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

CIRB INITIAL REVIEW APPLICATION

OMB #0925-0753 Expiration Date 3/31/2026

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 60 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 support@ncicirbcontact.zendesk.com or 888-657-3711.**

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____
Please provide the protocol and consent form with this Protocol Version Date.

STUDY CHAIR	
Name	
Institution Name	
Phone Number	
Email	
ADMINISTATIVE ASSISTANT	
Name	
Email	
Phone Number	

CONTACT PERSON (Person to contact with questions about this application)	
Name	
Title	
Institution Name	
Phone Number	
E-mail	

ADDITIONAL CONTACTS (Persons or centralized email inboxes to be copied. Limited to four per study)		
	Name	E-mail
1		
2		
3		
4		

Please remember to notify the CIRB if this list updates throughout the approval period to ensure all necessary parties receive the proper correspondence.

1.0 Summary of Study

Please answer each of the following questions in 250 words or less per question.

1.1 Indicate the FDA Phase of the study. _____

1.2 Describe the purpose of this study (i.e. hypothesis or study objectives).
_____

1.3 Provide the rationale for the study, including a summary of the background research that has led to your hypothesis/objectives. _____

1.4 Explain the study design and how it is appropriate to obtain an answer to the hypothesis.
_____

1.5 Describe the study intervention.
_____

1.5.1 Describe the standard of care treatment for this cancer. _____

1.5.2 How does the proposed intervention differ from the standard of care? _____

1.6 Describe any exams, tests, and/or procedures that are required for the research and are NOT part of routine cancer care. _____

1.7 List inclusion/exclusion criteria for this study. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

1.8 Will study participants be required to discontinue or modify current medication or be denied standard of care for any non-cancer condition?
☐ Yes ☐ No

If yes, provide rationale. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

1.9 Describe the safety monitoring plan for this study. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

1.10 How will the information gained from this study impact the treatment for this disease or condition? _____

1.11 How will the research findings be disclosed to study participants? _____

2.0 Participants

2.1 Number of participants to be enrolled in the study: _____

2.2 Are participants under the age of 18 eligible to participate in this study?
☐ Yes ☐ No

2.3 Provide the protocol section and page number for the Planned Enrollment Report tables for ethnic and racial categories. _____

2.3.1 Are there zeroes in any of the categories in either chart?
☐ Yes ☐ No

If yes, provide a rationale for the exclusion _____

2.4 Informed Consent Process

Provide the protocol section and page number outlining the plan for obtaining consent (as required by 45CFR46.116)
_____

2.4.1 Will a full written consent be obtained?
☐ Yes ☐ No

If Yes, continue to section 2.5.
If No, complete 2.4.2, 2.4.3

2.4.2 Is a waiver of documentation or alteration of informed consent requested?
☐ Yes ☐ No

2.4.3 Is a full waiver of informed consent requested?
☐ Yes ☐ No

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.

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

Waiver or Alteration of 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.

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This form 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 support@ncicirbcontact.zendesk.com or 888-657-3711 or refer to the Waiver of Consent (WoC) QuickGuide.

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).*

☐ 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)(iii)]

   ☐ 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:

2.5 Vulnerable Populations

2.5.1 Indicate which of the following vulnerable populations are eligible to participate in the study and select the applicable safeguards listed below each eligible vulnerable population (as required by 45 CFR 46.111(b) and 21 CFR 56.111(b)).

a. Children ☐ Eligible ☐ Ineligible

Possible safeguards for children:
- ☐ Youth Information Sheets to facilitate assent
- ☐ Risk-appropriate clinical monitoring
- ☐ Researchers participating in the study are credentialed in pediatrics
- ☐ Additional Safeguards: _____

b. Prisoners ☐ Eligible ☐ Ineligible

The CIRBs are not constituted to review research for the inclusion of prisoners. Please indicate eligibility for sites not utilizing the CIRB. _____

c. Pregnant women ☐ Eligible ☐ Ineligible

Possible safeguards for pregnant women:
- ☐ Inclusion is scientifically appropriate based on preclinical studies
- ☐ Information is provided in the protocol pertaining to how study intervention could impact the woman and the fetus
- ☐ Information is provided in the consent form pertaining to how study intervention could impact the woman and the fetus
- ☐ Risk-appropriate clinical monitoring
- ☐ Additional Safeguards: _____

d. Persons with Impaired Decision-Making Capacity

☐ Eligible ☐ Ineligible

Possible safeguards for persons with Impaired Decision-Making Capacity:
- ☐ Protocol permits Legally Authorized Representative
- ☐ Protocol permits assent
- ☐ Additional Safeguards: _____

e. Economically Disadvantaged ☐ Eligible ☐ Ineligible

Possible safeguards for economically disadvantaged participants:
- ☐ Cost burden is fully explained in the informed consent document.
- ☐ No financial incentives are provided to study participants.
- ☐ Additional Safeguards: _____

f. Educationally Disadvantaged ☐ Eligible ☐ Ineligible

Possible safeguards for educationally disadvantaged participants:

☐ Investigators are encouraged to provide verbal explanation of the research in lay language
☐ Investigators are encouraged to provide extra time to answer questions
☐ Investigators are encouraged to include family members/significant others in the consent form process at the participant's request.
☐ Additional Safeguards: _____

g. Physically Disabled ☐ Eligible ☐ Ineligible

Physically Disabled
☐ Investigators are encouraged to consider the unique needs of the disabled when considering them as study participants.
☐ Risk-appropriate clinical monitoring
☐ Additional Safeguards: _____

2.5.2 Rationale for Ineligibility: Federal regulations [45 CFR 46.111(a)(3) and 21 CFR 56.111(a)(3)] require equitable selection of participants. If you checked "Ineligible" for any of the categories above, provide a scientific reason for the ineligibility. _____

2.6 Recruitment

NOTE: As a reminder, any recruitment material targeted to potential study participants must be CIRB-approved prior to distribution. For **CTEP studies**, please submit directly to the CIRB for review. For **DCP studies**, please submit to DCP Protocol Information Office (PIO) for an Approval On Hold prior to CIRB review.

2.6.1 Have any recruitment materials targeted to potential study participants (videos, brochures, letters, advertisements, etc.) been prepared for this study?
☐ Yes ☐ No

2.6.1.1 If yes, please attach a copy of the recruitment materials and a description of the plan for distribution. _____

2.6.2 Will any recruitment materials targeted to potential study participants (videos, brochures, letters, advertisements, etc.) be prepared for this study in the future?
☐ Yes ☐ No ☐ Unknown at this time

2.6.2.1 If yes, please provide a description of the materials to be prepared and the plan for distribution. _____ If draft version is available attach for reference.

2.6.3 Will the participants receive agents/drugs/biologics, tests, procedures, or medical care without charge?
☐ Yes ☐ No

2.6.3.1 If yes, please describe. _____

2.6.4 Are there any incentives for participating in this study?
☐ Yes ☐ No

2.6.4.1 If yes, please describe. _____

2.7 Costs

2.7.1 Will the study participants be responsible for any research-related costs?
☐ Yes ☐ No

If yes, please describe. _____

2.7.2 Are there any plans to subsidize these extra costs for study participants who cannot afford them?
☐ Yes ☐ No

If yes, please describe. _____

3.0 Agents/Drugs/Biologics

3.1 Please provide the following information for all agents/drugs/biologics used in this study. Sections for three agents/drugs/biologics have been provided. Copy and paste additional sections if needed.

Information for Agent/Drug/Biologic

a. Agent/drug/biologic name (generic and trade): _____
b. Manufacturer: _____
c. Provided by: ☐ NCI ☐ Manufacturer ☐ Other, _____
d. For this study, is the agent/drug/biologic being used under an IND?
☐ Yes ☐ No
If yes, please provide:
IND#: _____
Holder of IND: _____
e. Is there an Investigator's Brochure? ☐ Yes ☐ No
If yes, please provide a copy of the Investigator's Brochure.
f. Is the agent/drug/biologic being used off-label? ☐ Yes ☐ No

Information for Agent/Drug/Biologic

a. Agent/drug/biologic name (generic and trade): _____
b. Manufacturer: _____
c. Provided by: ☐ NCI ☐ Manufacturer ☐ Other, _____
d. For this study, is the agent/drug/biologic being used under an IND?
☐ Yes ☐ No
If yes, please provide:
IND#: _____
Holder of IND: _____
e. Is there an Investigator's Brochure? ☐ Yes ☐ No
If yes, please provide a copy of the Investigator's Brochure.
f. Is the agent/drug/biologic being used off-label? ☐ Yes ☐ No

Information for Agent/Drug/Biologic

a. Agent/drug/biologic name (generic and trade): _____
b. Manufacturer: _____
c. Provided by: ☐ NCI ☐ Manufacturer ☐ Other, _____
d. For this study, is the agent/drug/biologic being used under an IND?
☐ Yes ☐ No
If yes, please provide:
IND#: _____
Holder of IND: _____
e. Is there an Investigator's Brochure? ☐ Yes ☐ No
If yes, please provide a copy of the Investigator's Brochure.
f. Is the agent/drug/biologic being used off-label? ☐ Yes ☐ No

4.0 Investigational Medical Device

Please provide the following information for all investigational medical devices used in this study.

Use the Repeat button at the bottom of this Page to create new pages to capture each unique investigational medical device.

Investigational Medical Device

Do any devices involved in this study meet FDA's definition of investigational medical device (see instructions)? (Required) ☐ Yes ☐ No

For each device being used in the study provide the requested information:

Common and/or proprietary name (Required) _____

Manufacturer (Required) _____

Current FDA Status

Search for FDA status: : Registration and Listing, Databases for Approvals and Clearances, 510(k) Exemptions. (Required)

☐ PMA Approved
☐ 510(k) Cleared
☐ 510(k) Exempt
☐ Investigational/Not Approved
☐ Unknown

Include a summary of any discussion held with the FDA regarding the device and the current FDA determination regarding the use of the device. _____

Reference documents, including device manual, instructions, photos, specification sheets, or other relevant safety/device information, should be included for the CIRB to review. *Add Attachment*

If there are no reference documents, please explain why. _____

Will you be testing safety or effectiveness of the device? (Required)

☐ Testing device safety
☐ Testing device effectiveness
☐ Neither

Does the device qualify as a "General Wellness Device – Low Risk" (Review FDA Guidance for this determination)? (Required) ☐ Yes ☐ No

Explain how it meets FDA's criteria:(Required) _____

Does the device qualify as "Non-Medical Exercise Equipment"? (Required) ☐ Yes ☐ No

Explain how it meets the criteria: (Required) _____

Does the device's use in the study meet criteria for exemption by the FDA (Review Instructions for guidance)? (Required) ☐ Yes ☐ No

Explain how it meets FDA's exemption criteria: (Required) _____

Devices that do not qualify as a General Wellness Device – Low Risk, Non-Medical Exercise Equipment, or IDE Exempt are considered a "Regulated Medical Device" and must undergo a risk determination by the CIRB.

Specify if your device qualifies as Non-Significant Risk (NSR) or Significant Risk (SR)* (see Instructions). (Required)

☐ Non-Significant Risk (NSR)
☐ Significant Risk (SR)
☐ N/A

Provide information about the device's safety and potential risks, in relation to the study's proposed use. The IRB will make the final NSR/SR determination. If you have evidence of a prior determination (from a sponsor or the FDA), provide documentation. Review FDA's full guidance on Significant Risk and Nonsignificant Risk Medical Device Studies to make this determination.

