Community Memorial Health System *Where Excellence Begins with Caring*	**Institutional Review Board** **WAIVER OF INFORMED CONSENT**

FOR REQUESTING A WAIVER OF THE INFORMED CONSENT PROCESS

- **If the research involves PHI, then the Principal Investigator must request a Waiver of HIPAA Authorization.**
- **It is the Principal Investigator's responsibility to provide the necessary information for each type of waiver request. Failure to address each of the elements for each type of waiver will delay the IRB's ability to act on the request.**

SECTION 1. PROTOCOL INFORMATION	
1A. Date:	
1B. Principal Investigator:	
1C. Title of Study:	
1D. Is this research regulated by the US Food and Drug Administration[1]? ☐ Yes ☐ No	
1E. Is this research regulated by the US Department of Defense[2]? ☐ Yes ☐ No	

[1] FDA regulated research is not eligible for a waiver of alteration of informed consent.

[2] If the research subject meets the definition of "experimental subject," a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of "experimental subject," the IRB may waive the consent.

SECTION 2. REQUEST FOR WAIVER

To approve a request for a **waiver** or alteration of the informed consent process under 46.116(f)(3), the IRB must find and document the following:

- The research involves no more than minimal risk to the subjects:
- The research could not practicably* be carried out without the waiver or alteration;
- 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;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, subjects will be provided with additional pertinent information after participation.

*The commonly accepted definitions of the term "practicable" are (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources. (Practicable means **possible**, it does not mean convenient.)

All 5 elements of 46.116(f)(3)(ii) must be explained and justified:

2A. Explain why and how the research involves no more than minimal risk to the subjects.

2B. Explain why the waiver will not adversely affect the rights and welfare of the subjects.

2C. Is the research team collecting identifiable private information and/or identifiable biospecimens? ☐ Yes ☐ No

If yes, explain why the research could not practicably be carried out without using such information of biospecimens in an identifiable format.

2D. Explain why the research could not be practicably be carried out without the waiver of informed consent.

2E. If a waiver of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation? ☐ Yes ☐ No
Explain/describe why:

Attach additional sheet if needed.

Community Memorial Health System *Where Excellence Begins with Caring*	**Institutional Review Board** **ALTERATION OF INFORMED CONSENT**

FOR REQUESTING AN ALTERATION TO THE INFORMED CONSENT PROCESS

- **It is the Principal Investigator's responsibility to provide the necessary information for each type of waiver request. Failure to address each of the elements for each type of waiver will delay the IRB's ability to act on the request.**

SECTION 1. PROTOCOL INFORMATION	
1A. Date:	
1B. Principal Investigator:	
1C. Title of Study:	
1D. Is this research regulated by the US Food and Drug Administration[1]? ☐ Yes ☐ No	
1E. Is this research regulated by the US Department of Defense[2]? ☐ Yes ☐ No	

[1] FDA regulated research is not eligible for a waiver of alteration of informed consent.

[2] If the research subject meets the definition of "experimental subject," a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of "experimental subject," the IRB may waive the consent.

SECTION 2. REQUEST FOR ALTERATION (Attach a copy of the proposed altered consent form.)

To approve a request for a waiver or **alteration** of the informed consent under 46.116(f)(3), the IRB must find and document the following:

- The research involves no more than minimal risk to the subjects:
- The research could not practicably* be carried out without the waiver or alteration;
- 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;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, subjects will be provided with additional pertinent information after participation.

*The commonly accepted definitions of the term "practicable" are (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources. (Practicable means **possible**, it does not mean convenient.)

All 5 elements of 46.116(f)(3)(ii) must be explained and <u>justified</u>:

2A. Explain why and how the research is no more than minimal risk to the subjects.

2B. Explain why the alteration will not adversely affect the rights and welfare of the subjects.

2C. Is the research team collecting identifiable private information and/or identifiable biospecimens? ☐ Yes ☐ No
If yes, explain why the research could not practicably be carried out without using such information of biospecimens in an identifiable format.

2D. Explain why the research could not be practicably be carried out without the alteration of informed consent.

2E. If an alteration of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation? ☐ Yes ☐ No
Explain/describe why:

Community Memorial Health System *Where Excellence Begins with Caring*	**Institutional Review Board** **WAIVER OF DOCUMENTATION (SIGNATURE) OF INFORMED CONSENT**

FOR REQUESTING A WAIVER OF THE DOCUMENTATION (SIGNATURE) OF INFORMED CONSENT

- **Use this form when potential participants, or the parents of children who are potential participants, are presented (either verbally or in writing) with the same information required in a written consent document, but the documentation of the process (signing of the consent form) has been waived by the IRB. This process is often used in minimal risk research involving the administration of online or mailed surveys, telephone interviews, or when anonymous sensitive information is collected and there is a desire not to have written documentation that links the participant to the research study.**
- **When applying for a waiver of documentation of consent, you must request a waiver or alteration of HIPAA Authorization. Complete and attach Waiver or Alteration of HIPAA Authorization Form.**
- **It is the Principal Investigator's responsibility to provide the necessary information for each type of waiver request. Failure to address each of the elements for each type of waiver will delay the IRB's ability to act on the request.**

SECTION 1. PROTOCOL INFORMATION	
1A. Date:	
1B. Principal Investigator:	
1C. Title of Study:	
1D. Is this research regulated by the US Food and Drug Administration? ☐ Yes ☐ No	
FDA regulated research is not eligible for a waiver of alteration of informed consent. (21 CFR 50)	
1E. Does the research involve newborn dried blood spots? ☐ Yes ☐ No If yes, research is not eligible for waiver.	

SECTION 2. REQUEST FOR WAIVER OF DOCUMENTATION

A consent procedure which does not document obtained consent through a physical signature may be approved by the IRB under certain conditions. To request IRB approval of a consent procedure which does not document consent through a physical signature, **provide a response to <u>only one</u> of the following**. Note that the IRB may require the investigator to provide subjects with a written statement regarding the research, even though the documentation requirement may be waived.

The IRB will take into consideration the risks and potential harms involved in the research and consent process before granting a waiver of documentation of informed consent.

2A. 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. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations.)

2B. 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 consent.

2C. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

2D. Attachments required:

- **Written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided electronically displayed. This must include the required and appropriate elements of informed consent.**
- **Waiver or Alteration of HIPAA Authorization Form. (When applying for a waiver of documentation of consent, you must request a Waiver or Alteration of HIPAA Authorization.)**

Community Memorial Health System *Where Excellence Begins with Caring*	**Institutional Review Board** **WAIVER OR ALTERATION OF HIPAA AUTHORIZATION**

FOR REQUESTING A WAIVER OR ALTERATION OF HIPAA AUTHORIZATION

- **Complete this waiver or alteration request if HIPAA authorization will <u>not</u> be obtained from the research subjects or will be altered in some way.**
- **It is the Principal Investigator's responsibility to provide the necessary information for each type of waiver request. Failure to address each of the elements for each type of waiver will delay the IRB's ability to act on the request.**

SECTION 1. PROTOCOL INFORMATION	
1A. Date:	
1B. Principal Investigator:	
1C. Title of Study:	
1D. Is this research regulated by the US Food and Drug Administration? ☐ Yes ☐ No	
[1] FDA regulated research is not eligible for a waiver of alteration.	

SECTION 2. REQUEST TYPE

I am requesting a: ☐ Complete Waiver of Authorization ☐ Alteration of the Authorization

If "Alteration of Authorization" is selected, include a proposed altered authorization form.

In order to waive or alter an authorization, the investigator must provide sufficient information on which the IRB may make the following three (3) findings specified by the Privacy Rule 45 CFR 164.512 (i)(2)(ii). **All must apply.**

- The use or disclosure of protected health information (PHI) involves not more than minimal risk to the privacy of individuals based on:
  - An adequate plan to protect the identifiers from improper use and disclosure.
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
  - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research which the use or disclosure of PHI would be permitted by the Privacy Rule.
- The research could not be practicably conducted without the waiver or alteration; and
- The research could not be practicably conducted without access to and use of the protected health information.

All 3 elements of 46.116(f)(3)(ii) (sections 4 and 5 below) must be explained and <u>justified</u>:

SECTION 3. DATA COLLECTED

3A. List the PHI to be collected and a list of the source(s) of the PHI. (Attach separate sheet if needed.)

SECTION 4. PRIVACY

4A. Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of individuals? ☐ Yes ☐ No
Explain:

4B. Where will PHI and identifiers be stored?

4C. Who will have access to PHI and identifiers?

4D. Describe how identifiers and PHI will be protected.

4E. Identifiers will be destroyed at the earliest opportunity. ☐ Yes ☐ No
If no, explain why not:

4F. Describe when and how all identifiers will be destroyed.

SECTION 5. RESEARCH PRACTABILITY

The commonly accepted definitions of the term "practicable" are (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources. (Practicable means **possible**, it does not mean convenient.)

5A. The research could not practicably be conducted without the alteration or waiver. ☐ Yes ☐ No
Explain:

5B. The research could not practicably be conducted without access to and use of the PHI. ☐ Yes ☐ No
Explain: