**IRB Research Protocol Application**

For office use only

Protocol #:
Date Received:

*This form is to be used for ALL new protocols.*

The Colorado Mesa University (CMU) Institutional Review Board (IRB) must review all projects that involve human participants. The IRB will determine whether the project meets federal guidelines and constitutes human participants research. **The project may not start until IRB approval is granted**. If the duration of the project exceeds the length of the approval period, a Request for Continuation must be submitted one month before approval expires.

**Note:** CMU policy requires that all persons listed on this document show successful completion of training in the protection of human participants in research. Please attach CITI training completion report for all listed persons. This protocol will not be reviewed until all CITI training records are attached. *Further instructions are in red.*

|  |
| --- |
| **General Submission Instructions:** |
| 1. This form is the application to request approval for your human subjects research.
2. If you are unsure if your research is human subjects research, please see the FAQ content here: <https://www.coloradomesa.edu/sponsored-programs/irb/index.html>
3. This application should be used for *new* protocols not previously approved by the IRB.
4. Proofread the protocol before submission. Spelling and grammar errors can make a difference in meaning.
5. Make sure all titles and labels are consistent.
6. All submitted protocols must be signed and dated.
7. Student research must be reviewed, signed and dated by the advisor.
8. Attach all support documentation to this protocol by saving this document as a PDF and using the Tools > Organize Pages function in Adobe Acrobat to combine this document and any/all attachments into a single PDF file.
9. Include the following IRB Approval statement in both the Informed Consent and Recruitment areas:

“This study has been reviewed and approved by Colorado Mesa University (CMU) Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies.  If you have questions or concerns regarding this study, please contact the Principal Investigator (Provide the name of one or more researchers who can be reached for assistance. If you are a student, provide your advisor’s name and contact information, too. The IRB recommends that researchers not include home addresses, personal emails or private cell phone numbers). If you have any questions regarding your rights as a research participant, please contact the Office of Sponsored Programs at (970) 248-1424 or irb@coloradomesa.edu. 1. Send completed electronic submission, as one PDF file, to irb@coloradomesa.edu.
2. To maintain proper record keeping, all communication with the IRB or the IRB Administrator must be through irb@coloradomesa.edu.
3. Questions may be addressed to the IRB Administrator at irb@coloradomesa.edu or by telephone at (970) 248-1424.
 |

|  |
| --- |
| **SECTION 1** *NOTE: CMU Investigators should use their CMU email address for IRB documentation and communication.* |
| **Principal Investigator:**        | **Email:**       |
| **Department:**       | **Phone:**       |
| **CITI training number:**       | **CITI Human Subjects completion** **date:**       |
| *If Principal Investigator (PI) is a student:* |
| Faculty Advisor/Chair of thesis or dissertation committee:        | CMU Email:       |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
|  |  |
| Co-Principal Investigator 1:       | Email:       |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
| Co-Principal Investigator 2:       | Email:        |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
| Co-Principal Investigator 3:       | Email:        |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
| Co-Principal Investigator 4:       | Email:       |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
| Co-Principal Investigator 5:       | Email:       |
| Department:       | Phone:       |
| CITI training number:       | CITI Human Subjects completion date:      |
|  |  |
| **Basic Project Details:** |
| **Project Title:**  |
| Is this project externally/internally funded? | Choose Yes or No |
| If so, please indicate the funding source:       |
| Is this project requested by a third party? *If so, please elaborate here.* | Choose Yes or No |
| Is the data for this study already collected and available to the public? *If data is derived from a proprietary data set, secondary analysis or any other combination, please elaborate here.* | Choose Yes or No |
| **Description of Human Participants:** |
| Are participants members of a protected/vulnerable class? * Under 18 years of age
* Confined in a correctional or detention facility
 | Choose Yes or No Choose Yes or No |
| Will personal records/data be collected without informed consent? | Choose Yes or No |
| If collected, will personal records/data be directly or indirectly identifiable? | Choose Yes or No |
| Is any of the research conducted at a location other than CMU? | Choose Yes or No |
| If yes, where:       |

|  |
| --- |
|  **SECTION 2. Describe the purpose of the project** |
| *Provide a brief (1-2 paragraph) description and explanation of the purpose of this project, including the significance of the research, and the research question(s).*      *\*(If a third party requested the project, also answer the following: Who is the requesting party? What is their request? What is the PI’s relationship with third party?)*       |

|  |
| --- |
|  **SECTION 3. Describe the methods and procedures** |
| *Describe the data collection procedures and what participants will have to do: If potentially sensitive information is collected in an interview or if there is concern about participants’ or the investigators’ safety, please address procedures to protect the participants’ confidentiality and/or participants’ and investigators’ safety during data collection.*       |
| *How long will this take participants to complete?*       |
| *Will follow-ups or reminders be sent? If so, explain (address the frequency, the modality, and attach a copy of the message):*       |

|  |
| --- |
| **SECTION 4. Describe the recruiting procedures** *(Please attach copies of all recruitment materials such as fliers, ads, phone scripts, emails, etc.)* |
| *Who will be recruited? Who are the participants? If this is an adult sample, how are the PI(s) verifying that participants are 18 or older? If applicable how are PI(s) informing participants they must be 18 or older?*       |
| *How will participants be approached about participating in the study?*       |
| *How will the names and contact information for participants be obtained?*       |

|  |
| --- |
| **SECTION 5. Describe compensation** |
| *Will compensation be provided to participants?* | Choose Yes or No |
| *If YES, please describe amount and type of compensation including money, gift certificates, extra credit, etc. If the study involves compensation through lottery, identify the odds of winning. If the study involves extra credit provide an explanation of the alternative activity participants are provided, and how much influence the extra credit might have on a student’s grade.*       |
| *When will compensation be given? How much participation is required to earn the incentive? What happens if the participant quits before completions or skips some questions? The PI(s) must state what happens to the data in these cases.*       |
| *Will compensation be paid by CMU?* | Choose Yes or No |
| *What participant information is required?* The consent form should cover the information that is required for payment and the length of time their information is retained by the payment system.       |
| *How will you avoid compensation having a coercive effect on participants (i.e., that they will feel compelled to participate to earn compensation)? How will the participants’ identity be kept confidential while allowing for compensation or extra credit to be awarded?*       |

|  |
| --- |
| **SECTION 6. Conflict of Interest** |
| *State any financial or other relationships that are held by you or any individuals or institutions involved in the research which could create perceived or actual conflict of interest*:       |
| *State whether you or any individuals or institutions involved in the research will receive any compensation other than a grant award:*       |
| *Describe what reasonable and appropriate actions you plan to take to protect participants from the influence of the above conflict of interest:*       |
|  |
| **SECTION 7. Benefits and Risks** |
| *Explain the benefits to participants or to others. State benefits in probabilistic terms such as may or might (i.e., may lead to better services). There must be some benefits either to the participants (direct benefits) or to others (indirect benefits).*       |
| *Are there any known or anticipated risks to participants greater than those experienced in daily life? If no, then this statement can be used in the consent form: “There are no anticipated risks greater than those experienced in daily life.”* | Choose Yes or No |
| *If YES, explain the risks.*       |
| *What will be done to minimize the risks? For projects that make a statement that counseling is not provided remember that there may be community resources available. Provide some examples. The CMU Student Wellness or Mind Springs Mental Health Center is often a good solution.*       |
|  |
| **SECTION 8. Informed Consent** (Please attach copies of informed consent/assent forms, emails, and/or letters. If participants are under 18 you must attach consent forms for parents or guardians.) Please describe your consent process, even if you believe this project is not human participants research and you have no formal consent form.  |
| *How will informed consent / assent be obtained?*       |
| *Are you requesting a* ***waiver of a signed consent form****?**Providing participants with informed consent information is always required. However, requesting a* ***waiver of a signed consent form*** *may be appropriate for situations such as:** *Low-risk, online, survey research, in which the participant consents to participate by checking a box; or*
* *Sensitive research, in which a signed consent form may put the participant at undue risk.*

*Tell us how participants can get a copy of the Informed Consent Form (i.e., screen shot, paper, attached to recruiting e-mail, downloadable pdf, other).* | Choose Yes or No |

|  |
| --- |
| **SECTION 9. Confidentiality** (Anyone who will collect, see or have access to the raw data must be CITI certified, and have their certification document [CITI Completion Report] attached to this protocol.) |
| *How will participant confidentiality be maintained? Address how the participants’ identity and data will be protected during data analysis and when the data is reported.*       |
| *How will confidentiality of records be maintained? Address how the participants’ identity will be protected when the data is reported. If you are using direct quotes, audio, or video clips, etc. these are identifying information and measures to protect confidentiality must be included.* A non-exhaustive list of identifying information is at the end of this form. Combining categories will often identify an individual. Aggregating data may lower this risk when cell sizes are 5 or greater.       |
| *Who will be collecting the data? In most cases these individuals will need CITI training.*       |
| *Who will be able to see or have access to the raw data? List everyone who has access to the raw data. This can include those who collect data, if they can see it, and those who analyze it. Submit CITI verification for anyone with access to the data.*       |

|  |
| --- |
| **SECTION 10. Data Security**  |
| *How will data be reported? List all the ways the data will or might be disseminated. Also list whether the data will be reported individually or in aggregate. If aggregated, what is the smallest cell size that will be reported? If the project was requested by another party is the data reported by that party? If so how? To whom will data be reported? Are there plans to present at a conference or publish? Will data only be reported to a third party?*       |
| *Where will the records be stored during data collection and analysis? Be specific.*       |
| *Records must be kept for three years beyond the life of the study. Where will the records/data be kept and who will have access? If the PI is a student, the advisor must have access to the data.*       |
| *What security measures are in place to protect the data during data collection, data analysis, and the 3-year storage?*       |
|  |

|  |
| --- |
| **SECTION 11. Attachment List** |
|[ ]  *CITI Training Records for all personnel. Do not send the certificate but rather the completion report that shows the completed modules.* *(Social & Behavioral Research Investigators Training and/or relevant training to the research purpose such as Biomedical are required.* *The CMU policy on training in the protection of human participants can be found at* [*https://www.coloradomesa.edu/sponsored-programs/irb/index.html*](https://www.coloradomesa.edu/sponsored-programs/irb/index.html)*)*  |
|[ ]  *Consent Forms and/or Assent Forms (See templates and guidelines at* [*https://www.coloradomesa.edu/sponsored-programs/irb/index.html*](https://www.coloradomesa.edu/sponsored-programs/irb/index.html)*)*  |
|[ ]  *Site Letter of Support or Permission (Students must include a signed letter from the appropriate functionary at each site indicating that they are aware of the plan to conduct a study and what the study entails. Others must include a draft of such a letter.)* |
|[ ]  *Recruiting Materials (Include the IRB approval statement (General Submission Instructions, Part F).)* |
|[ ]  *Questionnaire, survey, etc. (For online surveys attach a pdf or screenshots showing exactly what the participant sees. Make sure to include how the participant indicates consent.)* |
|  |

|  |
| --- |
| **Required Signatures:** |
| ***OPTIONS:*** *(1) Insert an image of your signature, such as those freely created and saved through sites like* [*SignWell*](https://www.signwell.com/online-signature/) *OR (2) Print this document, once completed but for signatures, sign, and scan the document with your signature.*  |
| **Principal Investigator (PI) Signature and Date:** **Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
|  *IF Primary Investigator (PI) is a student…* |
| **Advisor/Sponsor Signature and Date:** **Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
| **Advisor:** After reviewing, please send completed protocol package from your CMU e-mail account to irb@coloradomesa.edu. |
| **Co-Principal Investigator 1 Signature and Date:****Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
| **Co-Principal Investigator 2 Signature and Date:****Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
| **Co-Principal Investigator 3 Signature and Date:****Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
| **Co-Principal Investigator 4 Signature and Date:****Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |
| **Co-Principal Investigator 5 Signature and Date:****Signature:** {insert signature here}**Date:** Click for date. |
| [ ]  | By checking this box and typing or signing my name and date below, I certify that the information provided above is correct and that this research will be conducted in accordance with federal regulations and CMU IRB policies and procedures on research with human participants. |

**Non-exhaustive List of Identifying information.**

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic or code