NCI Adult/Pediatric CIRB Application for Ancillary Studies

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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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.

PART A
GENERAL INFORMATION

FORM COMPLETION DATE (Initial submission):

DATE OF CURRENT REVISIONS TO FORM INFORMATION:

COOPERATIVE GROUP:

GROUP STUDY NUMBER: CTSU PROTOCOL: ☐ **Yes** ☐ **No**

PROTOCOL VERSION AND DATE:

STUDY TITLE:

STUDY CHAIR

Name:
Title:
Specialty:
Site:
Address:
Phone Number:
E-mail Address:
FAX Number:

STUDY CO-CHAIR

Name:
Title:
Specialty:
Site:
Address:
Phone Number:
E-mail Address:
FAX Number:

CONTACT PERSON (Person to contact about this application if Chair not available)

Name:
Title:
Specialty:
Site:
Address:
Phone Number:
E-mail Address:
FAX Number:

PLEASE NOTE: CIRB membership includes individuals who are not part of the oncology and/or the scientific community. Therefore, you must use lay language and define all terms unique to science when completing this form.

PART B
SUMMARY OF STUDY

1. Briefly state the question that this study will answer (i.e. state the hypothesis):

2. Briefly describe the background research that has led to your hypothesis:

3. Briefly describe the study. (Include schema.)

4. How will the research design answer the hypothesis?

5. What significance will the new information gained from this study have?

PART C
SUBJECTS

1. Number of subjects to be enrolled in the study:

2. What is the age range of eligible subjects?

If subjects under the age of 18 are eligible, an assent form must be attached.

3. Which of the following groups are eligible to be subjects (Check each item yes or no. A "no" indicates that all persons in that category are excluded.):

Incompetent persons (excluding minors):	☐ **Yes**	☐ **No**

(Incompetent persons include those who have a legal guardian or those whose mental status prevents them from understanding the consent and making decisions [such as those with advanced Alzheimer's disease]).

Women of reproductive potential:	☐ **Yes**	☐ **No**
Pregnant women:	☐ **Yes**	☐ **No**
Men of reproductive potential:	☐ **Yes**	☐ **No**
Minorities:	☐ **Yes**	☐ **No**
Prisoners:	☐ **Yes**	☐ **No**

Explanation of Exclusion

Federal IRB regulations require equitable selection of subjects. In addition, NIH policy requires that minorities and women be adequately represented as research subjects. If you checked "no" to any of the categories above, you must provide a scientific reason for such exclusion:

4. Will the subject have specimens collected that would not be collected as part of standard care? (Either type or amount) ☐ **Yes** ☐ **No**

If yes, describe the means by which these specimens will be collected:

5. Will the subject have to make extra visits for specimen collection?
☐ **Yes** ☐ **No**

If yes,
a) Number of visits: _____
b) Frequency of visits: _____
c) Duration of visits: _____

6. Will the subjects bear any costs that are not a part of routine clinical care:
☐ **Yes** ☐ **No**

If yes, explain:

a) Please list the relevant tests, procedures, hospitalizations, etc., for which they would be liable.
b) Are there means of subsidizing these extra costs for subjects who cannot afford them? ☐ **Yes** ☐ **No**

If yes, explain:

PART D
RISKS, BENEFITS AND ALTERNATIVES

1. Describe any reasonably foreseeable risks or discomforts to the patient. Describe the frequency and complications associated with each.

2. Discuss measures taken to minimize risks.

3. How do you justify the risks inherent in participating in the study?

4. Describe any benefits to the subject or to others, which may be expected from the research (personal, social, scientific, etc.).

PART E
GENETIC RESEARCH

Does this study include genetic research on samples or tissues?* ☐ **Yes** ☐ **No**
If no, go to Part F.

***Human genetic research involves the study of inherited human traits. Much of this research is aimed at identifying DNA mutations that can help cause specific health problems, developing methods of identifying those mutations in patients, and improving the interventions available to help patients address those problems. Such research includes a) the analysis of human chromosomes or DNA from an individual and/or family members for the purpose of deriving information concerning the individual or family about the presence, absence, or mutation of genes, DNA markers, gene products or inherited characteristics or b) biochemical measurements of proteins and metabolites with the INTENT of collecting and**

evaluating information about heritable diseases and/or characteristics within a family.

If yes:

a) Why is this patient population appropriate for genetic research?

b) Will results be disclosed to the subjects? ☐ **Yes** ☐ **No**
If yes, describe in what way:

c) Will subjects be given the option of not receiving information about themselves?

d) Will the possible psychological and social risks of genetic research be adequately considered in the consent process? Will appropriate counseling be provided, both as part of the consent process and also when communicating test or other research results to subjects? Please explain.

e) Will subjects be informed about the possibility of incidental findings?

f) Will the data be protected from disclosure to third parties, such as employers and insurance companies? Describe confidentiality measures.

g) Will research findings be disclosed to subjects' physicians for clinical use? Will this plan be discussed with the subjects and their consent obtained?

h) Will vulnerable populations be adequately protected? ☐ **Yes** ☐ **No**

If yes, how?

i) What provisions have been made for protecting against misuse of tissue samples?

j) What provisions have been made for the treatment of data and tissue samples in the event of subject withdrawal from study?

k) Describe ways that subject's privacy and confidentiality will be protected when publications are planned.

PART F
STORAGE OF SPECIMENS FOR UNSPECIFIED FUTURE RESEARCH STUDIES

Does this study involve collection of specimens for unspecified future research studies? ☐ Yes ☐ No If no, go to PART G.

If yes:

a) What are the types and amounts of specimens to be collected? Justify the types and amounts.

b) Will you maintain identifying information or links to identifiers?

c) What information will be recorded?

d) Where will the tissue be stored?

e) For what types of research do you anticipate using the samples in the future?

f) Who will be responsible for distributing the tissue?

g) What steps will be taken to protect confidentiality?

h) What arrangements will you make with the clinical laboratories to guarantee that all clinically indicated procedures are completed?

PART G
FINANCIAL CONFLICT OF INTEREST

Definition: A financial conflict of interest exists or may appear to exist when a person has an economic interest in, receives funding or compensation from (for speaker's bureaus, advisory boards, research support, etc.), or acts as an officer of or a consultant to any organization or company whose financial interests would reasonably appear to be affected by this research.

1. Does any person who has a substantial role in: a) the decision about whether or not the study should be done; b) the design of the study; or c) the analysis or the management of the data from the study, have a financial conflict of interest or the appearance of a financial conflict of interest as defined above? ☐ Yes ☐ No

If yes, please explain.

2. Does any person as described in question #1 have a family member (spouse or dependent child) who has a financial interest in the study? ☐ Yes ☐ No

If yes, please explain.

3. Do individual investigators or sites receive additional funding for patient accrual to this study beyond that provided by the NCI? ☐ Yes ☐ No

If yes, please explain.

PART H
INFORMED CONSENT

Please attach a copy of the informed consent form for this protocol to this application form.

Please note: A Word or Word Perfect file containing the informed consent form(s) must also be emailed to the CIRB Project Office in order for this application to be considered complete.

Kindly send the CIRB application and the consent document in care of CIRB Contact at adultcirb@emmes.com or pediatriccirb@emmes.com. Thank you!