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**INSTRUCTIONS**

This application is for the submission of research for initial review of any kind.

If you believe your research is **EXEMPT**, submit the Exempt Application Form.

**Use lay language and spell out acronyms. Do not cut and paste from or refer to a grant or abstract.**

**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 at** **irb@montreat.edu****.**

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| **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:       |

**ADDITIONAL CONTACT PERSON (if applicable)**

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| You can name a person other than the PI as an additional contact for questions about the research. The PI will still be copied on all correspondence. |
| **3.** | Name:       | Phone:       |
| Title:       | Email:       |
| Home Department:       |

**STUDY LOCATION**

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| **4.** | Will the research be conducted at a physical location in the U.S. external to Montreat College? | ☐Yes  ☐ No |
| **If yes,** provide the following:  ***\*Attach a separate sheet if more than 2 external sites.*** |
| **Name of Site** | **City/State** | **Does this site have its own IRB?** |
|       |       | ☐ Yes – must attach IRB approval or waiver☐ No – must attach letter of support **Note**: IRB or support letters must be dated and should be on the site’s letterhead |
|       |       | ☐ Yes – must attach IRB approval or waiver☐ No – must attach letter of support **Note**: IRB or support letters must be dated and on the site’s letterhead |
|  |
| **5**. | Will any part of this research be conducted outside the United States? | ☐ Yes  ☐ No |
| **If yes,** complete **SUPPLEMENT: INTERNATIONAL RESEARCH** |

**RESEARCH PERSONNEL (other than the PI)**

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| **INSTRUCTIONS:** All Montreat and non-Montreat “**key personnel**” must be identified and complete the required training. ***Key personnel*** are defined as individuals who participate in the design, conduct (including data analysis), or reporting of human-subject research. At a minimum, include individuals who recruit participants, obtain consent, interact with participants, or collect and/or analyze identifiable study data. If the individual for an anticipated position is unknown at this time, a “Change in IRB-Approved Research” must be submitted and approved prior to that individual becoming involved in the research. ***\*Attach a separate sheet if you need more space for additional personnel.*** |
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| **6.** | **Name & Degree(s)** | **Role** | **Study Responsibilities** |
|       |       |       |
| ☐ MC    ☐ Other Institution:       |
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|       |       |       |
| ☐ MC    ☐ Other Institution:       |
|  |
|       |       |       |
| ☐ MC    ☐ Other Institution:       |
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|       |       |       |
| ☐ MC    ☐ Other Institution:       |

**FUNDING**

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| --- | --- |
| **7.** | Indicate the type of funding for this research: |
| ☐ | No external or internal funding.  |
| ☐ | Internal funding.    ☐ Approved    ☐ Pending Identify source(s):  ☐ Program funds ☐ Department funds ☐Other:       |
| ☐ | NON-FEDERAL External funding.   ☐ Approved    ☐ PendingList source(s) (no initials or acronyms):      Is Montreat the primary awardee?  ☐ Yes  ☐ No. If no, identify the primary awardee:      Has this proposal been submitted to the VPAA? ☐ Yes  ☐ No  |
| ☐ | FEDERAL External funding.   ☐ Approved    ☐ PendingList source(s) (no initials or acronyms):      Is Montreat the primary awardee?  ☐ Yes  ☐ No. If no, identify the primary awardee:      Has this proposal been submitted to the VPAA? ☐ Yes  ☐ No  |
| Does your research meet the definition of a clinical trial\*? ☐ Yes  ☐ No\*Clinical Trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. |
| ☐ | Intend to submit for funding. From whom?      Date of submission:      Has this proposal been submitted to the VPAA? ☐ Yes  ☐ No  |
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**TYPE OF SUBMISSION**

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| Select the item below that best describes the risk\* level for this research: ☐ Greater than minimal risk.\*\* Full Board review required. Skip to question #11. ☐ Minimal risk but the research includes radiation. Full Board review required. Skip to question #11. ☐ Minimal or no known risks. May be eligible for expedited review – answer question #10 below.\***Risk** means the potential for harm or discomfort. Risks can be physical, psychological, social, legal, or economic.\*\* **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. [FDA 21 CFR 56.102(i); HHS 45 CFR 46.102 (i)] |
| If your research involves:              ☐ N/A    |
| ☐ | Investigational/approved drugs, biologics, or dietary supplements |  | Submit **SUPPLEMENT: Drugs, Biologics, Supplements, and Botanicals** |

**RECRUITMENT**

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| --- | --- |
| **10.** | Identify the age group to include all subjects:       |
| Proposed number of research subjects:       |
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| **11.** | Does your research involve: |
| ☐ | Minors (as defined by the location where the research will occur)  |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** |
| ☐ | Pregnant women, fetuses, or neonates |  | Additional regulations apply. |
| ☐ | Prisoners |  | Additional regulations apply. |
| ☐ | Adults who are unable to consent for themselves (diminished decision-making capacity) |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** |
| ☐ | Students recruited in an educational setting (in class or at school; Montreat or non-Montreat)  |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** |
| ☐ | Montreat employees or faculty  |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** |
| ☐ | Non-English speaking  |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** |
| ☐ | Non-readers (due to physical impairment, illiteracy, or reading disorder) |  | Your consent form must contain a witness signature line. |
|  |
| **12.** | Does this research target one gender or a specific social, ethnic, or racial group? |  ☐ Yes  ☐ No |
| **If yes,** provide scientific rationale:       |
|  |
| **13.** | How do you plan to recruit subjects? **NOTICE**: **All** recruitment materials must be submitted for IRB review and approval prior to use.* Materials must be in their final format, including all images, colors, etc. (i.e., how they will be seen by potential subjects).
* If eligibility screening over the phone will take place, a script must be submitted.
* Placeholders for contact information that is unknown at the time of submission are allowable.
 |
| ☐ | Print Materials (flyer, brochure, letter, newspaper ad, etc.) | ☐ | Online/Mobile/Social Media (website, web posting, Facebook, Twitter, etc.) |
| ☐ | Email or text | ☐ | Personal Contact |
| ☐ | Audio Ads (radio or TV) | ☐ | From a database of individuals who have given prior permission to be contacted for research |
| ☐ | Referrals (from whom?)       | ☐ | Other:       |
| \*For radio and TV ads, scripts should be submitted with the recording. To avoid unnecessary production costs, pre-approval of scripts is highly recommended.  |

**CONSENT**

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| **14.** | Will any written or verbal screening materials to pre-screen individuals prior to consent be used? (e.g., telephone script, written or web-based screening forms, or questionnaires.)   | ☐ Yes ☐ No |
| **If yes,** describe the screening plan:      **NOTE**: Any scripts, forms, or questionnaires used for pre-screening must be submitted to the IRB. |
|  |
| **15.** | Check all that apply to your research: |
| ☐ | Written consent from adult subjects (or LAR\*) |  | Submit Consent Form(s). |
| ☐ | Written parental permission from parents/guardians of minor subjects |  | Submit Parental Permission Form(s) |
| ☐ | Written assent from minor subjects |  | Submit Assent Form(s) (older minors, e.g., 14+, may be assented on the parental permission form) |
| ☐ | Consent/Permission/Assent will not be obtained  |  | Submit **Request for Waiver or Alteration of Consent**  |
| ☐ | Verbal or Online consent from adult subjects  |  | Submit **Request for Waiver of Documentation Of Consent** |
| ☐ | Verbal or Online permission from parents/guardians of minor subjects  |  | Submit **Request for Waiver of Documentation Of Consent** |
| ☐ | Verbal or Online assent from minor subjects  |  | Submit **Request for Waiver of Documentation Of Consent** |
| \*LAR = Legally Authorized Representative. This is an individual who consents on behalf of another adult who does not have the legal capacity to consent to research. |
|  |
| **16.** | Will the research involve incomplete disclosure/deception to subjects?(i.e., some features of the research will not be revealed to subjects until after the research is concluded). | ☐ Yes   ☐ No |
| **If yes**, answer the following:1. Explain how the incomplete disclosure is truly necessary to accomplish the goals of the research:        2. Are there undisclosed risks to subjects that are more than minimal? ☐ Yes   ☐ No3. Participants should prospectively agree to incomplete disclosure/deception. Will the consent process contain notice that incomplete disclosure/deception is involved? ☐ Yes   ☐ NoIf no, explain why not:      4. Describe an adequate plan for debriefing subjects, when appropriate:       |

**SUBJECT INCENTIVES & COSTS**

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| --- | --- | --- | --- |
| **17.** | **a.** | Will subjects be paid or offered a monetary incentive?**If yes,** indicate the total possible amount (including any completion bonuses):       |  ☐Yes  ☐No |
| **b.** | **Payment Plan:** Indicate when subjects will be paid (e.g., at the end of each visit, at the end of the study, after each completed survey, etc.), and the amount each time.      **\*Note:** For studies conducted over multiple visits/days, payments should be prorated to compensate subjects for time and visits/procedures completed. Holding payment until the end of the study or requiring a subject to complete the entire study is potentially coercive or unduly influencing and requires justifiable rationale. |
| **c.** | How will subjects be paid (e.g., cash, check, gift card, etc.)?      |
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| **18.** | Will subjects be given any tangible gifts (e.g., t-shirt, mug, tote bag) or services without charge?**If yes**, describe and provide the value of any gifts or services:       |  ☐ Yes  ☐ No |
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| **19.** | Will subjects receive extra credit or course credit?**If yes**, an equivalent alternative to research participation must be provided. Describe:       |  ☐ Yes  ☐ No |
|  |
| **20.** | Will all subjects receive the same payment, gift, or other incentive?**If no**, describe the incentive plan and explain why it is appropriate for this research:        |  ☐ Yes  ☐ No       ☐ N/A |
|  |
| **21.** |  Will subjects be reimbursed for any expenses?**If yes,** describe:      **\*Note**: Expenses should only be reimbursed with appropriate documentation (e.g., receipt). A flat amount to help cover expenses is considered a payment, not a reimbursement. |  ☐ Yes  ☐ No |
|  |
| **22.** | Are there any potential costs to subjects (or his/her insurance) as a result of participating in the research?**If yes,** describe the costs:       |  ☐ Yes ☐ No |
|  |
| **23.** | Who will be financially responsible for the treatment of any psychological or physical problems that appear to be caused by participation in the research? (e.g., local infection due to blood draw, emotional distress, etc.)?  |
| ☐ | N/A – minimal risk research | ☐ | Study Sponsor  |
| ☐ | Subject  | ☐ | Other. Explain:       |

