1.0 Purpose:

1.1 To define and explain situations in which the standard written informed consent process may be waived or altered.

2.0 Definitions:

2.1 **Waiver of consent** – any circumstance in which standard written informed consent is ethically and appropriately not obtained

2.2 **Alteration of consent** – any circumstance in which the standard written informed consent process is ethically and appropriately modified, usually by shortening its length of time and/or its documents

3.0 Procedures:

3.1 **Full Waiver of Consent:**

3.1.1 In certain situations, the Hartford HealthCare Institutional Review Board (IRB) may waive the written informed consent process in accordance with laws, regulations, codes, and guidance.

3.1.2 When the IRB waives the requirement to obtain consent, it waives the entire requirement for consent, both the attributes of the consent process and the elements of disclosure. When the IRB approves a waiver of the consent process, records should document why (on what base(s)) the IRB judged that a waiver was appropriate for the specific protocol being reviewed.

3.1.3 **The IRB may waive or alter the consent process for FDA-regulated research that is no more than minimal risk.**

3.1.3.1 To approve a waiver of consent, the IRB must find and document that:

3.1.3.1.1 The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k));

3.1.3.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3.1.3.1.3 The research could not practicably be carried out without the waiver or alteration; and

3.1.3.1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation

3.1.4 To approve a **waiver or alteration of consent**, the Common Rule (45 CFR 46.116(f)(3)) requires that the IRB must find and document that:

3.1.4.1 The research involves no more than minimal risk to the subjects;

3.1.4.2 The research could not practicably be carried out without the requested waiver or alteration

3.1.4.3 If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

3.1.4.4 The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

3.1.4.5 Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

3.1.5 To approve a **waiver or alteration of HIPAA Authorization**, the Privacy Rule (45 CFR 164.512(i)(2)(ii)) requires that the IRB find that:

3.1.5.1 Disclosure of the PHI involves no more than minimal risk.
3.1.5.2 The waiver will not adversely affect the privacy rights or welfare of the subject.
3.1.5.3 The research could not practicably be carried out without the waiver.
3.1.5.4 The research could not practicably be carried out without access to the PHI.
3.1.5.5 The privacy risks are reasonable in relation to the information to be gained.
3.1.5.6 There is an adequate plan to protect the identifiers from improper use and disclosure.
3.1.5.7 There is an adequate plan to destroy the identifiers at the earliest opportunity.
3.1.5.8 There is written assurance that the PHI will not be further disclosed, with a few exceptions specified in 45 CFR 164.512(i)(2)(ii)(A)(3).

3.1.6 Examples of situations where the IRB may approve a full waiver of consent/authorization include:

3.1.6.1 Retrospective chart reviews where the subject is not available, and it would be impractical or impossible to contact that subject.
3.1.6.2 Chart reviews for screening purposes to determine which patients might be eligible to be contacted for participation in a study

3.2 **Screening, recruiting, or determining eligibility:**

3.2.1 The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

3.2.1.1 The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

3.2.1.2 The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. An alteration of some of the elements of consent/authorization is permissible in certain circumstances. However, to approve a partial waiver of consent/authorization the

3.2.2 When the IRB approves a "screening waiver", records should document the protocol-specific reasons justifying the waiver.

3.2.3 A screening waiver may be advantageous to avoid a prolonged consenting process, only then to realize that the subject is not eligible. This alteration involves asking permission of a potential subject to explain a study and ascertain whether the potential subject might be interested based on eligibility.

3.2.4 Examples of situations where the IRB may approve a screening waiver to alter the consent process include:

3.2.4.1 Mailing consents to participants rather than conducting the consent process in person
3.2.4.2 Conducting the consent process verbally rather than reviewing a written document (*e.g.*, via the telephone) – no written consent is obtained, but the same information as is provided
3.2.4.3 Telephone screens to assess study eligibility prior to consenting
3.2.4.4 Written screening forms or surveys to assess study eligibility prior to consenting

3.3 **Waiver of the Documentation of Consent:**

3.3.1 In certain situations, the IRB may waive the requirement to document the consent process. When the IRB approves a waiver of the requirement to document the consent process, records should document the protocol-specific reasons justifying the waiver.

3.3.2 A potential research subject's agreement to participate in a research study is usually documented by the subject indicating his/her approval to participate by signing and dating the consent form which includes the Health Insurance Portability and Accountability Act (HIPAA) authorization form. However, for certain types of research, the IRB may approve a waiver of documentation of consent (45 CFR 46.117(c) and 21 CFR 56.109(c)(1)) and HIPAA authorization (45 CFR 164.512(i)(2)). In this case, evidence of the subject's research participation would be evidence that the research subject had been willing to participate.