*Note: Significant Risk (SR) devices require submission of an IDE application to FDA to obtain the agency's approval of the study. If you have an SR device, include the current status of the IDE application. You may submit a protocol to the CIRB while the IDE is pending, but final CIRB approval of your protocol will not be granted until the IDE has FDA approval. Review FDA's guidance on the IDE Approval Process. (Required) _____

Describe your procedures for device accountability:

How/where you will obtain the device(Required) _____

Storage/secure access (Required) _____

Dispensing to subjects (Required) _____

Tracking use and inventory (Required) _____

Disposal of device at the conclusion of the study (Required) _____

If you have written SOPs for these procedures, you may attach them separately to provide these details. *Add Attachment*

Describe your monitoring plan for ensuring protocol(s) are appropriately followed during the conduct of research. (Required) _____

Describe your plan for monitoring data and subject safety. (Required) _____

If you have written SOPs for these procedures, you may attach them separately to provide these details. *Add Attachment*

5.0 Radiation

5.1 Does this study involve radiation? ☐ Yes ☐ No
(If no, skip to Section 5.0.)

If yes, specify the type of radiation that the participant will receive:
☐ Diagnostic ☐ Therapeutic ☐ Both

5.2 Is any radiation modality or dose experimental?
☐ Yes ☐ No

If yes, describe. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

6.0 Surgery

6.1 Does the study question involve experimental surgery? ☐ Yes ☐ No
(If no, skip to Section 6.0.)

If yes, describe. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

7.0 Genetic Research

Genetic research is carried out on a continuum comprising of four stages: (1) to discover the pattern of inheritance of a disease and to catalog the range of symptoms involved (pedigree studies); (2) to localize and identify specific genes (positional cloning studies); (3) to develop techniques for determining the presence of specific DNA mutations (DNA diagnostic studies); and (4) to develop treatments for genetic disease at the DNA level (gene therapy research).

7.1 Will the research identify genetic characteristics? ☐ Yes ☐ No

If yes, complete this section. If no, go to Section 7.0.

7.1.1 Will the identified genetic characteristics be disclosed to the study physician?
☐ Yes ☐ No

If yes, will study participants be given the option to not have the identified genetic characteristics disclosed to the study physician? ☐ Yes ☐ No

7.1.2 Is it the plan to disclose the identified genetic characteristics to the study participant?
☐ Yes ☐ No

7.1.2.1 If yes, will study participants be given the option to not receive the results?
☐ Yes ☐ No

7.1.2.2 Describe how the identified genetic characteristics will be communicated to the study participant. _____

7.2 Describe the confidentiality measures taken to protect the data from disclosure to third parties. _____

7.3 For genetic research, describe the possible psychological and social risks. _____

6.3.1 Describe measures taken to minimize these risks. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

7.4 Describe the storage and security measures taken to protect the tissue or specimen samples. _____

7.5 What will happen to the tissue samples in the event that a participant withdraws from the study? _____

8.0 Medical Risks

8.1 Describe the known or foreseeable risks or discomforts, including reproductive risks for both women and men, by agent/drug/biologic or regimen for all agents/drugs /biologics to be used in this study as listed in section 3.0.

_____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

8.2 Describe the known or foreseeable risks or discomforts, including reproductive risks for both women and men, associated with the radiation modality to be used in this study as listed in section 4.0. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

8.3 Describe the known or foreseeable risks or discomforts, including reproductive risks for both women and men, associated with the surgery to be performed in this study as listed in section 5.0.

_____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

8.4 Describe the known or foreseeable risks or discomforts, including reproductive risks for both women and men, associated with procedures that are done for research purposes as listed in question 1.6.

_____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

8.5 List measures planned to minimize known or foreseeable risks or discomforts identified in Questions 7.1, 7.2, 7.3, and 7.4.

_____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

8.6 What are the medical criteria for withdrawing a participant from the study? _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

9.0 Non-Medical Risks

9.1 Describe measures taken to maintain the confidentiality of identifiable information. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

9.2 Are there any other non-medical risks associated with participation in this research (for example, psychological, social, economic, or legal risks)?
☐ Yes ☐ No

If yes, describe. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

10.0 Benefits

10.1 Describe the potential benefits of participating in the study. _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

10.2 Do the potential benefits outweigh the risks inherent in participating in the study?
☐ Yes ☐ No

If yes, explain. _____

11.0 Alternatives

11.1 Other than standard of care, what alternatives to participating in the research are available?

_____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

12.0 Storage of Specimens for Future Research Studies

12.1 Does this study involve collection of specimens for future research studies?
☐ Yes ☐ No

If no, skip to Section 12.0. If yes, complete this section.

