

**Institutional Review Board**

**Application Form**

**Instructions:**

1. **Please only use this Word version of the IRB application if you are not using the IRBNet application wizard. Do not complete both versions.**
2. Complete all sections and required addenda. Submit one complete package via IRBNet.
3. CITI certification ([www.citiprogram.org](http://www.citiprogram.org)) must be completed for all team members at the time of application submission.
4. Titles of IRB protocols with funding/proposed funding must match the title on the funding application.
5. Research may not begin until you have received notification of IRB approval.
6. Handwritten and incomplete forms cannot be accepted.

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| **1.** **Study Title**: **Make sure the study title matches what is listed in IRBNet and the consent form** |
| **2. Study Investigators** A. Principal Investigator(*must be faculty/staff conducting research as a Mason employee and meet PI Eligibility,* [*University Policy 4012*](http://universitypolicy.gmu.edu/policies/principal-investigators/)) Name: **Full time faculty member (https://universitypolicy.gmu.edu/policies/principal-investigators/. )** Department:  Phone:  E-mail:  B. Co-Investigator/Student ResearcherName: **Name of student or co-investigator** Department:  Phone:  E-mail:  C. Are there additional team members?No [ ]  Yes [ ]  *If yes, complete Addendum J to list additional team members* D. Do any investigators or team members have [*conflicts of interest*](https://universitypolicy.gmu.edu/policies/financial-conflicts-of-interest-in-university-contracts-with-businesses-under-virginia-law/) related to the research?  No [ ]  Yes [ ]  If yes, explain  |
| **3. Study Type:** [ ] Faculty/Staff Research [ ] Doctoral Dissertation [ ]  Masters Thesis [ ] Student Project (**Specify**  [ ] Grad or [ ] Undergrad) [ ] Other (Specify)  |
| **4. Complete Description of the Study Procedures**A. Describe the aims and specific purpose of the study: **Include a full description of the purpose of the study, the aim of the study, and how it is intended to contribute to generalizable knowledge** B. Provide a COMPLETE description of the study procedures in the sequence they will occur including the amount of time each procedure will *take (attach all surveys, questionnaires, standardized assessment tools, interview questions, focus group questions/prompts or other instruments of data collection)*: **Include a full description of all study procedures from start to finish. Define any acronyms used, make and model of any device that may be used, etc. Distinguish between any procedures that may be happening anyway, regardless of the research, that you want to collect data on versus what is happening solely as part of the research procedures. Indicate whether there will be randomization in the study.****Clarify whether procedures are occurring remotely or in person, individually or in a group setting. Avoid including specific dates and instead use general timeframes.****If there will be recording, include that information here as well as what device will be used to record procedures. Specify if recording will be audio, video, or both and why procedures If the recordings will be transcribed, include how that will occur.** **Attach all study instrumentation that will be used, including screeners, surveys, interview questions, focus group questions, task prompts, video clips, audio clips, screenshots, etc.****If you plan to use existing data for research purposes, please complete the Existing Data/Specimens form.** C. Describe the target population (age, sex, ethnic background, health status, etc.): **Include a description of what the target population is for the study**1. Summarize the inclusion/exclusion criteria for participation in the study and how participants will be assessed/screened to ensure they meet the criteria: **This section should include any specific characteristics of who will be included or who would be excluded. Specify whether participants have to be 18 or older to be eligible. Include a description of how researchers will ensure that the participants selected for the study meet the inclusion eligiblity criteria (i.e., will a screener be used? If so, will the results be used as part of the data or will they be deleted upon confirmation of eligibility? Will they self-select in? etc.)** 2. Are there any enrollment restrictions based on gender, pregnancy, race or ethnic origins?  [ ] Yes [ ] No If yes, please describe the process and reasons for restriction(s): **if there are any restrictons on enrollment, include the rationale for why** 3. Do any researchers listed on the application have a relationship to any of the participants that could unduly influence them to participate (including a teacher/student relationship)? [ ] Yes [ ] No If yes, please describe the relationship and how any possibility of undue influence will be managed: **if there are any relationships or power differential between researchers and participants, include how the influence will be mitigated.** 4. Estimated number of subjects (may use a range): **We need the maximum goal total to ensure that researchers do not over-enroll** 5. Estimated amount of total participation time per subject: **Can give overall time or break down of total times per procedure. This should include the total time it would take one person to complete research-only procedures. Do not include time for things happening anyway, regardless of research.