1.0 Purpose:

1.1 This policy clarifies differences in state and federal definitions of key human research terms. Accordingly, the IRB periodically must apply such definitions to its assessment of a protocol or proposal.

1.2 This policy identifies research-related findings that may present themselves during the conduct of a protocol and must be reported outside of the institution under Connecticut State Law.

1.3 This policy identifies select State law provisions that may impact the conduct of human research.

2.0 Definitions:

2.1 **Statue** - federal or state written law enacted by the Congress or state legislature, respectively. Local statutes or laws are usually called "ordinances." Regulations, rulings, opinions, executive orders and proclamations are not statutes.

2.2 **Regulation** - rules and administrative codes issued by governmental agencies at all levels, municipal, county, state and federal. Although they are not laws, regulations have the force of law, since they are adopted under authority granted by statutes, and often include penalties for violations.

3.0 Procedure:

3.1 Definition of Key Terms

3.1.1 Legally-Authorized Representative (LAR)

3.1.1.1 Federal regulations that govern research involving human subjects define a legally authorized representative (LAR) as ***an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research*** [45 CFR 46.102(i) and 21 CFR 50.3(l)].

3.1.1.2 To the extent that next of kin (surrogate) consent is not expressly permitted under the Connecticut State law, legally authorized representative also means **an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research** [45 CFR 46.102(i)].

3.1.1.3 The HHC IRB will apply a risk continuum similar to the rules relating to parental permission for participation by a child in a research study (45 CFR 46.404, 405, 404 and 21 CFR 50.2, 53). In general, if there is scientific evidence to show that the experimental treatment is better than the available treatment, poses minimal or not unreasonable risk, is likely to provide direct benefit to the patient, and additional protections are implemented, surrogate consent may be deemed appropriate by the IRB.

3.1.1.4 The order of authority to provide consent as an LAR/surrogate on behalf of another adult for participation in clinical research is as follows:

- Spouse

- Adult child
- Parent
- Adult sibling

3.1.1.5 In addition to requiring that LAR/surrogate consent be provided according to the above hierarchy, approval of a proposal for LAR/surrogate consent in research that is not clearly therapeutic in nature will require demonstration of the fact that:
a) the research involves no more than minimal risk to the subject;
b) the research can only be performed through the enrollment of subjects whose consent must be provided by an LAR; and
c) the LAR has confirmed through IRB-approved language in the consent form that he or she has no conflict of interest in acting on behalf of the subject.

3.1.2 **Children**

3.1.2.1 For the purpose of applying DHHS regulations (45 CFR 46 Subpart D) and FDA regulations (21 CFR 50 Subpart D), children are ***persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.***

3.1.2.2 Connecticut law defines individuals less than 18 years of age to be minors (C.G.S. Section 1-1(d))(and thus children as defined in federal regulation), and Subpart D applies to such individuals. The general rule is that a person may consent for his or her own medical care at the age of eighteen. Therefore, the HHC IRB generally defines children as persons under eighteen years of age.

3.1.2.3 Connecticut law, however, provides minors with "majority" status in some circumstances, giving them the right to consent to their own medical care, as follows:

3.1.2.3.1 Emancipated minors (Connecticut law enumerates certain categories of individuals age 16 or older who may initiate procedures to have the right to make medical decisions on their own behalf, such as a minor who has been married; is active duty; willingly lives apart from parents and manages own financial affairs, etc.; (C.G.S Section 46b-150(b)). Emancipated individuals do not meet the federal definition of children and therefore Subpart D requirements do not apply;

3.1.2.3.2 Minors seeking medical care for certain conditions specified in state law may consent to participate in research if the research is limited to the categories noted below; in such circumstances the individuals are not considered children and therefore Subpart D is not applicable:

- All individuals under 18 years of age, if the research procedures are limited to: HIV testing, counseling, and treatment (19a-582; 19a-592); outpatient mental health services (19a-14c); testing or treatment for sexually transmitted diseases (19a-216); treatment or rehabilitation for alcohol or drug dependence (17a-688); abortion counseling and treatment (19a-602); or consenting to medical care for a child (19a-285);

- All individuals 14 years of age or older, if the research procedures are limited to inpatient mental health services (17a-79) (parents must be notified of admission within 5 days);

- All individuals 17 years of age, if the research procedures are limited to donation of blood or any component thereof and to the withdrawal of blood in conjunction with any voluntary blood donation program (19a-285a).

3.1.2.4 To the extent that Connecticut law does not specifically address consent of children with majority status to research, the HHC IRB will review issues of consent related to enrollment of these children in research on a case-by-case basis, and will seek guidance from the General Counsel as needed.

3.1.2.5 HHC applies the regulations of 45 CFR 46 Subpart D and 21 CFR 50 Subpart D to all individuals defined as minors as described above

3.1.3 **Guardian**

3.1.3.1 Under DHHS regulations "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

3.1.3.2 Under FDA regulations "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. A guardian may grant permission for a child to participate in research.

3.1.3.3 In Connecticut a “Guardian” of a minor means the duty and authority to act in the best interests of the minor, and includes the obligation of care and control, and the authority to make major decisions affecting the minor’s education and welfare (C.G.S 45a-604(5)).

3.2 **Mandatory Reporting**

3.2.1 Hartford HealthCare (HHC) must comply with the State of Connecticut mandatory reporting regulations. The HHC Institutional Review Board (HHC IRB) requires all Investigators and clinical study staff engaged in research approved by the HHC IRB to adhere to mandatory reporting requirements specified by State and local law.

