1. PURPOSE

1.1. This procedure establishes the process to institute a Principal Investigator’s (PI) Voluntary Suspension.
1.2. This procedure begins when a PI institutes a Voluntary Suspension of an IRB Approved Research Study or submits a revision to resume research activities.
1.3. This procedure ends when the IRB has taken action on the revision.

2. POLICY

2.1. A PI may institute a Voluntary Suspension of an IRB approved Research study. Examples of circumstances under which a PI or PI Proxy might voluntarily suspend previously approved research includes when the PI goes on sabbatical, takes a leave of absence, or wishes to conduct an interim analysis.
2.2. A Voluntary Suspension must not be used in lieu of reporting to the IRB and regulatory agencies any deficiencies or concerns regarding the safety, rights, or welfare of human research participants, research investigators, research staff, or others.
2.3. Activities interrupted by Voluntary Suspension remain subject to continuing review and all organizational policies, such as policies on reporting problems.
2.4. A Voluntary Suspension cannot be used to extend IRB approval beyond the expiration date of a protocol without IRB approval of continuing review.
2.5. If there is an unanticipated problem or noncompliance event involving risks to participants or others, the study is not eligible for a Voluntary Suspension until such problem or event has been resolved by the IRB.
2.6. Voluntary Suspensions are not suspensions or terminations, and are not an IRB directive requiring notification to regulatory agencies, but the IRB needs to be notified of Voluntary Suspensions to ensure that the rights and welfare of subjects are protected.

3. RESPONSIBILITY

3.1. The Principal Investigator who institutes the Voluntary Suspension of an IRB Approved Research study and the IRB Chair or designee carries out these procedures.

4. PROCEDURE

4.1 Reporting Voluntary Suspension of Research activities

4.1.1 The Principal Investigator must notify the IRB in writing within five days of the action that he/she is initiating a Voluntary Suspension of the study.
4.1.2 The Voluntary Suspension notification is submitted as a revision and must include:
   4.1.2.1 a description of the research activities that will be put on hold.
   4.1.2.2 a justification for the Voluntary Suspension and any supporting documentation that include the proposed actions to protect and notify currently enrolled subjects.
4.1.4 The revision may receive expedited review, if applicable. If full board review is required, the IRB staff assigns the submission to the next IRB meeting agenda for review.
4.1.5 The IRB Chair or the convened IRB reviews the suspended activities and determines whether any additional procedures need to be followed to protect the rights, safety and welfare of currently enrolled subjects.
4.1.6 The IRB Chair or the convened IRB notifies the PI of any additional procedures that need to be followed to protect the rights, safety and welfare of currently enrolled subjects.
4.1.7. The IRB will notify the PI, in writing, of what activities, if any, are authorized to continue and conditions for such continuation.

4.2 Resumption of Research Activities After Voluntary Suspension
4.2.1 The PI should notify the IRB when the Voluntary Suspension is lifted by submitting a revision and provide an explanation of how issues leading to the Suspension have been resolved. Research activities can resume after the revision has been approved by the IRB.

5. REFERENCES