

- INSTRUCTIONS -

Request for Waiver of Informed Consent /Authorization/Documentation Form

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Note: If you are applying for a waiver of both consent and authorization, only one form need be completed and submitted. All necessary forms are located in the forms section of our website and should be downloaded each time you need one.

Header Information: Protocol/Project Title: The title should reflect the title on the research protocol.
Investigator Information: The name of the local principal investigator should be placed here.

Does this project utilize a FDA regulated device or drug? If you answer “Yes” to this question, **stop completing this form** as the project is ineligible for a waiver. The FDA does not allow for a waiver of the consent under any circumstances.

Section I: Waiver of Informed Consent or Alteration of Informed Consent Procedures

This section is completed if you are requesting either a waiver of the informed consent (process and document) or an alteration to any of the elements of informed consent. Waivers of informed consent only occur in minimal risk studies. Alterations to the informed consent process are rare and occur most often when the research involves deception.

Is this is a request for waiver of informed consent or alteration of informed consent procedures?

Check appropriate answer. If you are not requesting either of these, check “Not applicable” and proceed to section III.

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

Does this request apply to the entire subject population?

Yes or No

In some research a waiver of consent may only apply to a subset of subjects. (An example would be a study that collected both retrospective data and prospective data, with a written consent required for prospective collection of data.) If “No,” describe for which subjects (or subset of the subjects only) the waiver is being requested.

1. Describe why the research involves no more than minimal risk to the individual. (Minimal risk means 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.)

Acceptable: “Study involves the examination of tissues/blood/data that have been previously collected and processed into slides and paraffin tissue blocks, final diagnosis rendered and the cases completed.”

Acceptable: “There is no risk to the subjects. Their identity is completely deidentified except to the research personnel reviewing the data. The collection of data for this study is limited to diagnostic x-rays, CTs and information in patient charts that was obtained during routine, standard care.”

Unacceptable: “The amount of risk perceived by the subjects in this study is much more than the actual risk presented to them. If the risks are explained, subjects will most likely say no, because they will think the risk is greater than it really is.”

If your project is emergency research skip this question and proceed to number 2.

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

Acceptable: “Our study will not alter the delivery of appropriate medical care as definitive care has already been provided prior to this study.”

Unacceptable: “The study budget does not cover staff to run the consenting process. If staff are given the added responsibility of consenting subjects, the subjects will suffer from the shortcomings of other parts of the study. Thus, the consent process would be deleterious to subject welfare.”

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

NOTE: Informed consent to participate in research is the cornerstone of ethical research. A waiver should not be sought for convenience or lack of resources.

Acceptable: “It is unlikely to be able to contact all patients to obtain consent and all available specimens are necessary to ensure the data is not bias, misleading or invalid.”

Acceptable: “Specimens come from a bank, already deidentified. It is therefore impossible to trace the specimens to their sources in order to obtain consent.”

Acceptable (alteration of consent): “If the participants knew that they were providing information as to the efficacy of the survey, they would answer the questions with more vigilance than they otherwise would. To accurately gauge the surveys, it is therefore essential that the participants continue to believe that the surveys are a routine part of their standard care.”

Unacceptable: “Retrospective chart reviews do not require consent.”

Unacceptable: “The investigative team prefers to carry out this study with a waiver of consent, as consenting is not practical.”

4. Will information be provided to the subject once the research is complete, when appropriate?

Investigative teams contemplating this point should consider that if participant contact can be made after the study is completed, contact before the study is probably just as practical. If post-study contact is included in the protocol, the waiver of consent must, logically, be sought for reasons other than inability to contact the participant.

However when contact is not possible, it should be explained as such.

Acceptable: “As there are no identifiers (other than birth dates as age is an important data component for this study) used in the performance and reporting of this research, it will not be possible to provide those subjects whose data is being utilized with any information about the research. Therefore providing subjects with additional pertinent information is not appropriate. Information gathered from this study will be shared with the community at large upon publication.”

Unacceptable: “The investigative team will not have the time or resources to disperse information to subjects after the study; they will be occupied with data analysis, publishing, and other post-study activities that are more important to the study as a whole than informing subjects.”

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

If yes, then a waiver of HIPAA authorization should also be requested. Complete Section II, “Waiver of Authorization.”

Section II: Waiver of Authorization

A waiver of authorization allows researchers to use protected health information without obtaining an authorization.

Not applicable: If there is no access to protected health information (PHI) from UVM or FAHC, check not applicable and skip to section III.

Check: If you are requesting a waiver of authorization, then you must have also completed Section I above requesting a waiver of informed consent.

1. a. There is minimal risk to the privacy of the subject

because: Check appropriate box.

1. 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:

Check appropriate box.

1.c. If identifiers will be retained indefinitely, check why:

Check appropriate box.

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

Check the appropriate box and

provide a detailed description which explains how PHI is essential to the research.

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. The information required should be consistent with that which is listed in your protocol.

Section III: Waiver of Documentation of Informed Consent

You may request a waiver of the documentation of informed consent (verbal consent is obtained but not a signed consent document) if the research meets either of the two criteria below.

If applying for this waiver, check below which applies:

a. 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;

b. 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 the process.

If a summary will be provided to each subject, please attach that summary for review. Otherwise please describe the process of verbal consent in the space above.

Section IV: Investigator Agreement and Signature

The principal investigator must review, sign and date the form.