

CIRB COMBINED WAIVER OF ELEMENTS OF INFORMED CONSENT AND WAIVER OF DOCUMENTATION OF CONSENT REQUEST SUPPLEMENTAL FORM

OMB #0925-0753 Expiration Date: 05/31/2024

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

This application has been designed to meet the regulatory requirements for review, so answer each question as completely as possible.

- All answers must be in lay language.
- If an answer to any question cannot be provided, provide an explanation for the missing answer.
- If you have any questions regarding the completion of this application, contact the CIRB Helpdesk at ncicirbcontact@emmes.com or 888-657-3711.

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____

INITIAL APPROVAL DATE: _____

A study must meet specific criteria in order to qualify for a [waiver or alteration of the regulatory elements of informed consent](#) or a [waiver of documentation of informed consent](#).

The questions below are designed to assist the CIRB in making either or both of these determinations. If you are requesting a waiver or alteration of the regulatory elements of informed consent or a waiver of documentation of informed consent, please complete this supplemental form, providing your assessment below along with the requested rationales.

INSTRUCTIONS: Answer the following questions. You may cite the protocol section and page number that includes this information:

Waiver or Alteration of Regulatory Elements of Informed Consent. Only complete this section if you are requesting a full waiver of consent or a waiver or alteration of the required elements of consent.

1. Type of waiver or alteration requested:

- Full waiver of consent (*Select only when there is no intent to obtain informed consent prior to participation in the research. Typically used for projects involving the secondary analysis of existing data or projects involving deception*).

Provide the details of the research activities and rationale for requesting a full waiver of informed consent:

Waiver or alteration of required elements of consent. *Check the elements of consent you are requesting to waive or alter:*

Basic Elements (*Unless a waiver is granted, basic elements of consent are required*) [\[45 CFR 46.116\(b\)\]](#):

- A Statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility
 - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements as Appropriate (*A waiver for these elements is only needed if the elements are applicable to your study. More information can be found here: [\[45 CFR 46.116\(c\)\]](#):*

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

Provide the details of the research activities and rationale for waiving or altering the elements of consent checked above:

2. The study involves only research activities that are no more than minimal risk to the subjects [\[46.116\(d\)\(1\) / 46.116\(f\)\(3\)\(i\)\]](#)

Yes No

Provide the details of the research activities and rationale for response:

3. The research activities could not be practicably carried out without the requested waiver or alteration. [\[46.116\(d\)\(3\) / 46.116\(f\)\(3\)\(ii\)\]](#)

Yes No

Provide rationale for this response:

4. 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. [\[46.116\(d\)\(3\) / 46.116\(f\)\(3\)\(ii\)\]](#)

Yes No N/A

Provide a rationale for this response:

5. The waiver or alteration will not adversely affect the rights and welfare of the subjects. [\[46.116\(d\)\(2\) / 46.116\(f\)\(3\)\(iv\)\]](#)

Yes No

Provide procedures for how subjects rights and welfare will be protected:

6. Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participation. [\[46.116\(d\)\(4\) / 46.116\(f\)\(3\)\(v\)\]](#)

Yes No N/A

Provide a rationale for this response, including a description of how participants or legally authorized representatives will be informed:

Waiver of Documentation of Informed Consent. Only complete this section if you are requesting a waiver of documentation of informed consent (waiver of the signature requirement).

1. The only record linking the subject and the research would be the informed consent form and the principal risk would be the potential harm resulting from a breach of confidentiality. [NOTE: If “Yes”, each subject (or legally authorized representative) should be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern]. [\[46.117\(c\)\(1\)\(i\)\]](#)

Yes No

Provide the details of the activity and rationale for response:

2. 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. [\[46.117\(c\)\(1\)\(ii\)\]](#)

Yes No

Provide the details of the activity and rationale for response:

3. If 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. [\[46.117\(c\)\(1\)\(iii\)\]](#)

Yes No N/A

Provide rationale for response:

4. Subjects or legally authorized representatives will be provided with a written statement regarding the research. [NOTE: A “Yes” response is not required but the IRB has the authority to require that a written statement be provided to subjects or legally authorized representatives.] [\[46.117\(c\)\(2\)\]](#)

Yes No

Provide rationale for response: