1. PURPOSE
   1.1. This policy describes the obligations of investigators conducting <Human Research> overseen by this [Organization].

2. POLICY
   2.1. Do not commence research until you have the IRB approval letter and obtained all other approvals required by the [Organization].
      2.1.1. If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study.
   2.2. Comply with all requirements and determinations of the IRB.
   2.3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
   2.4. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
   2.5. Personally conduct or supervise the research.
   2.6. Conduct the research in accordance with the relevant current protocol approved by the IRB.
   2.7. Protect the rights, safety, and welfare of subjects involved in the research.
   2.8. Submit proposed modifications to the IRB prior to their implementation.
      2.8.1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
   2.9. Submit continuing reviews when required by the IRB.
   2.10. Submit a continuing review to close research (end the IRB’s oversight) when all of the following are true:
      2.10.1. The protocol is permanently closed to enrollment
      2.10.2. All subjects have completed all protocol related interventions and interactions
      2.10.3. No additional identifiable private information about the subjects is being obtained
      2.10.4. Your analysis of private identifiable information is completed
   2.11. If research approval expires, stop all research activities and immediately contact the IRB.
   2.12. Promptly report to the IRB the information items listed in “POLICY: Prompt Reporting Requirements (HRP-071).”
   2.13. For studies regulated by a federal department or agency, follow any additional obligations, as applicable.
   2.14. Retain research records (including signed consent documents) for the greater of:
      2.14.1. Three years after completion of the research
      2.14.2. For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
      2.14.3. For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
2.14.4. The retention period required by the sponsor
2.14.5. The retention period required by law.

2.14.5.1. HIPAA requires signed authorizations to be retained for six years from
the date signed or the date when it last was in effect, whichever is
later.

2.14.6. The retention period required by a site that is not part of this [Organization].

3. REFERENCES

3.1. 21 CFR §56.103(a)
3.2. 21 CFR §56.108(a)
3.3. 21 CFR §50.20
3.4. 21 CFR §50.25
3.5. 21 CFR §50.27
3.6. 45 CFR §46.116
3.7. 45 CFR §46.117
3.8. FDA Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions –
     Statement of Investigator (Form FDA 1572)