Section 1: About the Waiver of Informed Consent

Use this form if none of the required elements of consent are given. A waiver of informed consent completely waives the requirement to obtain informed consent. The IRB may approve a consent procedure which does not include some or all of the required elements of informed consent provided all of the following are true:

* The research involves no more than minimal risk
* The waiver of informed consent will not adversely affect the rights and welfare of the subjects
* It is not practicable to conduct the research without the waiver or alteration

Whenever appropriate, participants will be provided with additional pertinent information after their participation.

Examples of types of studies in which some or all elements of consent have been waived include retrospective chart reviews, studies of existing pathology specimens, ethnographic research, or passive (opt-out) consent.

PLEASE NOTE: The IRB will take into consideration the risks and potential harms involved in the research before granting a waiver of informed consent. Additionally, there are restrictions for when the IRB may waive the requirements for child assent and parental permission.

Read more at: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-waiver-or-alteration-consent>

Section 2: Who Needs to Complete this Form

If you answered “Yes” to Section 8.9.2) Waiver of Informed Consent Process in the New Study Application for Human Subjects form, you will need to complete this form as part of your application.

If there are participants will not have a choice to participate in your study, and you did not yet select “Yes” in the New Study Application yet, please be sure update the information in that form, and then complete this form for your application.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Questions – Request Waiver of Consent

1) Purpose of the Waiver Request: Briefly state or summarize the purpose of this waiver.

For example: record review for all data collection, removing a consent element, using deception procedures, etc.

**Detail Below:**

Click or tap here to enter text.

2) Type of Waiver of Informed Consent Request

Select one option.

[ ]  Waiver of Informed Consent (no contact with participants and no documentation of consent, e.g. chart or record review)

[ ]  Alteration of Informed Consent (requesting that required element(s) of consent template be removed or altered e.g. use of deception in consent)

3) List of identifying information you plan to collect or keep a link to

For example: names, dates, or identification numbers such as social security numbers or University record numbers.

**Detail below:**

Click or tap here to enter text.

4) Explain why the research could not be practicably conducted without using identifiable information.

Examples of such explanations could include (but are not limited to) the following:

* Identifiable information is needed to identify eligible participant records
* Identifiable information is needed to link health records to additional information about the participants included in this study.
* Identifiable information is needed so that additional information can be collected and verified about participants throughout the course of the study.

**Please detail below:**

Click or tap here to enter text.

5) Explain why the research could not practicably be conducted without the waiver or alteration.

Examples of such explanations:

* If consent were a requirement, the investigator would be unable to obtain consent for about 30% of participants because they have moved and lost to follow-up and the contact information in our database is incorrect. With a loss of 30% of participants, the investigator would be unable to answer the research question.
* If consent were a requirement, the investigator would have to obtain consent on about 100,000 individuals which would require about 10 years of time for the two person staff to accomplish assuming that the staff spend 50% of their time on obtaining consent. The degree of effort would make it not practicable to conduct the research.

**Please detail your reasons for a waiver to consent below.**

For example, complete the following sentence, "If I had to obtain consent, the research could not be conducted because….":

Click or tap here to enter text.

6) Explain why the research and privacy risk of the research are no more than minimal.

Examples of such explanations could include (but are not limited to) the following:

* because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely.
* because the review of subjects' medical records if for limited information and is not sensitive in nature.

**Please detail your reasons below:**

Click or tap here to enter text.

7) Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the subjects.

Examples of such explanations could include (but are not limited to) the following:

* because the information collected is not sensitive and a reasonable person who is in the participant's position would not consider the waiver as adversely affecting his/her rights.
* because the information was collected for clinical care and the research will not change the care the individual received

**Please detail your measures below:**

Click or tap here to enter text.

8) Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information after they have participated in the study, or indicate "Not Applicable".

Examples of such explanations:

* Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals.
* Providing participants pertinent information after participation is not appropriate because deception was used and the participants should be debriefed according to the investigator's protocol.

**Please detail your answer below:**

Click or tap here to enter text.