**SAFETY & DATA MONITORING**

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| **24.** | Who will review this study on an ongoing basis for purposes of safety, data integrity, and adherence to the protocol? |
| ☐ | Principal Investigator (appropriate for minimal risk/low-risk research) | ☐ | The committee managed by the principal investigator |
| ☐ | Independent Monitor (e.g., data monitoring committee or data safety monitoring board) | ☐ | Other:       |
| **Note**: A description of the data and safety monitoring plan must be included in the protocol.  |

**PRIVACY/CONFIDENTIALITY**

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| **25.** | Check the identifiers that will be collected **at any point in the research**, even if they will be destroyed at a later time.       ☐ No identifiers will be collected or recorded. |
| ☐ | Names or initials | ☐ | Telephone or fax numbers |
| ☐ | Any geographical subdivision smaller than a state, including street address, city, county, precinct, and zip code | ☐ | Any element of a date (except the year) that is directly related to the individual (e.g., birth date, diagnosis date, admission date, etc.) |
| ☐ | Email addresses | ☐ | URLs or IP address numbers |
| ☐ | Any identifying number (e.g., student ID, medical record, social security or national ID, health insurance, account, certificate/license, vehicle identifiers and serial numbers, license plates, driver’s license) | ☐ | Full face or other identifying video/photographic images (e.g., tattoos, scars) |
| ☐ | Digital or online identities (e.g., avatars, personas, screen names, etc.) | ☐ | Biometric identifiers (e.g., fingerprints, voiceprints, dental x-rays, retinal scans, handwriting, etc.) |
| ☐ | Genetic information | ☐ | Any other unique identifying number, characteristic, or code |
| If any of the above boxes are checked, how long will the identifiers be kept?      |
|  |
| **26.** | If you are collecting identifiers, will a coding system\* be used?\*For privacy purposes, a **coding system means** a random unique ID is assigned to each subject’s data, and a separate document (key) is maintained that links the subject to the ID number. |  ☐ Yes  ☐ No ☐ N/A |
| **If yes**, who will have access to the key?      How long will the key be kept?       |
|  |
| **27.** | Does this study involve the collection of information from student school/university records? (If yes, FERPA requirements may apply.) | ☐ Yes  ☐ No |
|  |
| **28.** | Is it possible or planned that any data collected for this research will be used for other research in the future **not** **related** to the proposed research? | ☐ Yes  ☐ No |
|  |
| **29.** | Is this research being conducted at a location outside of MC that is a HIPAA-covered entity (such as a health care clinic or hospital)?         |  ☐ Yes ☐  No |
| **If yes,** identify the location:       |
| **If yes,** please note that no protected health information (PHI) should be brought onto campus of Montreat College or saved on any Montreat system unless certain conditions are met. **Check the appropriate box:**☐ All data I receive from a HIPAA-covered entity will be DE-IDENTIFIED prior to coming into my possession and/or being transferred to any Montreat system.☐ This research requires identifiable protected health information to be conducted. I will work with the IRB to make sure appropriate conditions are met. |

**CONFLICT OF INTEREST**

|  |  |  |
| --- | --- | --- |
| **30.** | Does the PI or any research staff have a financial conflict of interest?         |  ☐ Yes ☐ No |
| **If yes,** identify the conflict of interest:       |
| **If yes,** has the conflict of interest been reported to the IRB?  |  ☐ Yes ☐ No |
|  |

**Principal Investigator Attestation**

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| --- |
| By submitting this form electronically, you (the Principal Investigator or designee) are certifying the following: (check to indicate that you have read each one)☐ The information contained in this report is true, complete, and accurate to the best of your knowledge.☐ The research will be conducted in accordance with applicable laws, regulations, and Montreat College policies and procedures.☐ Research records will be kept for at least 3 years after completion of the research (a longer period may be required by the sponsor, funding agency, or the HIPAA Privacy Rule)☐ As the Principal Investigator, you are aware that you are ultimately responsible for the conduct of this research and the individuals to whom you delegate research responsibilities. |