C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

CIRB WAIVER OF CONSENT REQUEST SUPPLEMENTAL FORM

OMB #0925-0753 Expiration Date: 07/31/2021

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: _____

If you are requesting a waiver of documentation of informed consent or alteration of consent, please complete the following supplemental form.

1. Is the research activity for which the waiver is required related to screening, recruitment or determining eligibility?
   ☐ Yes ☐ No

   If No, continue to section 2.
   If Yes, complete the following:

   1.1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative
   ☐ Yes ☐ No

   1.2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
   ☐ Yes ☐ No

2. A study must meet several criteria to qualify for a waiver of documentation of informed consent or alteration of consent. The questions below are designed to assist the CIRB in making this determination. Please provide your assessments below along with justifications. Alternatively, you may cite the protocol section and page number which provide this information as long as it is provided in lay language:

2.1. The research activity for which the waiver is requested involves no more than minimal risk;
☐ Yes ☐ No

If yes, provide a rationale:

2.2. The research could not practicably be carried out without the requested waiver or alteration;
☐ Yes ☐ No

If yes, provide a rationale:

2.3. 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;
☐ Yes ☐ No ☐ N/A

If yes, provide a rationale:

2.4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
☐ Yes ☐ No

If yes, provide a rationale:

2.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
☐ Yes ☐ No

If yes, provide a summary of how participants will be notified: