**RESEARCH REQUEST**

**Template for Requesting Permission to Conduct Research at MSU Denver**

**Please complete this form.**

* As you are writing your RESEARCH REQUEST, 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 document.
* 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 RESEARCH REQUEST needs to make sense.

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name, Department, Telephone Number, Email Address*

**DATE:**

*Include the date of submission or revision.*

# 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. Please specify whether you intend to collect data from MSU Denver students, staff, administration, or if you intend to use de-identified aggregated Institutional Research Data.

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.

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 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.*

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.

* 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.

# 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.