COLORADO MESA UNIVERSITY

Institutional Review Board
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Human Subjects Research IRB Protocol Submission Guide

This form is intended to be used as a guide to prepare your responses for submission in Cayuse. This is not a substitute for completing a study submission in Cayuse. Please do not submit this document.

* = Question is required.

Your Research Team

*** 1: Under which status are you conducting research at Colorado Mesa University?**

We understand that a researcher may at times be both an adjunct professor and a graduate student (e.g. within the Nursing DNP program), or a staff member and a graduate student (e.g. while working on an MBA). Please select the role you are in as a researcher. (Meaning, if you are researching for your MBA capstone project, select that you are a graduate student).

- Faculty
- Staff
- Student
- Other

***2: Research Team Members**

- *Principal Investigator:
- *Primary Contact:
- Co-Principal Investigator(s):
- Other Investigators:
- Other Study Personnel:

Quick Screening Questions

Section 1: Third Party Driven Research

Definition: A third party (not CMU or any on the research team) contributes or donates cash or services (i.e. material/personnel/equipment) or other allowable items to the project.Examples of third-party funding:

- In-kind support of materials, e.g. drugs, devices, reagents
- In-kind support of services, e.g. laboratory services
- Financial support through a charitable third party that works in collaboration with CMU and that manages, accounts for, and distributes funds to study investigators in accordance with CMU program plans
- Financial support provided directly to a CMU-supported investigator for use in accordance with study plans

***Was this research requested by a third party?**

- **If yes:**
  - **Who is the requesting party?**
  - **What is their request?**
  - **What is the PI's relationship to the third party?**

Section 2: Funding Source(s) Screening Questions

Research funding is a term generally covering any funding for scientific research, in the areas of natural science, technology, and social science. Different methods can be used to disburse funding, but the term often connotes funding obtained through a competitive process, in which potential research projects are evaluated and only the most promising receive funding.

***Does your study have funding?**

- **If yes:**
  - **How is your study being funded? Internally or Externally**
    - **If external, please describe the funding source:**

Section 3: Biomedical Research Screening Questions

Biomedical research is the broad area of science that looks for ways to prevent and treat diseases that cause illness and death in people and in animals. This general field of research includes many areas of both the life and physical sciences. Utilizing biotechnology techniques, biomedical researchers study biological processes and diseases with the ultimate goal of developing effective treatments and cures. Biomedical research is an evolutionary process requiring careful experimentation by many scientists, including biologists and chemists. Discovery of new medicines and therapies requires careful scientific experimentation, development, and evaluation.

***Does your research qualify as biomedical research?**

- **If yes, also answer the supplemental biomedical research questions on page 13**

Section 4: Multi-Institutional Study Screening Questions

***Is this a multi-institutional study? (E.g., another university collecting data on their site in addition to data collection occurring at a CMU site.)**

- **If yes, also answer the supplemental multi-institutional research questions on page 16**

Section 5: Conflict of Interest Assessment

- Pursuant to the Colorado Mesa University's Conflict of Interest and Commitment Policy (CMU Policy Manual 301), an actual, potential or perceived Conflict of Interest (COI) has been identified that must be mitigated through a Conflict of Interest Management Plan (COIMP). This document, developed in accordance with Policy 301 sets forth the steps that have been agreed upon by the signatories below in order to manage the conflict(s). In particular, the Covered Person(s) agree(s) to cooperate with officials of CMU in managing actual, perceived or potential COIs identified in this section.
- Guiding Principles:
  - The term "financial conflict of interest in research" refers to situations in which financial considerations may compromise, or have the appearance of compromising, a researcher's professional judgment in designing, conducting or reporting research. The determination that one has a "conflict of interest" does not imply that the actions or character of an individual investigator are compromised.
  - The welfare and safety of research participants is paramount. The fact that an investigator has or appears to have a financial conflict of interest in research does not preclude conduct of that research,

but the interest must be disclosed and the conflict managed in a way that ensures that the welfare of subjects and the integrity of the data are not compromised by that interest.

***Do you or any investigator(s) participating in this study have a financial interest related to this research project?**

- **If yes:**
  - **Provide the name(s) of the person(s) (i.e., the Covered Person(s)) with financial interests to disclose:**
  - **Sponsor/Entity or individual with whom COI exists:**
  - **What is the nature of the conflict of interest? (check all that apply)**
    - Equity interest (e.g. means stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity)
    - Travel reimbursement
    - Consulting fee
    - Honorarium
    - Relationship (e.g., colleague, family member, etc)
    - Other
  - **What is the value of the financial interest? Check one:**
    - Not applicable
    - $0-$4,999
    - $5,000 or more
    - The value of this financial interest cannot be readily determined through reasonable measures of fair market value
  - **Provide a description of any actual or perceived conflicts of interest for any investigator(s) involved in the study:**
    - Examples:
      - The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the researcher has a financial interest
      - The project results could validate a treatment approach that is the same or similar or competitive to the approach developed, or offered by the entity in which the researcher has a financial interest
      - The researcher has a financial interest in an entity that might manufacture, commercialize or license a drug, device, procedure or any other product used in the project or that will predictably result from the project
      - The researcher has a financial interest in an entity and the project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity
      - The researcher has a financial interest in an entity that funds or participates in the project.

Study Information

Section 1: Anticipated Study Dates & Study Location(s)

1.1 *Anticipated Start Date for Your Study:

1.2 *End Date for Your Study:

1.3 *Study Site

- CMU Main Campus (Grand Junction, CO)
- CMU Montrose Campus (Montrose, CO)
- Western Colorado Community College (WCCC; Grand Junction, CO)
- Other CMU-connected location(s) (e.g., the Forensic Investigation Research Station [FIRS])
- External site(s) unaffiliated with CMU (e.g., the D51 School District)

Section 2: Study Details

***2.1 Please briefly describe the type of study you will be performing:**

- In your response, please indicate if this is a research study, a quality assurance/quality improvement (QA/QI) study, etc. Be sure to note if your research is making use of secondary data as well.
- Common types of research studies:
    - Surveys, questionnaires, focus groups, interviews
    - Physical/electronic games, experiments, or tasks
    - Biomedical/physical procedures, e.g., imaging, scanning, blood collection, exercise, etc.
    - Diet or nutrition studies, taste tests
    - Studies on the effectiveness of educational strategies, teaching methods, curricula
    - Use of instruments, sensors, electronic devices, apps, software, or recording mechanisms (e.g., video, screen capture, key logging, etc.) to collect data or monitor or influence behavior
    - Passive observation of private behavior (in physical/online environments, including social media)
    - Studies examining individuals' responses to manipulation of their physical/online environment
    - Any other activity that involves observation of, or interaction with, individuals to gather information for research (in physical or online environments, including social media)

***2.2 What is the purpose of your study?**

- Describe the purpose, specific aims, or objectives of this research. Be sure to address the significance of the research and why it is important.

2.3 Study Background

Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge:

- Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

2.4 References

Please include any references related to the scholarly background/rationale of your research and/or existing literature of import:

*2.5 Research Questions

Provide the research question(s)/hypothesis/hypotheses for your study:

- Note: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

*2.6 Study Design

Describe and explain the study design (e.g., case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational, survey/correlational, interview-based, etc.):

***2.7 Outcome Measures - What do you hope to find/conclude from this study?**

2.8 Attach any research instruments or measurement tools you intend to use in your study

- These may include interview questions, questionnaires, surveys, and other tools. Be sure to show how a participant indicates consent. Attachments should also show the tool exactly as a participant will see it, e.g., in the case of an online survey.

2.9 Study Sample & Recruitment

***2.9.1 Please enter the total number of subjects to be enrolled at all study sites.**

2.9.2 Participant Recruitment Procedures

2.9.2a Please attach copies of all recruitment materials such as fliers, ads, phone scripts, emails, etc.

***2.9.2b How will participants be approached about participating in the study?**

- Note: recruitment refers to how you re identifying potential participants and introducing them to the study. Include specific methods you will use (e.g., searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

***2.9.2c How will the names and contact information for participants be obtained?**

***2.9.2d Inclusion Criteria: List and describe the inclusion criteria for participation:**

***2.9.2e Exclusion Criteria: List and describe the exclusion criteria:**

***2.9.2f What is the expected duration and time commitment of participants in the data collection process?**

- Note: this should include time for member-checking activities, as well as taking surveys, participating in exercises/interviews, etc.

***2.9.3 Describe the circumstances under which a subject's participation may be terminated by the research team (or their eligibility to participate may otherwise change), including if/when this may be done without regard to their consent:**

- (E.g., the primary research intervention is exposing the subject to an unacceptable level of risk.)

<u>Section 3: Participant Protections – General</u>

***3.1 Do you anticipate study participants will be subject to any risks?**

- **If yes:**
    - **3.1a Describe immediate risks, long-term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible:**
    - **List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research:**
        - Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.
    - **If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable:**
    - **If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant:**
    - **If applicable, describe risks to others who are not subjects:**
        - Note: breach of confidentiality is always a risk for identifiable subject data.
    - **3.1b Describe any potential legal, financial, social, or personal effects on subjects of accidental data disclosure:**

***3.2 Describe what will be done to minimize the risks:**

- Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety:

***3.3 Will deception be used as a method of data gathering?**

- Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Examples include:
    - Subjects complete a quiz, and are falsely told that they did very poorly, regardless of their actual performance.
    - In order to induce stress, study personnel tell subjects that they will give a speech that evaluators will observe on video, when the subjects' speeches will not actually be recorded or observed.
    - The study includes a researcher's "confederate" (an individual who poses as a subject) but whose behavior in the study is actually part of the researcher's experimental design.
- **If Yes:**
    - **Justify and support the use of deception in this study:**

***3.4 Describe any costs that subjects may be responsible for because of participation in the research:**

- Note: some examples include transportation or parking. If there are no economic burdens to participating in this study, enter "N/A"

<u>Section 4: Participant Age Considerations</u>

***Select the age range(s) of subjects that may be enrolled in this study. (Select all that apply)**

- 18 years old and older
- At least 12 years old and under 18 years old
- Under age 12
    - **If anyone under 18: Please indicate which risk category participants under 18 will be subject to:**

- **Minimal risk or Greater than minimal risk**
  - Minimal risk means that the probability and magnitude of physical or psychological harm does not exceed that which is ordinarily encountered in daily life or in the routine medical, psychological, or educational examinations, tests, or procedures of the general population.
  - Examples of research with minimal risk to participants:
    - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (magnetic resonance imaging, moderate exercise, body composition assessment).
    - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).Collection of data from voice, video, digital, or image recordings made for research purposes.
    - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
  - **If greater than minimal risk, provide reasons for the greater than minimal risk to persons under 18 years of age:**

Section 5: Vulnerable Population Considerations

***Will your study enroll any vulnerable populations?**

- To be considered a vulnerable population, the targeted group must be the focus of the research. If the target is the general population, and one of these groups (except prisoners) will participate, they are not considered a "target" population:
  - Fetuses and/or pregnant women
  - Neonate
  - Minors
  - Prisoners
  - Tribal members
  - Military
  - Wards of the state
  - Cognitively impaired
  - Non-native English speakers (esp. for the purposes of informed consent)
  - Note regarding diminished capacity: The PI should identify the intent to enroll vulnerable subjects in the proposed research in the initial submission and provide justification for their inclusion in the study. The justification must include a description of how mental capacity will be assessed. If the research involves adults unable to consent, the IRB evaluates the proposed plan for consent of legally authorized representatives. The IRB evaluates and approves the proposed plan for the assent of participants. If mental capacity is over 7 years of age, an assent is needed with a guardian consent. Be aware that the

IRB evaluates the research to determine the need for additional protections and consider the use of a data and safety monitoring board or data monitoring committee as appropriate. The PI should provide appropriate safeguards to protect the subject's rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the subject's capacity to provide voluntary informed consent.

- **If yes:**
  - **5.1 Please check all the population(s) that will be enrolled**
    - Fetuses
    - Minors with parental/guardian consent
    - Pregnant women
    - Cognitively-impaired adults
    - Adult prisoners/incarcerated adults
    - Other special populations (e.g., non-English speaking subjects)
      - Please describe:
  - **5.2 Use of vulnerable populations & their protection:**
    - **5.2.1 Explain the necessity of using this particular group or groups:**
    - **5.2.2 Describe any special arrangements to protect the safety of the vulnerable population(s) in your study:**
      - Important: If your study involves non-English speaking subjects, please:
        - Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally-authorized representatives.
        - If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

<u>Section 6: Benefits</u>

***Describe the expected benefits for subjects (if any) and/or society that will arise from this study:**

- Describe 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).
- Questions to consider answering for this section:
  - Why does this study matter?
  - What are the expected benefits to participants?
  - What are the expected benefits to society?
- Examples:
  - Direct benefits that may result from participation (e.g., psychological or emotional benefits, learning benefits, physical benefits, diagnostic or therapeutic benefits, etc.). If there are no direct benefits to participants, clearly state this.
  - Benefits to the general participant population.
  - General benefits of the research for society, science and humanity; potential generalizable knowledge.

- NOTE: Compensation cannot be stated as a benefit.

Section 7: Informed Consent

Important:

- All participants must have an option for obtaining a copy of the informed consent form, including online survey participants. The option to click and download/save a copy of the form should be provided in a survey. Email correspondence can provide the form as an attachment. In-person interactions can offer the consent form as a paper copy. Researchers should ensure that any link provided to access/download/save a copy of the consent form is accessible to the participant (i.e., not behind a login, unless the population would be able to login; not password protected, etc.).
- If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

***7.1 Attach your informed consent form(s)**

- Please attach copies of informed consent/assent forms, emails, and/or letters.
- Note: if participants are under 18, you must attach parental/guardian consent forms and participant assent forms.

***7.2 Describe the procedures for obtaining informed consent:**

***7.3 To whom should participants direct questions/concerns regarding informed consent and their participation in this study?**

- Be sure to include name(s), titles/roles, and contact information.
- Note: this should also be documented on the informed consent form.

Section 8: Participant Compensation

About participant compensation:

- Compensation refers to anything given to subjects as remuneration for the time and inconvenience of participation in research. Compensation can be monetary or non-monetary, and can be offered in a range of forms, including but not limited to cash, gift cards, vouchers, trinkets, course credit, and the opportunity to enter a drawing for a prize. Compensation is distinct from participant reimbursement, whereby researchers pay some or all of the subjects' costs for participation - e.g. transportation, parking, lodging, etc.
- For all research, the method and value of compensation must be appropriate for the subject population and the research activities. What constitutes "appropriate" compensation for any study is determined by consideration of the research activities, subject population, and the cultural/social/political context in which the research will take place. In other words, some forms, amounts, and methods of compensation may be appropriate for some individuals or groups, but not others.
- Compensation cannot be so great that it entices participants to engage in any activity to which they are averse, or to act against their better judgment.

- Subjects participating in the same study and completing the same tasks should be compensated equitably. Variation in compensation is acceptable when it can be justified. For example, it is reasonable that compensation for subject populations in different countries may vary according to cultural customs.

***Will compensation be provided to participants?**

- **If yes:**
  - **8.1 Describe the amount and type of compensation including money, gift certificates, extra credit, etc.:**
    - Subjects participating in the same study and completing the same task should be compensated equitably. Variation in compensation is acceptable when it can be justified. For example, it is reasonable that compensation for subject populations in different countries may vary according to cultural customs.
    - Be sure to address the amount and type of compensation provided as well as how you will track that all participants received the same compensation.
    - Special notes:
      - Gift cards: Equitability could be all participants receive a gift card or using a raffle structure where all participants have the same odds of "winning" a gift card.
      - Extra credit: If offering extra credit to student participants enrolled in a course, there must be equitability for students who do not opt to participate in the study. An alternative option for extra credit should be available to them, other than study participation.
  - **8.2 Describe when compensation will be given to the participant:**
    - Include items such as:
      - How much participation is required to earn the incentive
      - What happens if the participant quits before completion of the study or skips some questions
      - What happens to the data if a participant quits
  - **8.3 Will compensation be paid by Colorado Mesa University?**
    - **If yes, please describe how this will be done:**
  - **8.4 What participant information is required for the method of compensation?**
    - Note: This information should also be included in the consent form and the length of time the information will be retained by the payment system. Be sure to address how participant information will be destroyed after the 3-year retention period.
    - Because providing compensation may require the use of personally identifiable information—from email addresses used to email gift cards, to Social Security Numbers required for tax reporting purposes—the mechanics of compensating participants can contribute to risks associated with a loss of privacy or breach of confidentiality. Researchers should develop mechanisms for compensating subjects that reduces the exposure to these risks.
  - **8.5 How will you avoid compensation having a coercive effect on participants (i.e., that they will feel compelled to participate to earn compensation)?**
    - Be sure to include information on how the participant's identity will be kept confidential while allowing for compensation or extra credit to be awarded

- Compensation should be presented in the same manner as other information in the recruitment and consent materials. Presentation of compensation must not detract from important information participants need to consider in order to fully understand the study and assess the risks associated with participation.

Section 9: Privacy & Security

- Anyone who will collect, see, or have access to the rata data must be CITI certified. Please ensure each member of your research team has the required CITI training certificates.
- Non-exhaustive list of frequently-collected identifiable information:
  - Names
  - 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.
  - 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.
  - Telephone numbers
  - Fax numbers
  - Electronic mail addresses
  - Social Security numbers
  - Medical record numbers
  - Health plan beneficiary numbers
  - Account numbers
  - Certificate/license numbers
  - Vehicle identifiers and serial numbers, including license plate numbers
  - Device identifiers and serial numbers
  - Web universal resource locators (URLs)
  - Internet protocol (IP) address numbers
  - Biometric identifiers, including finger and voice prints
  - Full face photographic images and any comparable images
  - Any other unique identifying number, characteristic or code

***9.1 Who will be collecting data?**

***9.2 Please provide a brief description of your data analysis plan:**

***9.3 What uses will be made of the information obtained from the subjects?**

***9.4 What precautions will be taken to safeguard identifiable records or individuals?**

- NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

- 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. Aggregating data may lower this risk when cell sizes are 5 or greater.

***9.5 Who will be able to see or have access to the data?**

- List everyone who has access to the raw data. This can include those who collect the data, if they can see it, and those who analyze it.

***9.6 How will data be reported?**

- List all the ways the data will or might be disseminated.
- 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 study 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?

***9.7 Where will the records be stored during data collection and analysis?**

- Be specific – be sure to address building/office location (room#, locked doors, locked cabinets, etc.), digital access (password protection, etc.) and all other pertinent details to record storage.

***9.8 What security measures are in place to protect the data during data collection, analysis, and the 3-year data storage period?**

- Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) and electronic files.

***9.9 Who will destroy data after the 3-year retention period?**

Biomedical Research – Additional Questions & Considerations

Research involving the collection of biological specimens, the use physiological or biomedical devices, or other biomedical procedures with human participants requires additional considerations regarding participant protections, handling of genetic and biohazardous material, use of biomaterials for future research, and other research-related activities.

Factors in review:

- General device safety information (e.g., manufacturer literature), if a device is being used
- Inclusion and exclusion criteria and screening procedures for research participants – to ensure that individuals who are not eligible to participate are appropriately identified and excluded
- Description of experience of or training for research personnel conducting the procedures
- Cleaning and sanitizing procedures for reusable devices
- Safeguards in place to assure the safety of study participants
- Location of the lab/procedure facilities – to determine if the space is suitable for the research procedures
- Any plans for storage and retention of biological materials
- Plans for protecting the privacy of participants
- Level of invasiveness/risks of the procedures and the appropriate level of medical oversight needed to protect participant health
- Device safety information (manufacturer literature)
- Safety precautions and emergency medical response procedures for study participants and research personnel and a contingency/medical assistance plan in the event that a participant experiences an unexpected physical reaction to a research procedure

Remember:

- Research activities may not commence until the PI receives a written notice of approval from the IRB.
- Researchers are responsible for ensuring full and continuing compliance with all University and IRB policies in the conduct of their research.

There are a number of procedures ordinarily considered to be “no greater than minimal risk” or minimally invasive to collect physiological information or human specimens/biological materials. Examples:

- Blood draw – heel stick, venipuncture
- Blood pressure measurements
- Bod Pod body composition measurements
- Body measurements (various) – skin fold, waist circumference, height, weight
- Cheek swabs
- EEGs
- Fecal sample collection
- Hair sample collection
- Heart rate monitoring
- Urine sample collection (for screening or data collection)
- Ultrasounds

There are also biomedical or physiological procedures that are ordinarily considered greater than minimal risk or invasive in nature. Examples:

- Biopsies (fat or muscle tissue)
- DXA scans
- fMRI/MRIs
- Vaginal Ultrasounds

Section 1: Methods & Procedure Justifications

***1.1 Please provide a detailed justification for the methods and procedures within your biomedical research study:**

- Include as relevant:
    - Justification for what data/specimens are being collected (throat swab, blood sample, etc.);
    - Appropriate safety and material handling precautions;
    - Appropriate response procedures for emergencies or unexpected outcomes that could impact the health or safety of participants;
    - Procedures for the handling and disclosure of any unanticipated or adverse findings in the research;
    - Procedures for complying with laboratory requirements;
    - Procedures for providing research participants with medically relevant information and referrals to a physician;
    - Procedures for obtaining informed participant consent for retention and use of biological materials or data for future research;
    - Detailed information and specifications for research devices;
    - Appropriateness of the physical facilities where procedures are being conducted (considerations of privacy, sanitation, access to safety equipment if needed, etc.); and
    - Other factors important in ensuring the safety of research participants and staff.

***1.2 Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects:**

***1.3 How will any risks or incidents of physical harm be addressed?**

- Examples of physical harm include but may not be limited to:
    - Exercise-induced or repetition-exacerbated physical harm, such as carpal tunnel syndrome, stress fractures, asthma attacks, or heart attacks
    - Exposure to minor pain, discomfort (e.g. dizziness), or injury from invasive medical procedures
    - Possible side effects of drugs

Section 2: Specimen Uses, Storage, & Confidentiality

Use of existing human specimens/biological materials - Examples:

- Serum from blood banks
- Residual tissue from surgical procedures (e.g., discarded tumor specimens)
- Placenta specimens

***Will specimens be collected or analyzed as part of this study?**

- **If yes:**

- **Describe the local procedures for maintenance of confidentiality of study specimens**
- **How long will the specimens be stored?**
- **Who will have access to the specimens?**
- **Who is responsible for receipt or transmission of the specimens?**
- **How will the specimens be transported?**

Section 3: Banking Data or Specimens for Future Use

***Is this study banking data or specimens for future use or research outside the scope of the present protocol?**

- **If yes:**
  - **If data or specimens will be banked (stored) for future use, that is, use or research outside of the scope of the present protocol, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens:**
  - **List the data to be stored or associated with each specimen:**
  - **Describe the procedures to release banked data or specimens for future uses, including the process the request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens:**

Section 4: Research-Related Risks/Injury

***If the research procedures carry a risk of research-related injury, describe the available intervention(s) and/or treatment(s) for subjects in the event that such injury should occur.**

- If the research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies), this section does not apply.

***If the research procedures carry a risk of research-related injury, describe the available intervention(s) and/or treatment(s) for subjects in the event that such injury should occur.**

- If the research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies), this section does not apply.

Multi-Institutional Studies

Multi-institutional research is...When CMU is one of the participating sites on a research study, with each site recruiting participants, consenting, and collecting data at their local institution, to combine for aggregate data analysis.

***1. In what role will you/will CMU participate in this multi-institutional study?**

- As participating site/investigator
- As lead investigator
    - **If lead investigator:**
        - **Describe the processes to ensure communication among sites:**
            - Such as regarding…
                - All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.
                - All required approvals have been obtained at each site (including approval by the site's IRB of record).
                - All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
                - All engaged participating sites will safeguard data as required by local information security policies.
                - All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.
                - All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.
        - **If lead investigator, describe the method for communicating the following to engaged participating sites:**
            - Problems (inclusive of reportable events)
            - Interim results
            - Study closure

***2. Who will serve as the IRB of record for this study?**

- CMU
- Each site will conduct its own IRB review
- Other institution
    - **If other institution, please provide the following information and documents:**
        - **Name of outside IRB of record**
        - **Attach study protocol for this study, already reviewed by outside IRB**
        - **Attach IRB approval letter from outside IRB**
        - **Attach all correspondence concerning the review of this study by the outside IRB**
        - **Attach outside IRB reliance agreement**