

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: <sup>1</sup>

- 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 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.
  
- 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