Manhattan College IRB- Frequently Asked Questions (FAQ's)

1. **What is an Institutional Review Board (IRB)?**

Manhattan College's Institutional Review Board (IRB) considers projects proposed by faculty, students and administrators involving the use of humans or animals as participants in research. The IRB Committee must approve any proposal before the research can be conducted. Completed applications should be submitted well in advance of when you plan to begin data collection.

2. **How do I know if I am conducting research with human subjects?**

Human subjects are "living individuals about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, identifiable private information." Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g, providing stimuli to gauge reaction and response).

Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews).

Private information includes:

- 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 (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of a participant is associated with the information or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

If you are unsure if your project involves research with human subjects, please consult with IRB staff who can provide guidance in making this determination.

3. **When am I required to submit a proposal involving research with human participants to the IRB?**

All research projects that will involve human participants must be submitted for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

4. **I am just doing a simple survey; do I need to submit my proposal to the IRB?**

Yes, if the study meets the definition for research with human participants, as explained above. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

5. **I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review?**

Yes, if your research project involves active data collection. Federal regulations and Manhattan College policy require that ALL research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the research study.

6. **What is meant by "exempt" protocol? What are the requirements?**

Research activities in which the only involvement of human subjects will be in one or more of the exempt categories defined by the federal regulations, will be given an exempt determination, rather than IRB approval.There are six (6) exempt categories:

- *Category 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.

  Examples: Evaluating the use of accepted or revised standardized tests, testing or comparing a curriculum or lesson, a program evaluation of pharmacy continuing education

- *Category 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.

  Examples: Surveying teachers, nurses, or doctors about a technique or an outcome, interviewing managers about a management style or best practice, conducting a focus group about an experience or an opinion of a community program.

- *Category 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 (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.

Example: Interviewing public officials about a local or global issue.

- *Category 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.

  Example: Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers.

- *Category 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.

- *Category 6* (See also FDA's Exempt Category)- 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.

  FDA Exempt Categories 21 CFR 56.104- Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
  Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

  Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

  Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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. **What are the IRB requirements for training?**

At Manhattan College, all investigators and research staff must successfully complete the CITI program training in the ethical conduct of research with human participants.

8. **Who is required to complete the human participants training?**

All faculty, students, and staff proposing to use human participants in research under the auspices of Manhattan College are required to complete the human participants training.

9. **How can I take the required training?**

You can access the CITI program website at www.citiprogram.org, then, proceed to click on “Register” button to being the registration process. Please remember to affiliate with Manhattan College and provide your manhattan.edu email address when registering.