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**EXEMPT APPLICATION FORM INSTRUCTIONS**

This application is for the submission of research for initial review of any kind that investigators believe to be **EXEMPT**.

**PLEASE ALSO INCLUDE YOUR PROTOCOL FORM AND CONSENT OR WAIVER OF CONSENT FORM**

**Study activities may not be implemented until the investigator receives written IRB notice of approval.**

**If you have any questions, please contact the Montreat IRB chair at:**

**irb@montreat.edu**

|  |  |
| --- | --- |
| **STUDY TITLE** |  |

**PRINCIPAL INVESTIGATOR**

|  |  |  |
| --- | --- | --- |
| **1.** | Name: | Degree(s): |
| Department: | Phone: |
| Campus Address: | Email: |
| ☐ Faculty                    ☐ Staff                     ☐ Student | |
|  | | |
| **2.** | **If student:** | |
| ☐ Traditional Undergraduate Student | ☐ Graduate or Adult Student  (degree program): |
| Faculty Advisor: | |
| Email: | |
| Phone: | |

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| --- | --- | --- | --- |
| **3.** | Which category of exempt does your study fall under? Reference: **HHS** **§46.104 Exempt research.** | | |
| ☐ | **1: Educational Setting** | 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: Educational tests, surveys, interviews, and observations of public behavior** | **Must meet at least one of these criteria:**  (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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)). |
| ☐ | **3: Benign behavioral interventions with adults** | **Must meet at least one of these criteria:**  (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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)). |
| ☐ | **4: Secondary research for which additional consent is not required** | **Must meet at least one of these criteria:**  (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: Other** (Please provide rationale below) |  |

**PLEASE ATTACH YOUR PROTOCOL FORM AND CONSENT OR WAIVER OF CONSENT FORM**