1.0 Purpose:

1.1 The purpose of this policy is to describe the obligations of the Hartford HealthCare Institutional Review Board (HHC IRB) and investigators in identifying, analyzing, and minimizing risks in proposed research to ensure that they are reasonable in relation to the potential benefits to participants and society.

2.0 Definitions:

2.1 **Minimal Risk -** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.0 Procedure:

3.1 The objective of the IRB in conducting a risk/benefit analysis is to judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks.

3.1.1 This analysis should consist of the following steps:

3.1.1.1 1. Identify the risks associated with the research, and distinguish them from the risks of procedures/treatments the subjects would receive even if not participating in the research;

3.1.1.2 2. Determine whether the risks will be minimized to the extent possible;

3.1.1.3 3. Identify the possible benefits to be derived from the research

3.1.1.4 4. Determine whether the risks are reasonable in relation to the benefits to subjects, if any, and assess the importance of the knowledge to be gained;

3.1.1.5 5. Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits via the informed consent document and process.

3.1.2 The IRB must determine that risks are minimized by using procedures that are consistent with sound research design and do not expose participants to unnecessary risk.

3.1.2.1 The research design and methodology are reviewed to determine that no obvious flaws would place participants at unnecessary risk. Experts are consulted when aspects of research design seem to pose a significant concern.

3.1.3 The IRB must ensure that, whenever appropriate, the investigator minimizes risks by using procedures already being performed on the subjects for diagnostic or treatment purposes.

3.1.3.1 In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research - as distinguished from risks and benefits of procedures/treatment subjects would receive even if not participating in the research.

3.1.4 The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3.1.5 The IRB will evaluate each research proposal to ensure that the investigator has the resources necessary to protect research participants. Such resources include staffing and personnel, in terms of availability, number, expertise, and experience; psychological, social, or medical services, including counseling or social support services that may be required because of research participation; psychological, social, or medical monitoring, ancillary care, access to the study population to allow recruitment of the necessary number of participants; adequate facilities; and equipment needed to protect participants.

3.1.6 Special consideration is given by the IRB to protect vulnerable participants.

3.1.7 The level of risk is considered during requests for waiver or alteration of informed consent requirements or waiver of the requirement to obtain written documentation of consent. A waiver is not usually appropriate for FDA regulated test articles.

3.2 In order for the IRB to make the assessment and determinations described above, the investigator must provide adequate information via the Research Application or protocol.

3.2.1 An accurate description of the risks must be clearly outlined in the Research Application or protocol with a corresponding explanation in the informed consent form for the participants.

3.2.2 The investigator should identify the potential harms associated with the research as physical, social, economic, psychological, and/or legal.

3.2.3 The investigator should present scientific evidence in the Research Application or protocol to support the expectation that anticipated benefits are greater than anticipated risks.

3.2.4 Every possible precaution to minimize risks must be pursued by the investigator and outlined in the informed consent form as appropriate.

3.2.4.1 The possibility of unknown risks must be clearly stated, when applicable.

4.0 Documentation:

4.1 Determinations (IRB Reviewer Checklists and minutes) and any discussions related to risk/benefit analysis of a research protocol will be retained for a minimum of 6 years after completion of a study at Hartford HealthCare.

5.0 References:

5.1 45 CFR 46.111(a)(1), 45 CFR 46.111(a)(2), 45 CFR 46.111(a)(6)

5.2 21 CFR 56.111(a)(1), 21 CFR 56.111(a)(2), 21 CFR 56.111(a)(6)

5.3 ICH-GCP: 2.2, 2.3, 3.13, 4.2.1, 4.2.2., 4.2.3, 4.2.4.

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

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	CLB	7/1/11	New Issue
01	CLB	3/15/20	General review

Elements II.3.A., III.1.C., and III.1.D.