12.1.1 Describe and justify the types of specimens to be collected, the procedure for collecting the specimen, and the amount of the specimen to be collected. _____

12.1.2 Will the specimens be linked to the study participants?
☐ Yes ☐ No

If yes, explain. _____

12.1.3 How will specimens be accessed and who will have access? _____

12.1.4 What will happen to the specimen if the study participant withdraws consent after the specimen has been collected?

_____

13.0 Ancillary Studies

13.1 Will study participants be asked to participate in any ancillary studies?

☐ Yes ☐ No

If yes, describe the study(ies). _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

13.2 Is participation in any other study required for participation in this study?

☐ Yes ☐ No

If yes, describe the study(ies). _____

You may cite the consent form or protocol section and page number as long as the information is provided in lay language; otherwise provide a lay language description here.

14.0 Materials Directed to Study Participants

NOTE: As a reminder, any material targeted to potential study participants must be CIRB-approved prior to distribution and requires a distribution plan describing how and when the submitted material will be distributed to study participants or potential study participants. For **CTEP studies**, please submit directly to the CIRB for review. For **DCP studies**, please submit to DCP Protocol Information Office (PIO) for an Approval On Hold prior to CIRB review.

14.1 Will study participants be asked to complete any forms such as Quality of Life (QOL) instruments or Patient Reported Outcome (PRO) questionnaires?

☐ Yes ☐ No

If yes, are these forms being submitted as part of the Initial Review Application?

☐ Yes ☐ No

If yes, please attach copies of the forms to be completed by study participants.

If no, please provide a description of the materials being prepared and the plan for distribution. _____ If a draft version is available attach for reference.

14.2 At time of enrollment will study participants be given any study-specific educational materials?

☐ Yes ☐ No

If yes, are the educational materials being submitted as part of the Initial Review Application?

☐ Yes ☐ No

If yes, please attach copies of any materials and the plan for distribution to study participants.

If no, please provide a description of the materials being prepared and the plan for distribution to study participants. _____ If a draft version is available attach for reference.

15.0 Conflicts of Interest

15.1 Does the Study Chair or any principal involved in the development or coordination of this study have any significant financial conflicts of interest as defined in the National Cancer Institute (NCI)/Division of Cancer Treatment and Diagnosis (DCTD) Conflict of Interest Policy for NCI/DCTD-supported Cooperative Group Randomized Phase 2 and Phase 3 Clinical Trials?

☐ Yes ☐ No If yes, please answer question 14.2

15.2 Is there a management plan in place to address the conflicts disclosed in question 14.1?

☐ Yes ☐ No

If yes, provide a copy of the management plan in place to address the conflicts disclosed.
If no, provide a rationale for why there isn't one in place. _____

Summary of CIRB-Requested Supporting Documents

☐ Word version of Consent form with the same Protocol Version Date as the protocol without change memo (REQUIRED)

The following materials are required, if applicable:

☐ Recruitment materials and distribution plans (Question 2.6.1.1)
☐ Investigator's Brochure(s) (Question 3.1.e)
☐ QOLs, PROs, or other materials to be completed by study participants (Question 13.1)
☐ Study-specific educational materials and distribution plans (Question 13.2)
☐ Management plan to address investigator conflicts of interest (Question 14.2)

The following materials are being submitted to the CIRB **for reference only** and will not be reviewed by the CIRB until final submission.

☐ Draft recruitment materials and distribution plan (Question 2.6.2.1)
☐ Draft QOLs, PROs, or other materials to be completed by study participants and distribution plans (Question 13.1)
☐ Draft study-specific educational materials and distribution plans (Question 13.2)