- **New Form: NCI Adult/Pediatric CIRB Application for Treatment Studies**
  New form combines Forms 5A and 5B to minimize and simplify form process. The questions being asked are the same for both Adult and Pediatric Applications for Treatment Studies. This facilitates and simplifies the process by implementing one form rather then having two separate forms. The form must be completed for either Adult or Pediatric Trial; therefore, there is not an increase or decrease in time to complete. The effort of burden remains the same.

NCI ADULT/PEDIATRIC CIRB APPLICATION FOR TREATMENT STUDIES

OMB#: 0925 – 0625 Expiry Date: 1/31/2014

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review is confidential and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 2 hours 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 (0925-0625*). Do not return the completed form to this address.

This application, when completed, contains information required by CIRB members to conduct a meaningful review of the study so answer each question as completely as possible. If an answer to any question cannot be provided, please provide an explanation for the missing answer. If you have any questions regarding the completion of this application, please contact the CIRB Helpdesk at 888-657-3711 or ncicirbcontact@emmes.com.

APPLICATION COMPLETION DATE: _____

GROUP STUDY ID NUMBER: _____

STUDY TITLE: _____

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

CTSU Menu? ☐ Yes ☐ No

STUDY CHAIR	
Name	
Title	
Institution/Address	
Phone Number	
E-mail	
FAX Number	
Administrative	

Assistant Name	
Administrative Assistant E-mail	
Administrative Assistant Phone Number	

STUDY CO-CHAIR (If applicable)	
Name	
Title	
Institution/Address	
Phone Number	
E-mail	
FAX Number	
Administrative Assistant Name	
Administrative Assistant E-mail	
Administrative Assistant Phone Number	

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

PLEASE NOTE: CIRB membership includes individuals who are not part of the scientific community. Therefore, you must use lay language (non-medical, non-legal terms) and define all terms unique to science when completing this application.

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. (Include schema.)

_____

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 part of routine cancer care. _____

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

1.8 List inclusion/exclusion criteria for this study. _____

1.9 Will study participants be required to discontinue or modify current medication or be denied standard of care for any non-cancer condition? _____

1.10 Describe the safety monitoring plan for this study. _____

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

1.12 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 Specify the age range of eligible participants: _____

If participants under the age of 18 years old are eligible, an assent form must be submitted.

2.3 Projected Enrollment Information at Study Institutions
For your convenience, we have retained the NIH formatting so that you can easily include the information in this application.

2.3.1 Describe the target population in terms of ethnicity:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total			

2.3.2 Describe the target population in terms of race:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
	Sex/Gender		
Racial Categories	**Females**	**Males**	**Total**
American Indian/Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Racial Categories: Total of all Subjects			

2.3.3 If there are zeroes in any of the categories in either chart, provide a justification for the exclusion. _____

2.4 Vulnerable Populations

2.4.1 Which of the following vulnerable populations are eligible to participate in the study?

a. Children ☐ Eligible ☐ Ineligible

b. Prisoners ☐ Eligible ☐ Ineligible

c. Pregnant women ☐ Eligible ☐ Ineligible

d. Persons with Impaired Decision-Making Capacity ☐ Eligible ☐ Ineligible

e. Economically Disadvantaged ☐ Eligible ☐ Ineligible

f. Educationally Disadvantaged ☐ Eligible ☐ Ineligible

g. Physically Disabled ☐ Eligible ☐ Ineligible

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. ____

2.4.3 If vulnerable populations are eligible to participate in the study, indicate safeguards included in the protocol to protect their rights and welfare per 45 CFR 46.111(b) and 21 CFR 56.111(b).

List of possible safeguards by vulnerable population:

a. Children
- ☐ Youth Information Sheets to facilitate assent
- ☐ Risk-appropriate clinical monitoring
- ☐ Researchers participating in the study are credentialed in pediatrics
- ☐ Additional Safeguards: _____

b. 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 informed consent document pertaining to how study intervention could impact the woman and the fetus
- ☐ Risk-appropriate clinical monitoring
- ☐ Additional Safeguards: _____

c. Persons with Impaired Decision-Making Capacity
- ☐ Protocol permits Legally Authorized Representative
- ☐ Protocol permits assent
- ☐ Additional Safeguards: _____

d. Economically Disadvantaged
- ☐ Cost burden is fully explained in the informed consent document.
- ☐ No financial incentives are provided to study participants.
- ☐ Additional Safeguards: _____

e. Educationally Disadvantaged

- ☐ 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 informed consent process at the participant's request.
- ☐ Additional Safeguards:_____

f. 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 Recruitment

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

If yes, please include a copy of the recruitment materials.

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

2.8.3.1 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 Does the Cooperative Group have 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 to be 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. _____

5.0 Surgery

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

If yes, describe. _____

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 11.0.

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

6.4 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.
_____

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. _____

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.
_____

7.4 Describe the known or foreseeable risks or discomforts, including reproductive risks for both women and men, associated with procedures pertaining to the research question.
_____

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.
_____

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

8.0 Non-Medical Risks

8.1 Describe measures taken by the Cooperative Group to maintain the confidentiality of identifiable information. _____

8.2 Describe the possible psychological and social risk associated with the genetic research, if applicable. _____

8.2.1 Describe measures taken to minimize these risks. _____

8.3 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. _____

9.0 Benefits

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

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, are there any alternative procedures or other courses of therapy for this cancer that could be used outside of the research?
☐ Yes ☐ No

If yes, explain. _____

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 For what types of research are study participants consenting to have the tissues used? _____

11.1.4 How will access to the specimens be governed? _____

11.1.5 What procedure will be used if the study participant withdraws consent after the specimen has been collected and stored?

_____

12.0 Ancillary Studies

12.1 Will study participants be asked to register in any ancillary/companion studies?

☐ Yes ☐ No

If yes, describe the study(ies) and indicate if the study(ies) is mandatory or option.

_____

NOTE ABOUT ANCILLARY STUDIES:

The CIRB reviews new ancillary/companion studies that have not been included in the main research study. Complete the Cooperative Group Ancillary Protocol Review Application - Treatment Studies.

13.0 Conflicts of Interest

13.1 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 Conflict of Interest Policy for Cooperative Group Phase 3 Clinical Trials?

☐ Yes ☐ No If yes, please answer question 13.2.

13.2 Does the Cooperative Group have a management plan in place to address the conflicts disclosed in question 13.1?

☐ 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)
☐ Informed consent document with the same Protocol Version Date as the protocol (REQUIRED)
☐ Recruitment material (Question 2.5.1, if applicable)
☐ Investigator's Brochure (Question 3.1.e, if applicable)

☐ Management plan to address new or revised conflicts (Question 13.2, if applicable)
☐ Materials for reconsenting participants (as outlined below, if applicable)

**** Special Section: Amendment-Specific Information****

This section should be completed only when this application is being updated as the result of an amendment to the study.

1.0 Briefly describe what prompted this amendment: _____

2.0 Are any of the changes in this amendment significant enough to impact a study participant's willingness to continue participation in the research?
☐ Yes ☐ No

2.1 If yes, describe how these findings will be presented to study participants.
_____

2.2 If yes, should the study participants be reconsented?
☐ Yes ☐ No

If yes, indicate how study participants will be reconsented (letter, addendum, reconsent). _____

Provide drafts of reconsent documents.

If you have any questions regarding the completion of this application, please contact the CIRB Helpdesk at 888-657-3711 or ncicirbcontact@emmes.com.

Thank you for completing the NCI Adult/Pediatric Application for Treatment Studies. Please submit the completed application and the required supporting documents via email to adultcirb@emmes.com or pediatriccirb@emmes.com.