A physician or other health professional must report certain conditions/circumstances/diseases to State and local agencies whether they are found in the course of non-research clinical care or as part of a research protocol.

The Principal Investigator must also report the event to the IRB only if the condition/circumstance is a serious, unanticipated and study-related adverse consequence of study participation.

3.2.2 **Select CT Statues that require reporting**

3.2.2.1 **CGSA § 17a-101 et seq. Child Abuse Reporting**

Connecticut General Statutes describe who is mandated to report child abuse as well as the content of such reports. Additional information is available on the Department of Children and Families website at http://www.ct.gov/dcf/cwp/view.asp?a=2556&q=314388

3.2.2.2 **CGSA § 17b-450 et seq. Elder Abuse Reporting**
Connecticut mandates that certain individuals report suspected elder abuse as described in this section. Additional information can be found on the Department of Social Services webpage at http://www.ct.gov/dss/cwp/view.asp?a=2353&q=305232

3.2.2.3 **CGSA § 19a-589-1 et seq. Confidentiality of AIDS-Related Information**
AIDS-related information is subject to mandated reporting requirements and its disclosure is protected such that patient authorization is required in cases other than those mandated under state law.

3.2.2.4 **CGSA §19a-36-A1 et seq. Reportable disease and laboratory findings**
Diseases and results of laboratory tests that are mandated to be reported under state law are described here. A list can also be found in the Hartford Hospital Infection Control Manual's "Policy for Communicable Disease Reporting" (Section 10, Policy #-010).

3.2.3 **Informed Consent Form Language**

3.2.3.1 When appropriate, the HHC IRB will require the addition of a statement in the consent form to alert research participants to the possibility that information they disclose, or the results of their medical tests, may have to be reported by law to State/local authorities. For example, additional language in a consent form would be appropriate and necessary when HIV or Hepatitis A, B, and/or C testing will occur as a part of a protocol.

3.3 **Select CT Statues that may impact conduct of human research.**

3.3.1 **CGSA § 52-146 et seq. Confidential Communications**
Connecticut limits disclosure of certain communications including doctor-patient, psychiatrist-patient, etc. as described in Chapter 899.

3.3.2 **CGSA § 1-56r Decision Making Designations**
This section allows an individual to designate another person to act on their behalf in certain contexts. In particular, this section allows health care decisions to be made by a personal representative as described in 19a-576.

3.3.3 **CGSA §46b-150b et seq, Emancipation Statutes**
Any minor who has reached his/her sixteenth birthday and is residing in this state, r any parent or guardian of such minor, may petition the superior court for juvenile matters or the probate court for the district in which either the minor or the parents or guardian of such minor resides for a determination that the minor named in the petition be emancipated. These statutes set forth the requirements for a minor to be granted an order of emancipation, describe the effect of emancipation, and allow for emancipation under common law.

3.3.4 **CGSA §17a-238. Rights of persons under supervision of Commissioner of Developmental Services**
Connecticut state law requires that each person placed or treated under the direction of the Commissioner of Developmental Services in any public or private facility be protected from harm and receive humane and dignified treatment which

is adequate for such person's needs and for the development of such person's full potential at all times, with full respect for such person's personal dignity and right to privacy consistent with such person's treatment plan as determined by the commissioner. The involvement of state-protected individuals in human subjects research requires the Commissioner's oversight and monitoring prior to its being undertaken.

3.3.5 **CGSA § 743n-42 Sweepstakes Requirements**
Connecticut state law regarding gaming allows "sweepstakes" to be conducted without a license or permit but requires certain information to be disclosed in any advertising, including word of mouth advertising. In particular, such advertisements must include 1) the value of the prize, 2) odds of winning, 3) any restrictions on winning, and 4) name of sweepstakes sponsor. Note that "raffles" and "lotteries" require a permit under state law.

3.4 **Research Occurring Outside Connecticut and Conducted by HHC Investigators**

3.4.1 Research conducted by a HHC investigator and subject to HHC IRB approval may occur in a jurisdiction other than Connecticut.

3.4.2 When the research involves informed consent for a subject's participation from an individual other than the subject, a child as a research subject and/or a guardian asked to provide permission for the child's participation the HHC IRB shall consult with the General Counsel to ensure that such other jurisdiction's laws relating to definitions of "legally authorized representative," "child," and "guardian," as applicable, are properly applied to the conduct of such research.

3.4.3 Such consultation shall not be required if an IRB other than the HHC IRB is responsible for reviewing the activity occurring in such other jurisdiction (i.e., if the HHC IRB's review relates to a multi-center trial coordinated by HHC but subject to separate review by local IRBs as to activities occurring in such local areas).

3.5 **The HHC IRB shall have direct access to HHC General Counsel for consultation on such matters in applying laws to research involving human participants and resolving conflict among those applicable laws.**

4.0 Documentation:

4.1 Not Applicable

5.0 References:

5.1 General Statues of Connecticut (listing by Title) https://www.cga.ct.gov/current/pub/titles.htm

5.2 Hartford Hospital Policy for Communicable Disease Reporting (Infection Control Manual, Section 10, Policy #-010)

5.3 45 CFR 46 Subpart A – *Basic HHS Policy for Protection of Human Research Subjects*

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	CLB	7/1/11	New Issue
01	CLB	7/22/15	Added process to consult with General Counsel to resolve any conflicts among applicable law
02	CLB	3/15/20	Updated definitions and regulatory references; checked the validity of website links.

Element I.1.G.