1.0 Purpose:

1.1 The purpose of the policy is to ensure that principal investigators are aware of their responsibilities when performing research.

1.2 The principal investigator (PI) is responsible for personally conducting or supervising the conduct of human subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research. The PI must ensure that all human-subjects research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies, and requirements or determinations of the Human Research Protections Program (HRPP).

2.0 Definitions:

2.1 **IRB** – Institutional Review Board

3.0 Procedure:

3.1 Principal investigators are expected to:

3.1.1 Be qualified by education, training and experience to assume responsibility for the proper conduct of the research, should meet all the qualifications specified by any applicable regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation that may be requested by the sponsor, IRB and/or regulatory authority.

3.1.2 Complete all institutional training requirements.

3.1.3 Obtain IRB approval before involving human subjects in non-exempt research.

3.1.4 Follow all applicable laws and regulations, and adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, protection of the rights and welfare of research participants is a primary concern. Risks are minimized and potential benefits are maximized.

3.1.5 Promptly report unanticipated problems/adverse events, and serious or continuing noncompliance with the regulations or requirements of the IRB

3.1.6 Be aware of which research activities are overseen by the HRPP, and seek guidance when appropriate.

3.1.7 Report financial and other interests that might affect relationships with research participants or the outcome of the research. Identify and manage, minimize or eliminate such interests as appropriate.

3.1.7.1 Provide a current Financial Disclosure form for each project.

3.1.8 Employ sound study design in accordance with the standards of the discipline.

3.1.8.1 Submit all research proposals involving human participants, their tissue or data to the IRB for review. This should include the protocol, informed consent forms, subject recruitment procedures and any other information to be provided to study subjects.

3.1.8.2 Be thoroughly familiar with the appropriate use of any investigational product(s) as described in the protocol.

3.1.8.3 Comply with all conditions of IRB approval, institutional policy, and federal and state regulations and laws.

3.1.8.4 Be responsible for the scientific conduct of all approved projects, and oversight of the research staff involved.

3.1.8.5 Obtain and document informed consent prior to the initiation of any study-related procedures using the current IRB-approved form.

3.1.8.6 Changes to approved protocol and/or the research consent form are submitted to the IRB, and are not initiated without IRB approval.

Note: A deviation or a change in the protocol may be implemented to eliminate immediate hazards to trial subjects without prior IRB approval as long as the implemented change and the reasons for it are submitted to the IRB as soon as possible for approval.

3.1.8.7 Adequate and accurate research records are kept and retained as required by the IRB and, when applicable, by the sponsor or regulatory authority.

3.1.8.8 Progress reports and requests for continuing review are submitted prior to expiration of approval in accordance with the IRB.

3.1.8.9 If approval lapses, research procedures, such as recruitment and enrollment of subjects, study procedures on currently enrolled subjects, review of health/medical records, collection of tissue or other samples, or analysis of data, are not conducted until the IRB re-approves the research.

3.1.8.10 When the research has been completed or is being closed out prior to completion, a final continuing review report is submitted to the IRB.

3.1.9 The PI is responsible for personally conducting or supervising the study. However, PIs are allowed to delegate certain study-related tasks to co-investigators and study staff. When tasks are delegated, the PI is

responsible for providing adequate supervision of those to whom tasks are delegated and is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the study.

3.1.9.1 When delegating study-related tasks to co-investigators and study staff, the PI must ensure that:

- Study personnel are qualified by training and experience to perform study-related tasks that have been delegated to them, and have the appropriate licensing/credentialing.
- Study personnel have the relevant formal medical training and, licensing and/or certification when tasks are delegated that are clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing study-related medical care to subjects,.
- Study personnel are aware of regulatory requirements and acceptable standards for the conduct of human-subjects research, both with respect to conduct of the study and human subject protection.
- Study personnel are informed of any pertinent changes to the protocol during the conduct of the study and are educated or given additional training as appropriate.
- If the sponsor provides training materials for investigators in the conduct of the study, the research staff receives and reviews these materials and/or participates as necessary in any in person training sessions pertinent to their role in the study.
- Additions or deletions of study personnel on a protocol, such as investigators or research staff, must be conveyed in writing to the HRPP as soon as possible.

Note: It is recommended that investigators maintain a list of the study personnel to whom significant study-related tasks have been delegated. This list should describe the delegated tasks, identify the training that individuals have received that qualifies them to perform the delegated tasks, and identify the dates of involvement in the study.

