Temple University

SOP: Suspension and Termination by the Organization

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1. PURPOSE

1.1. This procedure establishes the process to institute a <Suspension of IRB Approval> or <Termination of IRB Approval> outside of a convened IRB meeting.
1.2. This procedure begins when an authorized individual institutes a <Suspension of IRB Approval> or <Termination of IRB Approval>.
1.3. This procedure ends when the authorized individual has notified the HRPP staff.

2. POLICY

2.1. The officials authorized by "POLICY: Human Research Protection Program (HRP-010)" to institute a <Suspension of IRB Approval> or <Termination of IRB Approval> may take these actions when in their opinion the rights and welfare of subjects may be at risk before action can be taken through <Committee Review>.

3. RESPONSIBILITY

3.1. The individual who institutes a <Suspension of IRB Approval> or <Termination of IRB Approval> carries out these procedures.

4. PROCEDURE

4.1. Notify the investigator of the <Suspension of IRB Approval> or <Termination of IRB Approval> and the reasons for the action.
4.2. Ask the investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active intervention or long-term follow-up.)
4.3. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions:

4.3.1. Transfer subjects to another investigator
4.3.2. Make arrangements for clinical care outside the research
4.3.3. Allow continuation of some research activities under the supervision of an independent monitor
4.3.4. Require follow-up of subjects
4.3.5. Require adverse events or outcomes to be reported to the IRB
4.3.6. Notify current subjects
4.3.7. Other actions

4.4. Notify the HRPP staff member handling the protocol of the action to place on the agenda of a convened IRB meeting.

5. REFERENCES

5.1. 21 CFR §56.108, 21 CFR §56.113
5.2. 45 CFR §46.103 (Original Rule), 45 CFR §46.108 (Revised Rule), 45 CFR §46.113