***INSTRUCTIONS:***

This template can be used to develop a research protocol that includes information considered during IRB review. There is no requirement to use this exact template; however, all investigators are encouraged to review the guidance information provided here to ensure their research plan includes sufficient information about human subjects research.

* As you are writing your protocol, remove all text in blue italics (and re-set the font color to black), so this guidance is not contained in the final version of your protocol.
* Do not use this template like a form where you are answering questions or responding to guidance cues. Use complete sentences and describe all processes and procedures thoroughly. When you remove the instructions/guidance, your protocol needs to make sense.

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name, Department, Telephone Number, Email Address*

**VERSION NUMBER:**

*Include a version number on this protocol. Unless you are provided a numbering system by a sponsor, consider using a simple system: protocols can start at version 1.* *If you need to modify your protocol, this will help ensure that you are modifying the latest version.*

**DATE:**

*Include the date of submission or revision.*

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# Objectives

Describe the purpose, specific aims, or objectives of the study.

# Background

Describe the relevant prior experience and gaps in current knowledge.

Describe any relevant preliminary data.

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

Describe the resources available to accomplish this research. Specifically include a summary of the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe your knowledge of the local study sites, culture, language, and society.

# Subject Population

Describe the eligibility criteria that define who will be included and/or excluded in your study sample.

If you will include or exclude any of the following special populations, this should be clearly stated: adults unable to consent; children (< 18 years of age); pregnant women; and/or prisoners or individuals likely to become prisoners during the research.

Clearly state the total number of subjects to be accrued in this study. If this study is part of a larger multi-site project, clarify the total number of subjects to be accrued locally.

# Procedures Involved

Describe and explain the study design.

Provide a description of all research procedures being performed and how, when, and where they are performed. Use bullet points or simple step-by-step language to describe procedures in the order in which they will occur.

Include, when applicable:

* + - A list and description of all study instruments and/or data that will be collected (e.g., surveys, questionnaires, demographic questions, interview questions, data collection forms, observations, recordings, etc.). Study instruments should be referenced here and uploaded into IRBNet as separate documents.
		- If data will be collected via audio-taping, video-taping, or photography, this should be specified.
		- Expected time commitment for participants (per specific procedure or task and in total).
		- A description of any source records that will be used to collect data about subjects (e.g., student educational records, medical records, online resources, etc.). For record reviews, specify the date range for the collection of data.
	+ A description of the setting, sites, and/or locations where your research team will conduct the research.
	+ Any provisions to protect the privacy interests of subjects. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information. (Example of a privacy protection: Conducting interviews in a quiet setting where others cannot overhear the conversation.)
		- An overall timeline for the research.

# Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Consider physical, psychological, social, legal, and economic risks. Acknowledge any burden of time, inconvenience, etc.

Describe any plans or measures that will be taken to minimize risks, discomforts, hazards, and/or inconveniences related the subjects’ participation in the research.

# Potential Benefits to Subjects

Describe the anticipated benefits that individual subjects may experience from taking part in the research. Do not overstate benefits. If there is no direct benefit for participation (which is likely in many studies), simply state this.

Do not include benefits to society or others – this should be evident in your study objectives and background.

# Recruitment Methods

*Describe the methods that will be used to identify potential/eligible subjects.*

Describe when, where, and how potential subjects will be recruited.

Describe any materials that will be used to recruit subjects (upload copies of all recruitment materials with your submission in IRBNet). This may include:

* + - Verbal script(s) that will be used to introduce the investigators and the study.
		- A description of handouts, flyers, brochures, or any printed advertisements and how those will be distributed or where they will be posted.
		- For research conducted using the Dept. of Psychology’s Sona system, include the exact title and study description that will be used to recruit students.
		- For advertisements taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping if revisions are requested, provided the IRB reviews the final audio/video tape.

# Consent Process

Describe your step-by-step process for informing individuals about the research and gaining their permission to participate in the study (who, what, when, where, and how). Keep in mind:

* *The consent process is generally the next step after recruitment, but in some studies these processes are one and the same. Provide a clear description of how you will be interacting with subjects in your study.*
* *If you are using a written consent form or statement, describe how that form is being used. Don’t just refer to the form.*
* Refer to the IRB Checklist: Criteria for Approval (HRP-314) for the requirements for a consent process. IRB reviewers cannot presume anything about your process, it should be clearly stated.

If you will NOT be collecting signed consent forms from subjects in your study, you should describe your consent process fully and request a waiver of documentation of consent.

* Refer to the IRB Checklist: Waiver of Written Documentation of Consent (HRP-411) to ensure that you provide sufficient information for this waiver.
* Include any verbal consent scripts and/or written consent information provided to potential subjects. Clarify how an individual’s permission to participate is indicated (e.g., a verbal “yes”, clicking on an online link, completing the survey, etc.).

If you will NOT be informing individuals about the research and obtaining their consent to participate, you should clearly state that you are requesting a waiver of consent and provide justification.

* *Refer to the IRB Checklist: Waiver or Alteration of Consent Process (HRP-410) to ensure that you provide sufficient information for this waiver.*

# Data Management & Confidentiality

Describe the data analysis plan, including any statistical procedures.

Describe measures taken to ensure the confidentiality of the data. Specify the steps that will be taken secure the data during storage, use, transmission and final disposition (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, coding, de-identification, etc.).

Include, when applicable:

* A description of where, how, and for how long data will be kept.
* A statement of who will have access to the data. If data is being shared beyond the approved investigators, specify how and to whom.
* A description of all identifiable data collected. Clearly indicate why identifiable data are being collected and how identifiable data are being used (e.g., contact information collected to facilitate interviews, names used to link pre- and post-surveys, names to award extra credit, etc.).
* A description of how and when data may be coded and/or de-identified. Specify where any code-links are being kept and if/when links will be destroyed. If identifiable data will be kept indefinitely, this needs to be explicitly stated.
* If you are collecting audio or video data, explain how the data may be transcribed, if names or other identifying information will be removed in the transcription process, and if/when the audio or video files will be destroyed.
* Identify any online tools used to collect data (e.g., SurveyMonkey, Qualtrics, etc.) and specify settings on those tools to protect confidentiality or ensure anonymity (e.g., data provided to researchers without names, IP addresses, etc.).
* A description of how data would be represented in the publication or presentation of results (e.g., as aggregate data, using pseudonyms, etc.)

Keep in mind: “Confidentiality” pertains to treatment of data/information that an individual has disclosed to the researcher(s), with the expectation that this information will not be divulged to others without permission. The term “anonymous” should only be applied to data that is/was collected without any name or identifiable information, and no coding system is/was used that would allow data to be linked to an individual.

The IRB requests that study records (e.g. consent forms, etc.) be kept for a period of 3 years following the completion of the study (closure date).

***Additional Considerations…***

Depending on your proposed research, additional information may need to be included in your protocol. Include information about these components when applicable:

* **Cost to Subjects:**

Describe in the protocol, and disclose in the consent form, any costs to the subject that may result from participation in research.

* **Compensation, Payment, or Remuneration:**

Describe the amount, method, and timing of any compensation to subjects.

* Review the IRB Worksheet: Payments (HRP-316) to ensure that you have provided sufficient information.
* Refer to the IRB/HSPP website (<http://www.msudenver.edu/irb>) for guidance on compensation and information about MSU Denver Accounting Services’ policies related to research compensation.
* Compensation can be monetary (cash, gift card, etc.) or non-monetary (extra credit, gift item, etc.). For non-monetary items, please provide an estimated value. If extra credits or applied assignment credits are being awarded for participation, clearly identify alternatives to earning these credits.
* Do NOT include compensation as a benefit to subjects, either in the protocol or in the consent.
* If research-related injury (i.e., harm that is physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the federal regulations do not limit injury to only physical injury.
* **Research Teams and Collaborations**

For studies that involve multiple investigators and/or collaborations within and outside of MSU Denver, specify the roles and responsibilities of the investigators in the protocol.

* Clarify the role of any individual listed on the Initial Review Form (HRP-211) who will not be involved with human subjects (e.g. data analyst, translator, etc.).
* Address any agreements or issues involved in sharing or managing data or materials between institutions.
* **Prior Approvals**

In some research studies, approvals from other MSU Denver offices or entities, external organizations, and/or collaborating institutions are required. Your protocol should clearly acknowledge all approvals already obtained for this research and indicate any additional approvals pending.

* Describe any approvals that will be obtained prior to commencing the research (e.g., public or private school, collaborating institution, external site, or funding agency). Provide documentation of other approvals (letters of support, other IRB approvals, etc.) with your submission in IRBNet.
* If research activities (recruitment, data collection, etc.) will occur in any MSU Denver class be sure to seek permission from the instructor. Documentation of permission may be requested in the IRB process.
* If you propose to access personally identifiable information (PII) from educational records and/or obtain other identifiable institutional data that is not publically available, documentation of permission is required from the institutional official that holds those records (e.g., Registrar’s Office, Office of Institutional Research).
* **Vulnerable Populations:**

If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

* + If the research involves pregnant women, review the IRB Checklist: Pregnant Women (HRP-412) to ensure that you have provided sufficient information.
	+ If the research involves prisoners, review the IRB Checklist: Prisoners (HRP-415) to ensure that you have provided sufficient information.
	+ If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the IRB Checklist: Children (HRP-416) to ensure that you have provided sufficient information.
	+ If the research involves adults who are cognitively impaired, review the IRB Checklist: Cognitively Impaired Adults (HRP-417) to ensure that you have provided sufficient information.
	+ Students can be considered vulnerable to coercion or undue influence depending on the circumstances of the research. This applies especially to (but is not limited to) subjects who are current students of, or who report to, the investigator(s).
		- For any research that targets students in a classroom, the course(s) must be identified and it should be clearly stated who instructs those courses.
		- You should indicate in your protocol what steps you are taking to minimize potential coercion or undue influence (e.g., use of a third party to gain consent, analysis of data after grades are posted, etc.).
		- Refer to the IRB/HSPP website (<http://www.msudenver.edu/irb>) for guidance on avoiding or minimizing coercion or undue influence.
* **Assent Process:**

If you propose to enroll subjects in the research who have not obtained the legal age of consent (i.e. children) or adult subjects who are cognitively impaired, you must address the issue of assent in addition to consent in your protocol.

* *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years).*
* Describe the criteria that will be used to determine cognitive impairment of adult subjects, who is making that determination, and his/her qualifications to do so.
* If assent will be obtained in addition to consent, describe the assent process in the protocol and include all assent materials (verbal scripts, written information, etc.) with your submission in IRBNet.
* If assent will not be obtained in addition to consent, clearly state this and provide reasonable justification.
* **Use of Incomplete Disclosure or Deception:**

If information is withheld from subjects prior to participation or if your proposed research uses deception, these activities should be fully explain in your protocol and detailed justification is required.

* + - Review the IRB Checklist: Waiver or Alteration of Consent Process (HRP-410) to ensure you have provided sufficient information for the IRB to allow for an altered consent process.

When incomplete disclosure or deception is used, a debriefing process should be described in addition to the consent process. The debriefing script or written information should be included in your IRBNet submission. (Even when the study does not involve the use of deception, a debriefing process may be included simply as an educational tool for subjects.)

* **Non-English Speaking Subjects:**
	+ - Indicate what language(s) other than English are understood by prospective subjects or their representatives and the qualifications of the investigators to gain consent and conduct the research activities in the language(s) of the subjects.
		- Fully describe how the consent process and data collection will occur (e.g., in the language of the potential participant, use of a translator, etc.).
		- Specify all documents that are, or will be, translated from English (e.g., short form consent, fully translated consent form and study instruments, etc.). Indicate who has translated those documents and their qualifications to do so.
		- Provide all translated materials for IRB review with your submission, or indicate in your protocol that translated documents will be provided when the English versions have received IRB approval.