1.0 Purpose:

1.1 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. He/She 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. However, PIs are allowed to delegate certain study-related tasks (not responsibilities) 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**.

1.2 The purpose of the policy is to ensure that research staff that has been delegated study-related tasks is aware of their responsibilities.

2.0 Definitions:

2.1 **HRPP** – Human Research Protections Program

2.2 **IRB** – Institutional Review Board

3.0 Procedure:

3.1 Research staff are expected to:

3.1.1 Be qualified by training and experience to perform study-related tasks that have been delegated to them, and have the appropriate licensing/credentialing.

3.1.2 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.

3.1.3 Be 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.

3.1.4 Complete all institutional training requirements.

3.1.5 Have an adequate understanding of the research, and related duties and functions.

3.1.6 Report financial and other interests that might affect relationships with research participants or the outcome of the research. Complete a Financial Disclosure form for any project in which there may be a conflict. If not sure, contact the HRPP for guidance.

3.1.7 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.

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

3.1.9 Employ sound study design if writing protocols is a study-related responsibility. In doing so, ensure that protection of the rights and welfare of research participants is a primary concern, as well as minimizing risks and maximizing potential benefits. Refer to the Study Design policy for more specific information.

3.1.10 Follow all applicable laws and regulations, and adhere to ethical principles and standards

3.1.11 Be aware of any pertinent changes to the protocol during the conduct of the study and receive education and/or training as appropriate.

3.1.12 Receive and review sponsor-provided training materials specific to the conduct of the study, and pertinent to their role in the study.

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

3.1.14 Ensure that adequate and accurate research records are kept and retained as required by the IRB and, when applicable, by the sponsor or regulatory authority.

4.0 Documentation: Not applicable

5.0 References:

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

5.2 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

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

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

5.5 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

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

5.7 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	3/5/2020	General review. Updated regulatory references.

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