1.0 Purpose:

1.1 The purpose of this policy is to ensure that the Human Research Protections Program (HRPP) has resources sufficient to protect the rights and welfare of research participant for research activities that Hartford HealthCare (HHC) conducts and oversees.

1.2 This policy describes the roles and responsibilities of the various officials, administrative units, and individuals charged with the protections of the rights and welfare of participants in research at HHC.

2.0 Definitions:

2.1 HHC – Hartford HealthCare
2.2 HRPP – Human Research Protection Program
2.3 IRB – Institutional Review Board

3.0 Procedure:

3.1 **HRPP Organization** - The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. It consists of various individuals and committees such as: the Institutional Official, Director of the HRPP, the IRB, IRB staff, other committees or entities addressing human subjects protection (e.g., , Scientific Review Committee, Research Compliance Officer, etc.), investigators, and research staff. The objective of this system is to assist the institution in fostering an ethical culture in the research enterprise, and ensuring that the institution meets ethical principles and regulatory requirements for the protection of human subjects in research.

The following officials, administrative units and individuals have primary responsibilities for implementing the HRPP.

3.1.1 **Institutional Official**

3.1.1.1 The ultimate responsibility of the HRPP resides with the Institutional Official (IO). The Vice President for Research or the Director of Research may serve as the IO. In the absence of a Vice President, the Director of Research shall serve as the IO. The IO is responsible for ensuring the HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects research.

3.1.1.2 The IO also holds ultimate responsibility for oversight of the Institutional Review Board (IRB) and all HHC investigators; for assuring the IRB members and investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations; and for the development and implementation of an educational plan for IRB members, staff and investigators. The responsibility for the HRPP is delegated by the IO to the Director of the HRPP.

3.1.1.3 The IO may not, however, serve as a member of the IRB nor be directly involve in the day-to-day operations of the IRB review process.

3.1.2 **Director of the HRPP**

3.1.2.1 The Director of the HRPP (Director) has extensive knowledge and experience in the area of human subjects protection, and reports to the IO. He or she will have regulatory or legal expertise interpreting laws and regulations involving human subjects research, and advises the IRB, IO, and others as needed in ascertaining the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice.

3.1.2.2 The Director is responsible for:

3.1.2.2.1 Implementing the system's HRPP policy, including developing, managing and evaluating policies and procedures that ensure compliance with all state and federal regulations governing human subjects research, and overseeing all aspects of the HRPP program;

3.1.2.2.2 Providing system-wide guidance and recommendations regarding the evolving ethical and legal standards relating to human subjects research, as well as evolving trends.

3.1.2.2.3 Advising the Institutional Official and IRB Chairs on key matters regarding research with human subjects at HHC, and providing consultation and support as needed;

3.1.2.2.4 Acting as HRPP liaison to the IRB, serving as a voting member of the IRB, to assist with resolution of questions or problems that may arise;

3.1.2.2.5 In conjunction with the IRB Chair(s), conduct and/or oversee the conduct of data and safety monitoring and adverse event reporting, and notify the IRB as needed as issues arise;

3.1.2.2.6 Overseeing activities relating to observation of informed consent processes, as appropriate;

3.1.2.2.7 Reviewing and approving new policies and procedures developed at HHC (including revisions to existing policies and procedures) that have the potential to affect human subjects research;

3.1.2.2.8 Conducting review of requests for determinations of whether an activity qualifies as research, research not involving human subjects, and research exempt

from IRB oversight. The Director will have the institutional authority to make these determinations.

3.1.2.2.9 Managing and providing oversight for the HRPP and IRB staff, including training;

3.1.2.2.10 Providing oversight and guidance for the operations of the IRB Office;

3.1.2.2.11 Managing the day-to-day finances and budget of the HHC HRPP and IRB, including annually assessing and reporting to the IO the financial needs of the HHC HRPP;

3.1.2.2.12 Developing educational standards in human subjects protection as appropriate for investigators, IRB members, and research staff, and ensuring that training is completed on a timely basis; as well as providing educational opportunities throughout the institution on specific topics related to human subjects protection;

3.1.2.2.13 Working closely with the IRB Chair(s) as needed to assist with implementation of any corrective action plans deemed necessary in response to findings from routine compliance monitoring/auditing or other issues that may arise;

3.1.2.2.14 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program;

3.1.2.2.15 Serve as a resource to investigators in their efforts to carry out HHC's research mission;

3.1.2.2.16 In conjunction with the IO, ensuring that requirements regarding reporting to federal agencies are satisfied, and serving as a primary contact at HHC for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (DHHS) and other federal regulatory agencies, including drafting correspondence in response to government queries;

3.1.2.2.17 Submitting, implementing, and maintaining an approved FWA through the IO and OHRP;

3.1.2.2.18 Providing regulatory expertise in the review of sponsored contracts involving human subjects in research for compliance with HHC HRPP policies, in conjunction with the Grants & Contracts Office staff;

3.1.2.2.19 Serving as the HRPP/IRB representative on the Conflict of Interest Subcommittee, to act as liaison

and facilitate communication between the subcommittee, HRPP, and IRB;

3.1.2.2.20 Foster communication among the IRB, Grants & Contracts Office, and other HHC Research Institute offices or committees as appropriate to enhance a cohesive approach to research involving human subjects;

3.1.2.2.21 Overseeing process for obtaining and maintaining accreditation of the HRPP through the Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP")

3.1.2.2.22 Overseeing Quality Assurance/Quality Improvement activities for the IRB and HRPP.

3.1.3 **Institutional Review Board (IRB)**

3.1.3.1 HHC has two (2) IRB panels, appointed by the Institutional Official. The IRB prospectively reviews and makes decisions concerning all non-exempt human research conducted at its facilities or by its employees or agents, or under its auspices. The IRB is responsible for the protection of rights and welfare of human research subjects at HHC. It discharges this duty by complying with the requirements of the Common Rule; state regulations, the FWA; and institutional policies.

3.1.4 **Principal Investigators**

3.1.4.1 The investigator is the ultimate protector of the human subjects who participate in research. The investigator is expected to abide by the highest ethical standards and for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. All subjects must give informed consent (unless specifically waived by the IRB) and the investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility.

3.1.4.2 In addition to complying with all the policies and standards of the governing regulatory bodies, the investigator must comply with institutional and administrative requirements for conducting research.

3.1.4.3 The investigator is responsible for ensuring that all research staff completes appropriate training and must obtain all required approvals prior to initiating research.

3.1.4.4 The investigator is also responsible for ensuring that each research protocol maintains ongoing IRB approval while any research activities occur.

3.1.4.5 When investigational drugs or devices are used, the investigator is responsible for providing written procedures for their storage, security, dispensing and disposal.

3.1.4.6 *Additional responsibilities are detailed in HRPP Policy # 200 – "Principal Investigator Responsibilities"*

3.1.5 **Division/Department Heads**

3.1.5.1 Division/Department heads are required to be notified by way of copy on all Research Applications submitted to the IRB for review. They are obligated to make research administrative staff aware of any concerns they may have with the proposal.

3.1.5.2 Medical Division heads, Surgery Department heads, or qualified delegates are responsible for ensuring that the Principal Investigator (PI) is qualified by training and experience to conduct the proposed research.

3.1.5.3 Division heads are responsible for assuring that investigators have the resources required and sufficient to conduct the research in a way that will protect the rights and welfare of participants. Such resources include but are not necessarily limited to personnel, space, equipment, and time.

3.1.6 **Research Compliance Officer**

3.1.6.1 The Research Compliance Officer (RCO) conducts routine compliance monitoring of human research, as well as for-cause audits directed by the IRB or other circumstances. The RCO provides summary reports to the IRB and reports findings, determinations, and corrective action plans to the IO and Chief Corporate Compliance Officer.

3.1.6.2 The RCO performs initial review of Financial Disclosure Forms submitted by Investigators. The RCO has the authority to approve forms indicating no real or perceived conflict or refer those that may present real or perceived conflict to the Conflict of Interest Subcommittee for further review and management.

3.1.6.3 The RCO reports violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules to the Privacy Officer.

3.1.6.4 The RCO serves as the Research Integrity Officer (RIO) at HHC (in accordance with the HHC Policy and Procedures for Responding to Research Misconduct Allegations).

3.1.7 **General Counsel's Office**

3.1.7.1 The HRPP relies on the General Counsel as needed for the interpretations and applications of Connecticut law and the laws of any other jurisdiction where research is conducted as they apply to human subjects research. Legal opinion may be sought

from the General Counsel as issues arise in the context of a particular research proposal.

3.1.8 **Other Related Units**

3.1.8.1 **Scientific Review Committee**

3.1.8.1.1 The Scientific Review Committee (SRC) reviews proposed research for issues of study design and scientific merit. All proposals must be reviewed by the SRC prior to IRB review. The SRC assists investigators in identifying issues regarding study methodology including data collection and management, and may recommend changes as appropriate. The SRC assists the IRB in its evaluation of research protocols, and the signature of the SRC indicates that the study is found to be scientifically sound and can reasonably be expected to answer the proposed question. Final determinations are conveyed to the IRB. The IRB will consider the determination of the SRC but will ultimately determine whether the regulatory criteria for approval of research are met.

3.1.8.1.2 The SRC is the responsible body for receiving research misconduct allegations and/or evidence, coordinating and conducting the inquiry and, if applicable, conducting the investigation and preparing the necessary reports.

