TITLE: Waiver of Consent: Waiver or Alteration of Informed Consent and Waiver of Documentation of Consent		POLICY/PROCEDURE NUMBER: IRB 13	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
Date Originated:	6/30/05	Date Effective:	11/2020
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

There are situations for minimal risk research where it may be appropriated and permitted for an IRB to waive the requirement of informed consent or to approve a consent procedure that omits some, or alters some or all, of the required elements of informed consent. A waiver or alteration of informed consent may apply to an entire study or a component of the research, and may apply to written consent forms or to oral consent scripts.

Screening, recruitment, and determining eligibility

With the revisions to the Common Rule effective as of January 21, 2019, IRBs no longer need to grant waivers or alteration of informed consent if a study team 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, as long as:

1. The study team will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The study team will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Waivers or alterations when broad consent was not obtained (the CHS CIRB has chosen not to implement the Broad Consent procedure)

1. Waiver or Alteration of Informed Consent: An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
    a. The research involves no more than minimal risk to the subjects;
    b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
    c. The research could not practicably be carried out without the waiver or alteration; and
    d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. Waiver of the Requirement to Obtain Documentation of Consent: An IRB may waive the requirement to obtain a signed consent form provided the IRB finds and documents that:
    a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
    b. 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 of the research context; or

c. 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.
d. In some cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or the legally authorized representative with a written statement regarding the research.

If the research involves using identifiable private information or identifiable biospecimens, under the Common Rule, the IRB also must find and document that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Waivers or alterations for public benefit and service programs

The Common Rule also permits a waiver or alteration of informed consent for research involving public benefit and service programs. The research or demonstration project must be:

1. Conducted by or subject to the approval of state or local government officials, and
2. Designed to study, evaluate, or otherwise examine:
    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in or alternatives to those programs or procedures; or
    d. Possible changed in methods or levels of payment of r benefits or services under those programs.

The IRB must find and document that the research could not practicably be carried out without the waiver or alteration of informed consent.

Investigator Responsibilities

1. Complete and submit the *Protocol Submission Form.*
2. Submit the documentation required on the *Protocol Submission Form.*
    a. The investigator should designate either “waiver of informed consent” or “waiver of documentation of informed consent” in Part F, Documents to be Submitted/Reviewed.
    b. Include all documentation justifying a waiver, alteration or documentation of informed consent and why the research could not be practicably be carried out without the waiver
    c. For those studies using identifiable private information or identifiable biospecimens, document that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
    d. Submit a copy of the altered consent document, information sheet, or oral consent script (if applicable)
3. Continue with submission process. (Refer to policy/procedure “Submission of a Protocol”).

Department Responsibilities

1. Will process protocol as routine initial submission. (Refer to policy/procedure “Submission of a Protocol”)
2. Complete the *Waiver of Consent Checklist* to assess whether the protocol qualifies for a waiver. Protocol and Checklist may be referred to the CHS CIRB Chair for further assessment.
3. Protocol will be placed on the agenda of the next scheduled CHS CIRB meeting for discussion.
4. Investigator will be notified of waiver status with *Notice of Review* following the meeting.
5. *Waiver of Consent Checklist* will be maintained in the study binder in the CHS CIRB office.

CROSS REFERENCE:
Code of Federal Regulations 45 CFR 46 116 & 117
Code of Federal Regulations 21 CFR 50.24
Code of Federal Regulations 21 CFR 56.105
CHS CIRB Policy: Submission of a Protocol
Addendum I: Waiver of Consent Checklist
Addendum II: Waiver of Written Documentation of Consent Checklist

ACCEPTED BY:

Elizabeth Yee
Vice President, Clinical Ancillary Services

Andrej Zajac, M. D.
Co-Chair, CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director, IRB/Bio-Ethics

DATE REVISED: 8/10/06, 3/2013, and 12/2018

REVIEWED AND APPROVED BY: CHS CIRB 8/9/05, 9/13/06, 6/2009, 5/2013, 4/2016, 1/2019, 11/2020

Date	Initials
6/2009	JL
3/2013	JL
3/2016	JL
12/2018	JL
11/2020	JL