1.0 Purpose:

1.1 Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, this policy defines the procedures to be followed by the Institutional Review Board (IRB) and investigators in carrying out their responsibilities to provide additional safeguards for the protection of prisoners participating in biomedical or behavioral research.

1.1.1 **These concerns apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research**. In the latter situation, it is unlikely that review of the research and the consent document contemplated the constraints imposed by incarceration.

1.2 This policy applies to all biomedical and behavioral research conducted under the auspices of Hartford HealthCare (HHC) involving prisoners as subjects regardless of funding source. The requirements in this policy are consistent with Subpart C of 45 CFR 46, which applies only to DHHS- conducted or supported research.

1.2.1 Even though the IRB may approve a research protocol involving prisoners as subjects according to this policy, investigators are still subject to the Administrative Regulations of the Connecticut Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

2.0 Definitions:

2.1 **DHHS** – Department of Health and Human Services

2.2 **OHRP** – Office of Human Research Protections

2.3 **Prisoner –** as defined by DHHS regulations at 45 CFR part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

2.3.1 Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

2.3.2 Common examples of the application of the regulatory definition of prisoner are as follows:

2.3.2.1 Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or

alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

2.3.2.2 Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

2.3.2.3 Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

2.3.2.4 Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

2.4 **Minimal Risk Prisoner Research -** the probability and magnitude of **physical** or **psychological** harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of **healthy persons** (45 CFR 46.303(d)).

3.0 Procedure:

3.1 **Special Composition of IRB -** In addition to satisfying the requirements of 45 CFR 46.116 and 46.117, when the IRB reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following requirements of DHHS regulations at 45 CFR 46.304(a) and (b):

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

3.1.1 In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB should choose a prisoner representative who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.

3.1.2 For research involving prisoners as subjects, the IRB must meet the special composition requirements of 45 CFR 46.304 <u>for all types of</u>

review of the protocol, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects.

3.1.3 If a protocol involving prisoners as subjects is to be reviewed by more than one IRB, only one IRB must satisfy the requirement that at least one member of the IRB be a prisoner or a prisoner representative.

3.1.4 IRBs will be alert to the impact of roster changes on quorum requirements under HHS regulations at 45 CFR 46.108(b).

3.1.4.1 The HRPP office will maintain the Curriculum Vitae of the prisoner representative serving on the IRB

3.2 **IRB Findings for Approval** - When the IRB is reviewing a DHHS-funded protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, Subpart A, seven (7) additional findings under 45 CFR 46.305(a), as follows:

3.2.1 The research under review must represents one of the 5 categories of research permissible under 45 CFR 46.306(a)(2):

3.2.1.1 study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3.2.1.2 study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3.2.1.3 research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register of his intent to approve such research;

3.2.1.4 research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.

3.2.1.5 research conducted under a Secretarial waiver that involves epidemiologic studies meeting the following criteria:

3.2.1.5.1 Research in which the sole purposes are (i) To describe the prevalence or incidence of a disease by identifying all cases, or (ii) To study potential risk factor associations for a disease, and

3.2.1.5.2 Where the institution responsible for the conduct of the research certifies to OHRP, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that (i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and (ii) Prisoners are not a particular focus of the research.

3.2.2 any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

3.2.3 the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

3.2.4 procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

3.2.5 the information is presented in language which is understandable to the subject population;

3.2.6 adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

3.2.7 where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Note: In order to both conclude that the above 7 conditions are met and satisfy the requirements of 45 CFR 46 Subpart A, the IRB must be familiar with the specific conditions in the local prison or jail site(s) where

the research will be conducted before approving the research for implementation at the site(s).

3.3 None of the exemption categories in DHHS regulations for research involving human subjects at 45 CFR 46.104apply to research involving prisoners (45 CFR 46.104(b)(2).except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3.4 Informed consent can be waived or altered in research involving prisoners. As long as the appropriately constituted IRB reviews the research and makes the appropriate findings regarding the waiver or alteration of informed consent requirements, research involving prisoners may be approved with a waiver or alteration of informed consent. However, even if informed consent is waived or altered, subpart C of 45 CFR part 46 still requires that the subjects be clearly informed in advance that participation in the research will have no effect on their parole, if such notification is relevant (45 CFR 46.305(a)(6)).

3.5 Prisoners cannot be involved in planned emergency research (OHRP [OPRR] Report 97-01) where the requirement for informed consent has been waived by the Secretary of DHHS under the authority of 45 CFR 46.101(i).

3.6 In the case of an adolescent detained in a juvenile detention facility, the provisions of Subpart C apply, and if the adolescent is a child, the provisions of Subpart D apply. An adolescent would be considered to be a child if he/she were less than 18 years old, were not married and had not been declared by a court order to be emancipated

3.7 **Certification of IRB Findings** – When Hartford HealthCare intends to conduct DHHS-supported research involving prisoners as subjects, the Institutional Official (IO) must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2).

3.7.1 **The certification letter sent to OHRP will include**:

- 3.7.1.1 the name and address of the institution
- 3.7.1.2 specific identification of the research protocol, including the relevant grant number
- 3.7.1.3 A statement that the IRB has made the 7 findings required under 45 CFR 46.305(a)
- 3.7.1.4 OHRP Federalwide Assurance (FWA) number
- 3.7.1.5 Registration Number for the designated IRB that conducted and issued the approval
- 3.7.1.6 Date(s) of IRB Meeting(s) in which protocol was considered, including a brief chronology that encompasses: (a) Date of initial IRB review (b) Date of Subpart C review

3.7.2 In addition to the certification letter, OHRP requires the institution, to submit a copy of the research proposal so OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2). The term “research proposal” includes:

3.7.2.1 the HHC IRB-approved protocol; any relevant DHHS grant application or proposal(s) or excerpts from the proposal including the Notice of Grant Award and background and methods sections, and the name of the Agency program officer who administers the grant;
3.7.2.2 any IRB application forms required by the HHC IRB; and
3.7.2.3 any other information requested or required by the HHC IRB that is considered during its initial review.

3.7.3 The Secretary (through OHRP) must determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so which one. Following its review of the certification letter, OHRP will issue a letter authorizing the involvement of prisoners in the proposed research, if OHRP determines that the research involves one of the permissible categories.

3.7.4 If a study involving prisoners previously authorized by OHRP is amended, HHC does not have to recertify with DHHS. However, if there is a fundamental change in the research that alters the applicability of the approved category under 45 CFR 46.306, OHRP will be notified.

3.7.5 Note that research proposals that are not conducted or supported by DHHS do not require a Secretarial consultation, nor do they require certification to OHRP

3.8 **What to do When a Research Subject <u>Becomes</u> a Prisoner**

3.8.1 If a human subject involved in ongoing research becomes a prisoner during the course of the study, and the research proposal was not reviewed and approved by the IRB in accordance with Subpart C of 45 CFR part 46, the investigator must <u>promptly</u> notify the IRB in writing.

3.8.2 All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject <u>must be suspended immediately</u> (except as noted below) until the requirements of the IRB policy have been satisfied with respect to the relevant protocol. This is necessary because it is unlikely that the design of the research and the informed consent document contemplated the constraints imposed by the possible future incarceration of the participant.

3.8.2.1 Soliciting information from the parents or spouse, rather than the incarcerated subject, for information about the subject's behavior and attitudes would constitute "obtaining identifiable private information about" the incarcerated subject, and would invoke Subpart C.

3.8.3 In special circumstances in which the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of Subpart C are satisfied. The investigator must request this permission in writing from the IRB. The IRB Chair will

determine whether the subject may continue participation until requirements of the policy are met.

3.8.4 If the participant was involved in a drug trial in which precipitant withdrawal of the medication could imperil the subject's health, then the investigator must notify the IRB Chair in writing with a plan for notification of appropriate directors of medical departments in the State of Connecticut Department of Corrections or other involved entity (e.g., Department of Children and Families), and plans for appropriate monitoring and interventions for withdrawal from the medication or for appropriate continued dosing. If the study involves a double blind administration of medication, when the investigational medication requires tapering for withdrawal, the investigator is responsible for breaking the blind to determine appropriate withdrawal action and inform the appropriate directors of medical departments in the State of Connecticut Department of Corrections or other involved entity. If the participant can continue in the study (through agreement by the State of Connecticut Department of Corrections or other involved entity), then the investigator must collaborate with the medical director to assure that proper administration, monitoring, and taper is conducted while the participant is incarcerated.
NOTE: These considerations may also be relevant for other interventions such as implanted devices.

3.8.5 Upon receipt of the investigator's report that a previously enrolled research subject has become a prisoner, **if the investigator wishes to have the prisoner subject continue to participate in the research**, the IRB must promptly re-review the proposal in accordance with the requirements of Subpart C, and the institution(s) engaged in the research involving the prisoner subject must send a certification to OHRP and wait for a letter of authorization in reply if the study is DHHS-conducted or –supported.

3.8.5.1 Note that in these circumstances, some of the findings required by 45 CFR 46.305(a) may not be applicable; for example, the finding required under 45 CFR 46.305(a)(4) regarding the selection of subjects within the prison may not be applicable, if the subject was recruited outside of an incarcerated context. The IRB should document findings of non-applicability accordingly.

3.8.5.2 The investigator must promptly secure approval from the State of Connecticut Department of Corrections Research Advisory Committee and any other involved entity (e.g., Department of Children and Families) before conducting research procedures with prisoners.

3.8.6 During detention, the subject does not have to be formally withdrawn; as long as there is no interaction/intervention/obtaining with the subject while incarcerated Subpart C is not invoked. Therefore, there is no need to withdraw and re-enroll. If the investigator can wait until the person is no longer incarcerated, Subpart C is never an issue.

3.8.7 Data that had been acquired prior to incarceration may continue to be analyzed.

4.0 Documentation:

4.1 The IRB shall prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under DHHS regulations at 45 CFR 46.305(a). The documentation of protocol-specific information justifying each IRB finding required under 45 CFR 46.305(a) will adequately document the IRB activities required under Subpart C.

4.2 The HRPP office will maintain documentation related to IRB review of studies conducted under Subpart C, including initial submissions, continuing reviews, and modifications, as well as reports of unanticipated problems, complaints, deviations, non-compliance, and correspondence related to review of such items, as well as checklists pertinent to the reviews, for a minimum of 6 years after completion of the study.

5.0 References:

5.1 45 CFR 46 Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (45 CFR 46.301, 302, 303, 304, 305, 306)

5.2 Federal Register /Vol. 68, No. 119 / Friday, June 20, 2003 /Rules and Regulations: DEPARTMENT OF HEALTH AND HUMAN SERVICES, 45 CFR Part 46, Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects

5.3 OHRP Guidance on the Involvement of Prisoners in Research – May 23, 2003 (http://www.hhs.gov/ohrp/policy/prisoner.html)

5.4 OHRP Prisoner Research Frequently Asked Questions (http://answers.hhs.gov/ohrp/categories/1568)

5.5 State of Connecticut Department of Correction, Administrative Directive 1.7 – Research (effective 1/31/2009)

5.6 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)
01	CLB	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	3/15/20	General review. Update regulatory citations per the Revised Common Rule

Element II.4.A. and III.1.C.