# Instructions

* Complete and submit this form when there are any questions of whether an activity meets the federal definition of “human subject research.”
* **Submit the following documents in addition to this form:**
	+ Informed consent
	+ Research Design/Protocol
	+ Proof of Primary Researcher Training
		- The HSIRB has determined that a minimal amount of training needs to be completed by the primary researcher for a proposed project to be approved or considered exempt.
			* MINIMAL TRAINING IS DEFINED AS ONE OF THE FOLLOWING OPTIONS:
				1. One of the two CITI Training for investigators. Free for LCC Employees and students.

Group 2: Social, Behavioral, Educational Researchers

###  or

Group 3: Students

* + - * 1. Free training found on the Association of Clinical Research Professionals (ACRP) webpage
				2. Training provided by home institution of the investigator
		- Minimal training will be proven by submitting a Certificate of Completion, from any of the defined training options, to the HSIRB. Date of Certificate must be after January 20, 2019 and within 3 years of the proposal submission.
	+ Survey/interview questions (if applicable)
	+ Other documents that may apply (recruitment brochures, rubrics, etc.)
	+ Department conditional approval plan or department letter of approval to conduct research on LCC students or employees
	+ If working with an institution(s) other than Lansing Community College, as part of this research, we will need a copy of that institution’s IRB approval or exemption status documentation.
* Only certain activities require LCC HSIRB approval. These include activities that meet the federal definition of research involving human subjects. If it is determined that the activity is not “human subject research”, and is not otherwise subject to LCC HSIRB review, a determination letter will be provided. See the LCC HSIRB Policy for more information, a downloadable pdf can be found on the [LCC HSIRB Website](https://www.lcc.edu/consumer-information/institutional-review-board.html).
* Submit completed form and documents to: lccirb@star.lcc.edu

# Contact Information

* If you have questions about completing this form, please contact us at 517-483-1123 or lccirb@star.lcc.edu

Lansing Community College is committed to providing equal employment opportunities and equal education for all persons regardless of race, color, sex, age, religion, national origin, creed, ancestry, height, weight, sexual orientation, gender identity, gender expression, disability, familial status, marital status, military status, veteran's status, or other status as protected by law, or genetic information that is unrelated to the person's ability to perform the duties of a particular job or position or that is unrelated to the person's ability to participate in educational programs, courses services or activities offered by the college.

The following individuals have been designated to handle inquiries regarding the nondiscrimination policies: Equal Opportunity Officer, Washington Court Place, 309 N. Washington Square Lansing, MI 48933, 517-483-1730; Employee Coordinator 504/ADA, Administration Building, 610 N. Capitol Ave. Lansing, MI 48933, 517-483-1875; Student Coordinator 504/ADA, Gannon Building, 411 N. Grand Ave. Lansing, MI 48933, 517-483-1885; Sarah Velez, Human Resource Manager/Title IX Coordinator, Administration Building, 610 N. Capitol Ave. Lansing, MI 48933, 517-483-1874; Christine Thompson, Student Title IX Coordinator, Gannon Building, 411 N. Grand Ave. Lansing, MI 48933, 517-483-1261.

# Form

## Title:

*Click or tap here to enter title.*

## If this form relates to a previously submitted IRB application, please provide the title of the related project and the name of the original requester:

*Click or tap here to enter text if applicable.*

## Name of individual completing form and contact information (email/phone/address):

*Click or tap here to enter name.*

## Please list any collaborations with other institutions along with their contact information.

*Click or tap here to enter text if applicable.*

## Provide a brief description of your project including a description of your methodology, your project outcomes, timeline for data collection, and your plans to protect the identity of your subjects:

*Click or tap here to enter text.*

## Are there any potential conflict of interest/coercion in this study? [Conflicts of interest exist when potential power dynamics exist that could compromise the consent of the human subjects.]

### Are you affiliated with LCC as an employee, member of the Board of Trustees, or current student?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Are you a family member of an LCC employee, member of the Board of Trustees, or current student?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Are any participants students, employees, colleagues, or subordinates where grades, incentives, evaluations, or any appearances of authority over the subjects might coerce, convinces, or skew participation?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Do you have any sort of relationship related to the research or research site, regardless of compensation?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Are you doing research on a technology, process, or product, where there is a potential for personal financial gain, patentable invention, or trademark?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Are you doing research on a technology, process, or product, owned by a business in which you or a family member holds a financial interest?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

### Other potential conflicts not addressed above?

[ ]  YES [ ]  NO

*If yes, please describe the conflict and management plan here:*

## **A.** Is the activity a systematic investigation?

[ ]  YES [ ]  NO

***Systematic*** means having or involving a system, method, or plan including plans for analyses.

***Investigation*** means a searching inquiry for facts; a detailed or careful examination.

***To be considered a “systematic investigation,” the concept of the activity must:***

* Attempt to answer research questions;
* Is methodologically driven, i.e. collects data or information in an organized and consistent way;
* Data or information is analyzed in some way, be it quantitative or qualitative;
* Conclusions are drawn from the results.

Please explain:

*Click or tap here to enter explanation.*

## **B.** Is the activity designed to develop or contribute to generalizable knowledge?

[ ]  YES [ ]  NO

***Designed*** (differentiated from intended) means proficiently structured to develop or contribute to generalizable knowledge.

***Contribute*** means to result in or help to cause.

***Generalizable*** means universally or widely accepted to apply to a population beyond the site or population studied.

***Knowledge*** means conclusions expressed, for example, in theories, principles, and statements of relationships in a particular discipline or body of knowledge.

***Generalizable knowledge*** means such knowledge contributes to an already established theoretical framework or body of knowledge, and that these results are expected to be generalized to a larger population beyond the site of data collection, or population studied.

Please explain:

*Click or tap here to enter explanation.*

## Is the activity research?

[ ]  YES [ ]  NO

***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Please explain:

*Click or tap here to enter explanation.*

## Does the activity involve human subjects?

[ ]  YES [ ]  NO

***Human subjects*** means a living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information.

***Intervention*** means both physical procedures by which data are gathered, and manipulations of the subject or subject’s environment that are performed for research purposes.

***Interaction*** means communication or interpersonal contact between investigator and subject (e.g. this includes surveys, interviews, and focus groups).

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

Please explain:

*Click or tap here to enter explanation.*

## Do you believe that your project should be classified as exempt based on one or more of the criteria found in the list below?

[ ]  YES [ ]  NO

**If yes, please explain which exemption category describes your project and your rationale here. Please note, the IRB reserves the right to make the final determination on exemption status for research projects involving human subjects:**

*Click or tap here to enter exemption category and rationale.*

**Criteria for Exemption Categories (45 CFR 46.104):**

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(3) (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

***Please note that categories 7 and 8 require limited IRB review for broad consent and privacy protections.***