

SOP: Designated Exempt Reviewers

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1. PURPOSE

- 1.1. This procedure establishes the process to designate or remove individuals from the list of IRB members who can review and approve exempt <Human Research>.
- 1.2. This procedure begins when [IRB Executive Chair] considers adding or removing an individual designated to review and approve exempt <Human Research>.
- 1.3. 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.

2. POLICY

- 2.1. Florida Hospital may designate one or more individuals to review and approve exempt <Human Research>.
- 2.2. Individuals designated to review and approve exempt <Human Research> do not need to be IRB members.
- 2.3. In general, individuals designated to review and approve exempt <Human Research> are granted authority for only one exemption category.

3. RESPONSIBILITY

- 3.1. The [IRB Executive Chair] carries out these procedures.
- 3.2. 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.

4. PROCEDURE

- 4.1. To designate an individual to review and approve exempt <Human Research> in one category or a limited number of categories:
 - 4.1.1. Train the individual to approve exempt <Human Research> in one or more categories using the following documents.
 - 4.1.1.1. POLICY: IRB Records (HRP-023)
 - 4.1.1.2. SOP: Designated Exempt Review Conduct (HRP-135)
 - 4.1.1.3. FORM: Promptly Reportable Information (HRP-204)
 - 4.1.1.4. WORKSHEET: Human Research (HRP-421)
 - 4.1.1.5. WORKSHEET: Exemptions (HRP-423), modified to limit the exemption category or categories to those authorized.
 - 4.1.1.6. POLICY: Investigator Obligations (HRP-070)
 - 4.1.1.7. POLICY: Prompt Reporting Requirements (HRP-069)
 - 4.1.2. Notify IRB staff to update the list of individuals designated to review and approve exempt <Human Research> to include the name of the individual and the categories of exemption on which the individual has been trained.
- 4.2. To remove an individual's designation to review and approve exempt <Human Research>:
 - 4.2.1. Notify IRB staff to update the list of individuals designated to review and approve exempt <Human Research> to remove the name of the individual.
 - 4.2.2. Inform the individual that he or she may no longer review and approve exempt <Human Research>.

5. REFERENCES

- 5.1. 45 CFR §46.101(b)