3.3.3 The IRB must always approve a waiver of documentation of consent if the investigator will not obtain a consent form signed and dated by the research participant.

3.3.4 Under certain circumstances, the Common Rule allows the IRB to waive written consent (45 CFR 46.117(c)). The IRB may waive the requirement for the investigator to obtain a signed and dated informed consent form for some or all subjects, if it finds any of the following:

3.3.4.1 That the only record linking the subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked

whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; r

3.3.4.2 That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

3.3.4.3 If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

3.3.5 In cases in which the documentation requirement is waived, the IRB may require the PI to provide subjects with a written statement regarding the research.

3.3.6 For FDA-regulated research (21 CFR 56.109(c)(1)), the IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that:

3.3.6.1 the research presents no more than minimal risk of harm to subjects and

3.3.6.2 involves no procedures for which written consent is normally required outside the research context

3.3.7 Whenever the IRB approves a consent process involving waiver of documentation of consent/authorization, the IRB ordinarily will require the researcher to provide participants with a written statement regarding the research and the IRB would need to review the information that will be provided to them. The written statement or description of the study must contain all of the elements of consent/authorization. This written description may be in one of two forms;

3.3.7.1 a script for verbal use or,
3.3.7.2 a written “information sheet” that will be given to participants.

3.3.8 The written description of the research should also include contact names and numbers including, but not limited to:

3.3.8.1 Principal Investigator (PI)
3.3.8.2 IRB contact
3.3.8.3 Independent entity (i.e. Patient Relations)

3.3.9 The IRB will consider any of the following applicable points when assessing whether to approve a waiver of documentation of consent:

3.3.9.1 Does the research involve no more than minimal risk, and would written consent be required for the study procedures if they were not part of a research study?

3.3.9.2 Does the written description or script for presentation to the potential subject include the required elements of consent, and additional elements, if applicable?

3.3.9.3 Does the written description or script for presentation to the potential subject include the required elements of authorization?

3.3.10 To approve a waiver of documentation of consent the IRB must still consider all of the elements listed above in sections 3.1.4 and 3.1.5.

3.3.11 When the IRB waives the requirement for written documentation of consent/authorization, the findings will be documented in either the minutes of the IRB's full board meeting or supporting documents submitted by the PI (*e.g.*, the Human Studies Form) and/or person(s) conducting the HRPP review.

3.3.12 Examples of situations where the IRB may waive or alter the requirement for documentation of consent/authorization include:

3.3.12.1 studies limited to focus groups (*i.e.*, "focus group research")
3.3.12.2 mail surveys or interviews
3.3.12.3 telephone surveys or interviews

3.4 **How to Request a Waiver of Consent/Authorization from the IRB;**

3.4.1 Research must not be conducted under any type of waiver without **prior** IRB approval.

3.4.2 To obtain IRB approval for any type of waiver investigators must submit a written request to the IRB. This can be done in 2 ways;

3.4.2.1 Requesting a waiver for a **new study**: Address all of the elements in the "Waiver of Consent/Authorization" section of the Research Application. If the study involves multiple types of waivers all waivers should be submitted with the application for review and approval.

3.4.2.2 Requesting a waiver for an **on-going study**: Investigators should submit a modification form to the IRB clarifying why they are requesting approval for a waiver. Please submit the waiver with the modification form for review and approval.

3.4.3 Once a waiver is approved, the Chair, Vice Chair, or Designated Reviewer will sign and date the waiver to indicate that it has been approved. A signed copy will be sent to the investigator for their records. Investigators should not conduct any research under a waiver until they have received the signed waiver from the IRB.

4.0 Documentation:

4.1 The HHC HRPP office will maintain all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

4.2 Records will be archived for a period of at least three years following the termination or completion of the research activities.

5.0 References:

5.1 45 CFR 46.116(f), 45 CFR 46.116(g), 45 CFR 46.117(c)

5.2 45 CFR 164.512(i)(2)(ii)

5.3 21 CFR 56.109(c)(1), 21 CFR 56.109(d)

5.4 Informed Consent, Legally Effective and Prospectively Obtained (OPRR Letter, 1993)

5.5 FDA Guidance for Sponsors, Investigators, and Institutional Review Boards – IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects (July 2017)

8.4 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	PMJ	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	10/13/11	Added a statement that waiver of consent for FDA-regulated research is prohibited (see section 3.1.3.). Re-ordered section 3.3, clarified the criteria in which FDA allows documentation of consent to be waived, clarified that the IRB will required and review written material to be given to subjects when documentation of consent is waived.
03	CLB	3/15/20	Revision to address Revised Common Rule and waivers for minimal risk research that is FDA-regulated

Elements II.3.G. and III.1.F.