CIRB INITIAL REVIEW APPLICATION

OMB#: 0925-xxxx Expiration Date: xx/xx/xxxx

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 1 hour 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-xxxx*). 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: _____

Please provide the protocol and consent form with this Protocol Version Date.

STUDY CHAIR	
Name	
Institution Name	
Phone Number	
Email	
Administrative Assistant Name	
Administrative Assistant E-mail	
Administrative Assistant Phone Number	

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

1.0 Summary of Study

Please answer each of the following questions <u>in 250 words or less per question</u>.

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. _____

<u>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.</u>

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 Vulnerable Populations

2.4.1 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: _____

2.4.2 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. _____

2.5 Recruitment

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

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

NOTE: As a reminder, any recruitment material targeted to potential study participants must be CIRB-approved prior to distribution. We encourage you to submit drafts for review prior to final production.

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

2.5.2.1 If yes, please describe. _____

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

2.5.3.1 If yes, please describe. _____

2.6 Costs

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

If yes, please describe. _____

2.6.2 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 Radiation

4.1 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

4.2 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.

5.0 Surgery

5.1 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.

6.0 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).

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

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

6.1.1 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

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

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

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

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

6.3 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.

6.4 Describe the storage and security measures taken to protect the tissue samples.
_____

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

7.0 Medical Risks

7.1 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.

7.2 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.

7.3 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.

7.4 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.

7.5 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.

7.6 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.

8.0 Non-Medical Risks

8.1 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.

8.2 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.

9.0 Benefits

9.1 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.

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

If yes, explain. _____

10.0 Alternatives

10.1 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.

11.0 Storage of Specimens for Future Research Studies

11.1 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.

11.1.1 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. _____

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

If yes, explain. _____

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

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

_____

12.0 Ancillary Studies

12.1 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.

12.2 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.

13.0 Materials Directed to Study Participants

13.1 Will study participants be asked to complete any forms such as Quality of Life (QOL) instruments?

☐ Yes ☐ No

If yes, please include copies of any materials or instruments to be completed by study participants.

13.2 At time of enrollment will study participants be given any educational materials specific to the study?

☐ Yes ☐ No

If yes, please include copies of any educational materials specific to the study to be given to study participants as well as a description of the plan for distribution of the materials.

14.0 Conflicts of Interest

14.1 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.

14.2 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.

Summary of CIRB-Requested Supporting Documents

☐ Protocol upon which this application is based (REQUIRED)
☐ Consent form with the same Protocol Version Date as the protocol (REQUIRED)

The following materials are required, if applicable:
☐ Recruitment material and distribution plan (Question 2.5.1)
☐ Investigator's Brochure (Question 3.1.e)
☐ Management plan to address new or revised conflicts (Question 14.2)
☐ Forms intended to be completed by study participants (Question 13.1)
☐ Study-specific educational materials (Question 13.2)

Submit the completed application and the required supporting documents via email to adultcirb@emmes.com, earlyphasecirb@emmes.com, pediatriccirb@emmes.com, or cpccirb@emmes.com within 10 days of CTEP Approval-On-Hold date.