SOP: Expiration of IRB Approval

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1. PURPOSE

1.1. This procedure establishes the process to monitor when IRB approval expires and studies enter Lapsed status.
1.2. This procedure begins each business day.
1.3. This procedure ends when reminders, notifications, and corrective actions are complete.

2. POLICY

2.1. Reminders and notifications required by this SOP are to be provided in writing and may also be provided orally.

3. RESPONSIBILITY

3.1. HRPP staff members carry out these procedures or ensure that they are carried out electronically.

4. PROCEDURE

4.1. Remind investigators whose study has a continuing review progress report due in 30 days.
4.2. Notify investigators whose study is no longer approved due to lack of continuing review.

4.2.1. Upon request of the investigator, consult with an IRB chair to determine whether already enrolled subjects should continue in the research because it is in their best interest.
4.2.2. Inform the investigator:

4.2.2.1. Which subjects may continue
4.2.2.2. What procedures may continue
4.2.2.3. All other research activities must stop, including advertisement, recruitment, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information
4.2.2.4. New subjects may not be enrolled
4.2.2.5. The continuing review progress report must be submitted as soon as possible

4.2.3. Process as a <Finding of Noncompliance> using “SOP: New Information (HRP-112).”

5. REFERENCES

5.1. 21 CFR §56.104(c)