Black Hawk College
Exempt Status Application
Form A

If you believe your research is exempt, submit a narrative statement in support of your "exempt status" for review to the IRB subcommittee. You are to specifically address the category into which your research falls to make it exempt. You are to address the issues of "minimal risk." Finally, if conducting potentially exempt survey or interview research you are to address the issues of "informed consent" and "confidentiality." If the IRB does not concur with your determination that the research is exempt, they will articulate in writing why they believe your research is not exempt. Once you receive their response, you can request a hearing before the full IRB Committee. The full IRB Committee will then render a decision regarding the exempt status, with their decision being final. The full IRB Committee will articulate their decision in writing. Additionally, all research conducted at the College requires a yearly review and reauthorization. The reauthorization must be approved before the twelfth month of the original approval.

Research is exempt from full committee review if the project meets the following requirements:

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from review by the Black Hawk College IRB. This determination is based on the exempt categories established in Title 45 CFR part 46, Protection of Human Subjects: [1]

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

B) 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 identifies 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.

C) 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.

D) 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.

E) 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.

F) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food 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.

….and the research involves minimum risk, which is defined as:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life/or during the performance of routine physical or psychological examination or tests.

….furthermore, obtained informed consent for research that involve survey or interview procedures, such consent is to include:

a) a fair explanation of the procedures to be followed including reference to data gathering techniques.
b) a description of any risks by participating in the research
c) a description of any benefits by participating in the research study
d) a specific instruction that the participant is free to decline participation and is free to withdraw consent and discontinue participation at any time without loss of benefits or negative consequences.

…..additionally, assurance of confidentiality for research that involves survey or interview procedures through meeting the following expectations:

a) responses that record information obtained is done in such a manner that human subjects can not be identified, directly or through identifiers linked to the specific subjects

Black Hawk College
Summary of Research Involving Human Subjects
FORM B

*A member of Black Hawk College faculty must be principal investigator, co-investigator or faculty sponsor for projects utilizing human subjects in research. The faculty member is considered the responsible party both for content of the application and for subsequent supervision of the project. In order to facilitate project approval, it is necessary that the application is complete and that all required information is included in the application. Delays in approval are frequently a result of insufficient information. Insert N/ A if not applicable.

Principal Investigator(s)* _____

Check one: Faculty _____ Undergraduate _____Staff_____

Department _____ Phone number _____

Mailing Address _____

Email _____

Faculty Sponsor* (if applicable) or Co-investigator _____

Check one: Faculty _____Undergraduate _____ Staff _____

Department _____Phone number_____

Mailing Address _____

Email _____

Co-investigator _____

Check one: Faculty _____Undergraduate _____ Staff _____

Department _____Phone number_____

Mailing Address _____

Email _____

Project Title

_____

Course Number and Name (if research is a class project)

_____

Proposed Starting Date_____ Proposed Completion Date_____
MM/DD/YY MM/DD/YY

Filing Status (Please check one)** ____ Exempt _____ Nonexempt

Note one year limitation for Research Review

****The IRB should receive four (4) COPIES OF ANY Exempt proposal and ten (10) copies of any Nonexempt proposal.**

OFFICE USE ONLY - PLEASE DO NOT FILL IN

Date Received_____ Copies to_____

Review Date_____ Action Taken_____

PLEASE ATTACH THE INFORMATION BELOW TO FORM B

If you are eligible for exempt status, include items 1-5 and skip questions 6-11. If you are applying for nonexempt status, please answer all questions, 1-11. All individuals must sign the investigator's assurance.

1. Briefly describe the methods and procedures to be used during this research project. Include: a short paragraph describing the purpose and objectives of this research and a description of the subject population.

2. Include a copy of any questionnaire, survey, testing instrument, participant instructions, etc. to be used in this project.

3. Describe the methods by which informed consent will be obtained from the subjects (include a copy of the informed consent document, survey, cover letter of instructions, etc.)

4. Provide information regarding any other approvals which have been or will be obtained (e.g., school districts, cooperating institutions).

5. Sign investigator's assurance.

6. Describe the overall purpose and primary objectives of the project.

7. Briefly describe the subject population (Le. sample) to be used. Also describe the procedures for identifying or obtaining the subjects, subject compensation (if any), and the research procedures to be used in treating or obtaining information from the subjects.

8. Briefly describe the procedures to be used to assure the confidentiality of subject data specifically addressing whether subjects will be identifiable from raw and/or refined data, how such data will be protected from non-project personnel, whether the identifiable data will be destroyed when no longer needed, and whether project publications will allow identification of individual subjects. Describe how subject's welfare will be safeguarded (e.g. through screening of risk-prone individuals or ensuring availability of psychological or medical aid). Where appropriate, describe also the methods to be used to ensure the confidentiality of subjects' data and/or responses.

9. Describe the potential risks to subjects that may result from the project. Provide a frank description of potential risks (physical, psychological, social, legal or other) to subjects, together with assessment of their likelihood and seriousness. If methods are to be used which create risks, explain why these methods are suggested in preference to others which might not entail such risks. If no risk is seen, indicate why unless it is obvious to a non-specialist.

10. Describe the potential benefits to subjects or society that may result from the project. Provide an assessment of the potential benefits of the investigation for both the research participants and society in general.

11. Provide an explanation of how the benefits of the project justify the risk to research participants.

Black Hawk College
Research with Children
Form C

Research with children is especially sensitive due to their vulnerable status. Any research conducted with children will be held to the highest standards. "Children" is defined as anyone who has not reached a legal age of 18 by the beginning of their participation in the research study. Before the age of 18, consent can only be given in specific situations. Instead, assent is assessed from child participants in research. Assent is defined as "- a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent." (Definitions - 45 CFR 46.402)

A child's ability to assent should be assessed by researchers and based on appropriate understandings of child development, level of maturation, and level of duress from parents, guardians and researchers. At any time, if a child deems his/her participation in the research in question, assent should be deemed withdrawn.

As Wards of the state hold unique status in our society, In the event that Wards of the state will be included in research, an advocate must be appointed for the child. The advocate must have previous knowledge of the child, agree to be the child's representative and be committed to act in the child's best interest, at the beginning of and for the duration of, the research study.

Legally emancipated minors may assent to participate in research in research, with the consent of a self-appointed advocate for the consent procedure. If no advocate can be found that will act in the best interest of the minor, participation can not move forward. Any individual who has reached legal age of 18 may act as an advocate if appointed by the minor.

In addition to assent from the child participant, permission from a parent or guardian (as defined by local statute) is required for the child to participate in research at Black Hawk College.

An assent form needs to be prepared to garner written or verbal assent from research participants. The assent form needs to be targeted to children's age, level of maturity, appropriate understanding for the research study in language and all attempts at communication written and verbal. The document needs to secure assent after explaining the details of the study, potential risks, potential benefits, outline of what to expect within the confines of the study, what "assent" means, and the ability to withdraw "assent".

A consent form needs to be prepared to acquire written consent from the parent or guardian for the child, and in the case of Wards of the state, appropriately appointed advocates.

It is very rare that the IRB committee will consent to waiving parental consent in the situation of children's research. Within the case of parental custody situation, both parents with any partial or full custodial arrangement must consent to the child's participation in research. Where this disagreement between parents or guardians can not be resolved regarding the child's participation, the child may not participate in research.

Four separate categories are usually given to children who are included in research.

For any protocol involving children, the IRB must determine which of the four categories of research apply to that study, if any. OHRP recommends that the IRB document the rationale for this choice.

The HHS regulations at 45 CFR part 46, subpart D permit IRBs to approve three categories of research involving children as subjects:

45 CFR 46.404 - Research not involving greater than minimal risk to the children.

To approve this category of research, the IRB must make the following determinations:

the research presents no greater than minimal risk to the children;

and

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

45 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.

To approve research in this category, the IRB must make the following determinations:

the risk is justified by the anticipated benefits to the subjects;

the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; ***and***

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

45 CFR 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.

In order to approve research in this category, the IRB must make the following determinations:

the risk of the research represents a minor increase over minimal risk;

the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;

the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; ***and***

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

A fourth category of research requires a special level of HHS review beyond that provided by the IRB.

45 CFR 46.407 - Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the

understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

If the IRB believes that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406, but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, it may refer the protocol to HHS for review. The research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) the following:

> the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
>
> the research will be conducted in accordance with sound ethical principles; ***and***
>
> adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

For more information on the HHS 45 CFR 46.407 review process see OHRP Guidance, Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process [PDF - 37.5KB]