The University Of Vermont Committees on Human Research

Request for Waiver of Informed Consent/Authorization/Documentation

This form needs to be submitted when you are requesting a waiver of informed consent or alteration, waiver of HIPAA authorization or waiver of written consent. **Note:** If this is emergency research you must also complete the Request for Review of Emergency Research form. See the Research Manual for form completion instructions.

Date Stamp	Shaded Areas	Protocol Number
	For Committee on Human Research Use Only	

Protocol/Project Title

Principal Investigator (PI):

Does this project utilize a FDA regulated device or drug? Yes ☐ No ☐

If yes, **do not complete** as FDA does not allow for a waiver of consent under any circumstances.

I. Waiver of Informed Consent or Alteration of Informed Consent Procedures ☐ **Not applicable**

Is this is a request for waiver of consent or alteration of consent procedures? ☐ Waiver ☐ Alteration

If alteration, describe how the alteration deviates from normal consent procedures.

Does this request apply to the entire subject population? Yes ☐ No ☐

If no, describe for which populations the waiver or alteration is being requested below.

1. Describe why the research involves no more than minimal risk* to the individual:
   (Skip this question if conducting emergency research.)

**The probability and magnitude of harm is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of the general population.*

2. Describe why the research will not adversely affect the rights and welfare of subjects:

3. Describe why the research would not be possible to conduct without a waiver or alteration of consent:

4. Will information be provided to the subject once the research is complete, when appropriate?
   (Skip this question if conducting emergency research.)

5. Will PHI be used in this study? Yes ☐ No ☐

   If yes, complete Section II and IV. If no, check not applicable in Section II and proceed to Section III.

II. Waiver of Authorization ☐ **Not applicable**

1.a. There is minimal risk to the privacy of the subject because:
(Safeguards must be in place to protect identifiers from improper use or disclosure.)

- ☐ The information will not be disclosed unless it is stripped of all identifiers *(see HIPAA policy)*
- ☐ Data will be coded prior to any disclosure
- ☐ Other (explain):

b. Identifiers must be destroyed at the earliest opportunity consistent with conduct of the research unless otherwise justified. Identifiers will be destroyed upon completion of:

- ☐ Data collection
- ☐ Data analysis
- ☐ Specimen processing
- ☐ Other (explain)

c. If identifiers will be retained indefinitely, check why: ☐ Not applicable

- ☐ Longitudinal study
- ☐ Federal requirements (specify below)
- ☐ Other (specify below)

2. The research cannot practicably be conducted without access to the PHI because:

- ☐ PHI is needed to identify subject eligibility. Explain below:
- ☐ PHI is needed to answer the research question. Explain below:
- ☐ Other Explain below:

3. Summarize what protected health information (PHI) is needed.
This is very important information as this summary will be used by FAHC Health Information to pull the appropriate records. FAHC Health Information will only pull the information that has been approved under this waiver.

III. Waiver of Documentation of Informed Consent *(For further information click here.)* ☐ Not applicable

If requesting a waiver of documentation of a signed consent form, check applicable below:

- ☐ 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.

OR

- ☐ 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.

Describe process:

(If a written summary will be provided to the subjects, it must be reviewed and approved by the IRB.)

IV. Investigator Agreement and Signature

Investigators are required to only obtain the minimum necessary data in order to achieve the goals of the research. You have certified by signing this form that only the minimum necessary data will be obtained to meet the needs of this study, to the greatest extent possible, access to the information will be limited within the study team, and you will not re-use or disclose PHI to any other person or entity, except as required by law, research oversight, or those outlined above.

PI Signature **Date**