CIRB INITIAL REVIEW APPLICATION
FOR EXEMPT STUDIES

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 30 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-xxxx*). Do not return the completed form to this address.

This application is designed to help determine whether or not the study qualifies for exemption from CIRB review. If he study is determined to be exempt you will receive a letter from the CIRB Operations Office documenting the determination. If CIRB review is required, a separate application will be sent.

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 Determining Whether the Activity is Human Subjects Research

Please answer each of the following questions. Space is provided with each question to provide a brief explanation. Providing an explanation may assist in making a timely determination with minimal need for follow-up.

1.1 Is the study a systematic investigation designed to develop or contribute to generalizable knowledge?

☐ Yes, proceed to question 1.2.
☐ No. The activity is not research. Skip to section 3

You may provide an explanation for your answer in the space below:

_____

1.2 Does the study involve obtaining information about living individuals?

☐ Yes. Proceed to question 1.3
☐ No. The activity is not research involving human subjects. Skip to section 3.

You may provide an explanation for your answer in the space below:

_____

1.3 Does the study involve prospective intervention or interaction with the individuals?

☐ Yes. The activity is research involving human subjects. Skip to section 2.
☐ No (proceed to question 1.3.1)

You may provide an explanation for your answer in the space below:

_____

1.3.1 Is the information **individually identifiable** (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?

☐ Yes (proceed to question 1.3.2)
☐ No. The research is not research involving human subjects. Skip to section 3.

You may provide an explanation for your answer in the space below:

_____

1.3.2 Is the information **private**? (about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.)

☐ Yes. Unless the note below applies, the activity is research involving human subjects, proceed to question 2.0.

☐ No. The activity is not research involving human subjects. Proceed to section 3.0.

You may provide an explanation for your answer in the space below:

_____

Note: Per OHRP's "Guidance on Research Involving Coded Private Information or Biological Specimens", OHRP does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.

2.0 Determining Whether the Research is Exempt from CIRB Review

Please answer each of the following questions. Space is provided with each question to provide a brief explanation. Providing an explanation may assist in making a timely determination with minimal need for follow-up.

2.1 Does the research involve prisoners?

☐ Yes (**STOP** – the research cannot be exempt. Contact the CIRB Coordinator to request an application for initial review by the CIRB.)

☐ No (proceed to question 2.2)

2.2 Does the research involve children?

☐ Yes (proceed to question 2.2.1)

☐ No (skip to question 2.3)

2.2.1 Does the research involving children include survey or interview procedures or observation of public behavior?

☐ Yes (proceed to question 2.2.2)

☐ No (skip to question 2.3)

2.2.2 Will the investigators participate in the activities being observed?

☐ Yes (STOP – the research cannot be exempt. Contact the CIRB Coordinator to request an application for initial review by the CIRB.)

☐ No (proceed to question 2.3)

2.3 Will the ***only*** involvement of human subjects be in one or more of the following categories?

NOTE: If there is involvement of human subjects in activities beyond those described in the categories below, the research cannot be exempt. Contact the CIRB Coordinator to request an application for initial review by the CIRB.

Space is provided with each category to provide a brief explanation. Providing an explanation may assist in making a timely determination with minimal need for follow-up.

2.3.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

2.3.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

2.3.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

2.3.4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

2.3.5 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

2.3.6 Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ Yes
☐ No

You may provide an explanation for your answer in the space below:

_____

3.0 Additional Documentation

If sections 1 and 2 of this application indicate that the activity is not human subjects research or is exempt human subjects research, submit this application along with additional documentation (e.g. protocol or research plan) to include the following information:

- The rationale for the study, including a summary of the background research that has led to your hypothesis/objectives.
- An explanation of the study design and how it is appropriate to obtain an answer to the hypothesis.
- A description of procedures including efforts to maintain confidentiality of data (such as how data will be de-identified and measures to prevent re-identification of individuals).
- Copies of any surveys or scripts for interviews.
- A description of possible risks of the research and efforts to mitigate risks.

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.