TYPES OF RESEARCH REVIEWED BY THE IRB

For the purposes of the Rocky Mountain College Institutional Review Board policies, and in accordance with the Code of Federal Regulations, Title 45, Part 46, **Research** *"means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities" (source: The Code of Federal Regulations, Title 45, Part 46.102(l).*

The Institutional Review Board (IRB) recommends that investigators carefully consider which type of research review of their proposed research is most appropriate before submitting a research protocol. The IRB conducts three types of research reviews:

1. **Exempt Review**, in which the investigator submits a modified protocol that is then treated as an expedited review and is subsequently exempt from continuing review;
2. **Expedited Revie**w, in which reviews are conducted by a subcommittee of the IRB; and
3. **Full Review**, which requires review by the full IRB at a convened meeting.

The IRB also requires that parties conducting class-based or program evaluation-style research with human subjects submit materials to the IRB to notify the IRB of their intent to work with human subjects and to request a non-reviewable determination letter.

While researchers must make a preliminary judgement about which type of review they should apply for, the IRB is responsible for determining if a proposal requires full review, expedited review, or is exempt from review. Standard requirements for informed consent apply regardless of the type of review — exempt, expedited, or full (convened) — utilized by the IRB.

Please be aware that research covered by this policy that has been approved by the Rocky Mountain College IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Please contact the office of the Provost <phone: 406.657.1020> to learn more about Rocky Mountain College's Institutional Officials. However, those officials may not approve the research if it has not been approved by an IRB.

The following review levels and definitions are drawn from The Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), published by the Office for Human Research Protections defines the following review levels and definitions:

EXEMPT REVIEW

Research that qualifies for exempt review is exempt from review by the full committee and from continuing review, unless otherwise specified by the IRB. In order for human subject research to qualify for exempt review the research must pose **minimal risk** (little to no risk) to subjects and the research must fit one of the following categories laid out in Code of Federal Regulations, Part 46, section 104 (see Table 1., below). According to 45 CFR 46.102 (f), ***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 examinations or tests". Click here to examine Office for Human Research Protections (OHRP) decision charts address decisions on whether IRB review may be performed by **expedited procedures.**

Investigators please note:

- If your research involves minors, pregnant women, prisoners or other vulnerable populations it is not eligible for review under the "Exempt" category and must be reviewed at the "Expedited" or "Full" level.
- If identification of participants and/ or their responses would reasonably place them at risk of criminal or civil liability or damage to reputation or financial or academic standing, employability, reputation, or be stigmatizing it is not eligible for review under the "Exempt" category and must be reviewed at the "Expedited" or "Full" level **unless** reasonable and appropriate protections are implemented so that risks related to loss of confidentiality are no greater than minimal.

- Standard requirements for informed consent apply regardless of the type of review — exempt, expedited, or convened — utilized by the IRB.

Table 1. Exempt categories.

Category 1 - Research conducted in established or commonly accepted educational settings, involving normal educational practices such as	● research on regular and special education instructional strategies **OR** ● research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Category 2 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:	● information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects **AND** ● 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; **AND** ● 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 section 16.111(a)(7).
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 category 2 of this section, if:	● the human subjects are elected or appointed public officials or candidates for public office; **OR** ● federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter
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** ● the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects
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:	● public benefit or service programs; ● 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.
Category 6 - Taste and food quality evaluation 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 FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Requests for exemption will be reviewed by the IRB Chair and/or IRB Administrator and/or IRB subcommittee. If this review determines the research to be exempt, a memorandum of concurrence will be sent to the investigator. The title of the research and the decision will be recorded and reported to the IRB at its next meeting. Any member of the IRB may request that the investigator submit a full application for expedited or full IRB review.

EXPEDITED REVIEW

Certain kinds of research that involve minimal risks to participants may be approved by expedited review or by the IRB Chair or by one or more experienced reviewers designated by the Chair from among the members of the IRB, according to policies and procedures in section 110 of 45 CFR 46. According to 45 CFR 46.102 (f), *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 examinations or tests". Reviewers may exercise all of the authorities of the IRB except that reviewers may not disapprove the research. Research activity may only be disapproved after review in accordance with the non-expedited procedure set forth in §46.108(b).

FULL (CONVENED) REVIEW

Research involving human participants or their data that poses greater than minimal risk or that is not eligible for exempt or expedited review must be reviewed by the convened IRB. Protocols requiring full review fit one or more of the following criteria:

- greater than minimal risk;
- minimal risk activities that do not meet the criteria of the expedited categories;
- Sensitive topics;
- involve vulnerable subjects requiring additional protections (e.g. minors, prisoners, cognitively disabled individuals, pregnant women).

The IRB convenes monthly throughout the academic year, and once in the summer (usually August). The IRB accepts full board submissions year round, and protocols requiring full review will be placed on the next available meeting agenda.

CLASS-BASED or PROGRAM REVIEW-STYLE RESEARCH, NOT FOR DISSEMINATION

Many in-class and program review-style projects that use human subjects are not systematic or generalizable -- i.e. they are not intended to use surveys, tests, or evaluation in order further generalizable knowledge in the field via publication or another form of dissemination outside of the classroom or institutional setting. Instead, they are intended to fulfill part of a course requirement. This style of class research project does not fit the technical definition of "research" as spelled out in federal code 45cfr46. Therefore, such projects do not need to be submitted for IRB review.

It is crucial, however, that such class-based research projects be conducted in a manner that (i) protects the confidentiality of participants, (ii) is not coercive, (iii) aligns with the procedures established by the Rocky Mountain College IRB, and (iv) aligns with the ethical standards associated with the field of inquiry (e.g. for a psychology class, these would be American Psychological Association ethical standards). For this reason, researchers conducting in-class, not for dissemination research must use the Track 2 submission portal on moodle to notify the IRB of their intent to conduct research activity involving human subjects. Once the Track 2 materials have been submitted, the IRB will review them and issue a non-reviewable determination letter.

In order to ensure that class-based research projects that involve human subjects are conducted in a way that protects the rights and interests of said human subjects, faculty members advising and/or assigning the projects as well as students and or/staff who interact with the projects' human subjects or their data are required to complete the CITI program training for Social & Behavioral Research.

Click here to read the technical definition of "research" as spelled out in federal code 45cfr46.

Please Note: Data collected for a class project or a program review-style project may not be used for publication or presentation, unless the project was reviewed and approved by the IRB prior to recruitment and data collection. Should there be any possibility of or intent to publish, present, or otherwise disseminate research data or findings outside the course in the future (e.g., for a Senior Paper, a Master's Thesis, by the instructor), thereby making the data generalizable and meeting the definition of research, an application must be submitted for review and approval by the IRB prior to the start of recruitment and data collection.

Examples of Track 2 (non-reviewable) projects include:

1. **Class-based research projects designed specifically for educational or teaching purposes** and the results **WILL NOT be disseminated** outside of the class setting nor used to contribute to generalization knowledge;
2. **Program evaluation-style projects** where results will be used only to evaluate and/or improve programs (i.e. will be used only for an institution's own operational monitoring and program improvement purposes) but for which the results **WILL NOT be disseminated** outside of the institutional setting nor used to contribute to generalization knowledge.

Examples of Track 2 projects that may appear to be T2 projects but, in fact, are actually considered research (and should be reviewed using the T1 process):

1. Projects involving human subjects that will be presented at the RMC Undergraduate Symposium or a similar event.
2. Thesis and dissertation activities that involve human subjects.
3. Surveys and interviews with RMC students that will be used to inform the development of higher education and or administrative best practices among small private colleges.