3.1.10 Determine that the resources necessary to protect study subjects are present before conducting each research study. These resources might include research personnel, space, equipment, time, and availability of medical or psychological care for problems that arise during participation in the research.

3.1.10.1 Study personnel have an adequate understanding of the research, and their related duties and functions.

3.1.10.2 Study personnel follow the IRB-approved protocol, and adhere closely to the research plan, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of subjects and confidentiality of identifiable data, in order to minimize risks to subjects, including the recruitment and consent procedures described in the protocol summary.

3.1.10.3 The investigator or other identified, qualified individual provides study subjects with reasonable medical care for any adverse events, including clinically significant laboratory values, related to the research. Additionally, when participation in the research might impact the subject's health and/or medical care, the PI should inform the subject's primary care physician about the subject's participation in the research if the subject has a primary care physician and if the subject agrees to the primary care physician being informed.

3.1.10.4 The PI has provisions in place for referral of subjects for any needed healthcare, both during a study and for follow-up after study completion.

3.1.10.5 Unanticipated problems involving risks to subjects or others (including adverse events) are reported immediately to the sponsor, regulatory authority, and the IRB.

3.1.11 Recruit participants in a fair and equitable manner, weighing the potential benefits of the research against their vulnerability and the risks to the participants.

3.1.11.1 When research is not federally funded or supported, apply for a *Certificate of Confidentiality* when collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial status, employability, insurability or reputation

3.1.12 Employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of participant comprehension and voluntary participation.

3.1.13 Have a process in place to address participants' concerns, complaints, or requests for information.

3.1.14 Manage and control drugs, biological products, and devices being investigated or used, as required by institutional policy and, when applicable, FDA regulations 21 CFR 312 and 21 CFR 812;

3.1.15 When conducting clinical trials subject to ICH-GCP(E6) guidelines::

3.1.15.1 Where allowed or required, the investigator may assign some or all duties for investigational articles accountability at the trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator.

3.1.15.2 The investigator, pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused products. These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

3.1.15.3 Investigators should maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.

3.1.15.4 The researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.

3.1.15.5 The researcher informs the participant’s primary physician about the subject’s participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

3.1.15.6 Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the subject’s rights.

3.1.15.7 The researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.

3.1.15.8 The researcher is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

3.1.15.9 The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

3.1.16 Permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority.

3.1.17 Register all applicable clinical trials on the ClinicalTrials.gov website.

3.1.18 Be responsible for accuracy of proposal information provided in grant applications.

3.1.19 Comply with specific terms of each grant award, i.e. restrictions on foreign travel, equipment purchases, and principal investigator salary support.

3.1.20 Be responsible for the proper allocation of funds, such as, salary support, supplies, and travel.

3.1.21 Be responsible for accuracy of cost transfers.

3.1.22 Monitor budget accounts for accuracy.

4.0 Documentation: Not applicable

5.0 References:

5.1 45 CFR 46.102(l), 45 CFR 46.102 (e)

5.2 OHRP Investigator Responsibility Frequently Asked Questions: http://answers.hhs.gov/ohrp/categories/1567

5.3 21 CFR 50.3(a), 21 CFR 50.3(c), 21 CFR 50.3(g), 21 CFR 50.3(j), 21 CFR 56.102(c), 21 CFR 56.102(l), 21 CFR 312.53(c) (1), 21 CFR 312.60, 21 CFR 312.61, 21 CFR 312.62, 21 CFR 812.43(c) (4), 21 CFR 812.100, 21 CFR 812.140

5.4 Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c))

5.5 Guidance for Industry: *Protecting the Rights, Safety and Welfare of Study Subjects – Supervisory Responsibilities of Investigators*. October 2009.

5.6 Guidance for Industry: *E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)* March 2018

5.7 ICH GCP: 2.7, 2.8, 4.1.1 – 4.1.5, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.4.1 – 4.4.3, 4.5.1 – 4.5.4, 4.6.1 – 4.6.6, 4.7, 4.9.1-4.9.5

5.8 Institutional Review Board Management and Function, Bankert, E. A., Amdur, R. J., 2nd Edition, 2006

5.9 Association for the Accreditation of Human Research Protection Programs, *Accreditation Standards*

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	EHP	6/2/2011	Conversion to new policy template; expansion of policy
02	CLB	7/22/15	Addition of responsibilities for the conduct of clinical trials as required by ICH-GCP (E6)
03	CLB	3/15/20	General review. Updated regulatory references.

I.1.D., III.2.A.