florida Hospital may designate one or more individuals to review and approve exempt &lt;Human Research&gt;.</li> <li>2. Individuals designated to review and approve exempt &lt;Human Research&gt; do not need to be IRB members.</li> <li>3. In general, individuals designated to review and approve exempt &lt;Human Research&gt; are granted authority for only one exemption category.</li> <li>4. To designate an individual to review and approve exempt &lt;Human Research&gt; in one category or a limited number of categories: <ol style="list-style-type: none"> <li>4.1. Train the individual to approve exempt &lt;Human Research&gt; in one or more categories using the following documents. <ol style="list-style-type: none"> <li>4.1.1. POLICY: IRB Records (HRP-023)</li> <li>4.1.2. SOP: Designated Exempt Review Conduct (HRP-135)</li> <li>4.1.3. FORM: Promptly Reportable Information (HRP-204)</li> <li>4.1.4. WORKSHEET: Human Research (HRP-421)</li> <li>4.1.5. WORKSHEET: Exemptions (HRP-423), modified to limit the exemption category or categories to those authorized.</li> <li>4.1.6. POLICY: Investigator Obligations (HRP-070)</li> <li>4.1.7. POLICY: Prompt Reporting Requirements (HRP-069)</li> </ol> </li> <li>4.2. Notify IRB staff to update the list of individuals designated to review and approve exempt &lt;Human Research&gt; to include the name of the individual and the categories of exemption on which the individual has been trained.</li> </ol> </li> </ol>

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5. To remove an individual's designation to review and approve exempt <Human Research>:
  - 5.1. Notify IRB staff to update the list of individuals designated to review and approve exempt <Human Research> to remove the name of the individual.
  - 5.2. Inform the individual that he or she may no longer review and approve exempt <Human Research>.
  - 5.3.

<b>Definition(s)</b>	IRB: Institutional Review Board
<b>Reference(s)</b>	45 CFR §46.101(b)
<b>Related Documents</b>	Not applicable.
<b>Keywords</b>	IRB, institutional review board, IRB member