3.1.8.2 **Grants & Contracts Office**

3.1.8.2.1 The Manager (or designee) of the Grants & Contracts Office will review all research agreements with federal, foundation, or non-profit sponsors. This institutional review ensures that all terms of award are in compliance with institutional policies. Only the Vice President for Research or the Vice President for Academic Affairs will have the authority to endorse research proposals and execute research agreements on behalf of the institution.

3.1.8.2.2 When the grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of HHC, a subcontract is executed between HHC and the collaborating institution. The subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval. The collaborating institution must also ensure that key personnel involved in human subjects research are in

compliance with the NIH policy on education in the protection of human research subjects and provide documentation of education of key personnel to HHC.

3.1.8.3 **Pharmacy**

3.1.8.3.1 A HHC pharmacist serves on each IRB panel, allowing the Pharmacy to have knowledge about all IRB approved research that takes place at HHC and under its jurisdiction. The Pharmacist member collaborates with the Research Pharmacy Technician to assure that information about studies involving drugs used in research is shared with both the Pharmacy Staff as appropriate and that, when deemed appropriate by the pharmacist IRB member (e.g., reasons of safety/cost/therapeutic efficiency), the Pharmacy and Therapeutics Committee is made aware of IRB approved research involving drugs.

3.1.8.3.2 The Research Pharmacy Technician is typically responsible for engaging in the ordering/providing, dispensing, or compounding of drugs used in research conducted through the Clinical Research Center. If the drug is a controlled substance, it is ordered/received by the Pharmacy and re-issued in appropriate quantities to researchers pursuant to a study-specific and patient-specific medication order developed by the Pharmacy in collaboration with the Researcher. The manufacture/compounding of drug products not commercially available is coordinated by the HHC Pharmacy with outside vendors. However, insofar as inpatient drug studies and/or those outpatient drug studies that have subjects who become inpatients at HHC, the Pharmacy coordinates the use of the study drug while the subject is an inpatient, and all such inpatient study drugs must be provided through the Pharmacy.

3.1.8.3.3 The Pharmacy is available to provide guidance to investigators in relation to the management of the study drugs.

3.1.9 **Relationship Between Components**

3.1.9.1 The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects regulations.

3.1.9.2 Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve research if it has been disapproved by the IRB.

3.1.9.3 **HHC Research Institute Executive Board**

3.1.9.3.1 The Executive Board is chaired by the Senior Vice President & Chief Medical Officer of Hartford HealthCare and Hartford Hospital. Membership composition is determined by the HHC System CEO. Members include Senior Leadership of the system, the Institute Director (Vice President for Research/IO), and key researchers within the system.

3.1.9.3.2 Responsibilities of the Board include developing strategic direction, setting institutional priorities, making policy decisions, research resource consolidation and allocation at the System level, penetration of research culture at System level, and educating executive leadership on appropriate metrics to measure research success.

3.1.9.3.3 The Board meets quarterly with ad-hoc meetings scheduled as needed. The IO provides updates on operations and issues as they relate to the HRPP.

3.1.9.4 **Research Institute Manager's Meeting Group**

3.1.9.4.1 The Institutional Official (IO) chairs the Research Institute Manager's Meeting Group, which meets monthly to ensure a dialogue is maintained between the leadership of various entities engaged with and responsible for research at HHC. Membership includes but is not limited to: HRPP Director, Manager of the Grants & Contracts Office, Senior Scientist members of the Departmental Scientific Review Group, Director of the Clinical Research Center, Director of Pre-Clinical Research, Director or Research Data Management, Nurse Coordinator of the Cancer Clinical Research Office, and others as determined by the IO.

3.1.9.4.2 The Manager's Meeting Group will provide a regular forum for informal discussion and communication among the various stakeholders regarding current issues in the research environment.

3.2 HRPP Operations

3.2.1 HRPP Office

3.2.1.1 The HRPP Director has primary responsibility for the day-to-day management of the HRPP Office, and has expert knowledge in

regulatory issues regarding human subjects protection. The HRPP Director reports directly to the Institutional Official. The Director also serves as the Human Protections Administrator and is the primary contact at HHC for the Office for Human Research Protections (OHRP).

3.2.1.2 The Director of the HRPP has oversight of the operations of the IRB. This includes responding to investigator, student, and research staff questions about human subjects research as well as oversight of organizing and documenting the review process. The Director works closely with the IRB Chair in the development of policy and procedures and he or she is a voting member of the IRB.

3.2.1.3 Additionally, the office is staffed by four (6) FTE IRB Administrators. The duties and responsibilities for all staff are described briefly below; more complete information is included in their respective job descriptions.

3.2.2 **IRB Administrator(s)**

3.2.2.1 The IRB Administrators are responsible for all aspects of the IRB throughout the review process of a research proposal involving human subjects. This responsibility includes the initial review of documents and screening of research proposals and informed consent forms prior to review by the IRB, as well as serving as the liaison between the investigators and the IRB.

3.2.2.2 The IRB Administrator is responsible for overseeing IRB record retention, and maintaining complete IRB files, records of all research protocols, and IRB correspondence (including e-mails).

3.2.2.3 The IRB Administrator drafts minutes and correspondence to PIs documenting IRB decisions and is responsible for the accuracy of the minutes and for ensuring proper documentation of discussions including controverted discussions and actions taken by IRB during convened meetings.

3.2.3 **HRPP Business Systems Analyst**

3.2.3.1 The Business Systems Analyst is responsible for providing program management for the installation, maintenance, and ongoing support of the web-based forms submission system (iRIS) and the internal Research Institute Database (Customized Microsoft Access Database). The Business Systems Analyst also works closely with the HRPP Director and other HRPP staff as needed to support gathering and analysis of data to assist with HRPP/IRB quality assurance and quality improvement activities.

3.2.4 **Selection, Supervision, and Evaluation of HRPP Supporting Staff**

3.2.4.1 Selection Process

3.2.4.1.1 HRPP and IRB staff are selected in accordance with applicable HHC Human Resources job descriptions and policies and procedures.

3.2.4.2 Supervision

3.2.4.2.1 The HRPP Director is responsible for the day-to-day management and supervision of the HRPP and IRB Office staff, in accordance with applicable HHC Human Resources and institutional policies and procedures.

3.2.4.3 Evaluation

3.2.4.3.1 All staff are evaluated annually in accordance with applicable HHC Human Resource performance management policies and procedures. The HRPP Director is responsible for conducting evaluations of the IRB Administrators and IRB Coordinator.

3.2.4.3.2 The IO is responsible for conducting evaluations of the HRPP Director.

3.2.4.3.3 The Director of Research Data Management conducts the yearly performance evaluation of the Business Systems Analyst. The HRPP Director provides input.

3.3 **HRPP Resources**

3.3.1 The IRB/HRPP Offices are located in the Education and Resource Center (ERC) at 560 Hudson Street (2nd floor, East Wing). The mailing address for the IRB/HRPP Offices is 80 Seymour Street, P.O. Box 5037, Hartford, CT, 06102. They are equipped with all necessary office space, storage space, and equipment to perform the functions required for the IRB and HRPP.

3.3.2 Meeting space for monthly IRB meetings is provided at the main hospital location at 80 Seymour Street, Hartford. Complete protocol files will be accessible to IRB members prior to and during meetings.

3.3.3 The Institutional Official provides resources to the IRB and HRPP Offices, including adequate staffing to efficiently conduct IRB and HRPP functions, and adequate meeting and office space. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and HRPP staff. The adequacy of personnel and non-personnel resources of the HRPP program is assessed on an annual basis by the HRPP Director and is reviewed and approved by the IO, in conjunction with the annual budget review process.

3.3.4 In addition, the HRPP Director will prepare an annual report of the volumes and types of research conducted over the last period to assess whether the number and composition of IRBs is appropriate or if adjustments are warranted. This report will also include a detail of

current staffing for the program. This report and any recommendations will be reviewed with the IO and IRB Chair and also presented to the IRB members during the "Continuing Education" time period of the next scheduled fully convened IRB meeting.

4.0 Documentation: Not Applicable

5.0 References:

5.1 45 CFR 46.103(b)(2), 45 CFR 46.103(b)(4), 45 CFR 46.103(b)(5), 45 CFR 46.103(d), 45 CFR 46.114 Subpart A – *Basic HHS Policy for Protection of Human Research Subjects*

5.2 21 CFR 56.108(a), 21 CFR 56.108(b),

5.3 ICH-GCP: 2.1, 2.3, 2.6, 2.13, 3.3.1, 3.3.6, 4.2.3.

5.4 Terms of Assurances for FWA: http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	CLB	7/1/11	Conversion to new policy template; elaboration of responsibilities based on comprehensive review of regulatory guidelines; added other related review units; addition of HRPP operations.
02	CLB	1/28/13	Section 3.3.4 was added to establish an assessment of resource allocation.
03	CLB	3/1/15	Removed section 3.1.8.1.2 (FCOI management is no longer a subcommittee of the SRC committee); Deleted section 3.2.3 – the position of IRB Coordinator has been eliminated; Number of IRB Administrators has been updated from 4 to 6; Updated the Role of Business Systems Analyst
04	CLB	7/1/16	Updated section 3.1.1.1. to reflect that the role of Director of Research may also serve as the IO.

Element I.1.D. and I-2