** D. Where will the study occur (*list all study sites and collaborators*)? **Provide location where study will occur. If online, specify online platform that will be used** E. Describe other approvals that have been/will be sought prior to study initiation (facility authorizations, biosafety review, IRB approval from collaborating institutions, approval from public school system IRBs, etc.): **If using private/closed social media groups or otherwise private places to recruit, add that permission will be sought prior to posting recruitment material. If a study is occurring at another institution and/or their researchers are helping conduct human subjects research procedures, confirm that the other researchers will seek IRB approval from their respective institution(s), as applicable.** **If Mason athletes are being used as subjects, confirm that researchers will contact Dr. Margaret Jones and Dr. Derek Vigon for approval. If active duty military will be used as subjects, confirm that a scientific review will be conducted by either the DoD or by a scientific professional in the field of study. Email the IRB reviewer for a copy of the scientific review sheet that will be completed if needed. If biospecimens will be collected, confirm approval will be sought from the Biosafety committee.****We do not need documentation of any of the above approvals(except the scientific review sheet for active duty military), but assurances that permissions will be sought.** F.Is this study a clinical trial that requires registration on [ClinicalTrials.gov](https://rdia.gmu.edu/wp-content/uploads/Clinical-Trials-Registration-information-1.pdf)? [ ] Yes [ ] No If yes, please provide the NCT number assigned to the study:       |
|  **5. Recruitment and Consent**A. Describe the processes used for selecting subjects and the methods of recruitment including when, how, and by whom the subjects will be recruited (***attach all recruitment materials including flyers, emails, SONA posting, scripts, etc. and please include the IRBNet number of the project and the PI’s name on all recruitment documents***)? **Answer all part of this question and attach all recruitment messages, emails, flyers, posts, etc. to the package. Include how contact information is being obtained, who is doing the recruitment process, etc. If using snowball sampling, ensure that the researcher contact information is being passed along rather than the participants sharing other people’s contact information with the research team. Make sure the recruitment language includes that the project is research, what they will be asked to do, how long it will take them to complete, inclusion criteria, researcher contact information, and the IRBNet number for this project. If recruitment will be in another language other than English, please be sure to attach the translated versions of the document(s) as well.** B. Describe the consent process including how and where the consent will take place, who will conduct the consent process, information that will be discussed with and distributed to subjects, and how participants will indicate consent even if a waiver of signature is being requested below (*attach all consent documents***): All participants must provide consent. Answer all parts of this question and attach the consent form. Participants must provide consent to participate in research. Opt-in consent process is required. Describe how the consent process will work, confirm how the participants will receive a copy of the form, how they will return the consent form to the researcher, and how they will indicate their consent to participate (i.e., verbally, clicking an I agree button, typing their name, physical pen-to-paper signature, completion of a survey, etc.). If consent will be in another language other than English, please be sure to attach the translated version.** **Use the IRB consent template found on IRBNet to create your consent form. Edit the last 2 pages to fill in the relevant information of your study.****Anyone who assists with the consent process must complete the CITI Basic training course and be added as a member of the research team.** C. Is a waiver of signature on the Informed Consent being requested? [ ] Yes [ ] No If yes, complete the following: 1. This waiver is being sought because (*check one*): [ ] The only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality. [ ] The research presents no more than minimal risk of harm to subjects AND involves no procedure for which written consent is normally required outside of the research context. [ ] The subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained. 2. Explain why the waiver of signature is being requested: **If participants indicate consent in any way other than a pen-to-paper signature, explain why the alternate consent method is being used. Often reducing burden on participants for online procedures or to protect participant confidentiality are acceptable rationales.** |
| 1. **Privacy & Confidentiality**

 A. How will the researchers protect the [*privacy*](https://rdia.gmu.edu/topics-of-interest/human-or-animal-subjects/human-subjects/glossary/) of the participants and the [*confidentiality*](https://rdia.gmu.edu/topics-of-interest/human-or-animal-subjects/human-subjects/glossary/) of the data obtained? **Privacy refers to people (i.e., will procedures take place in a private room? Public space? Password protected Zoom? Etc.) and confidentiality refers to the data. Explain whether data will be linked together or collected in aggregate if using multiple data collection procedures (e.g., survey and interview). Will names or other identifiers be included in reports/publications? Will there be an identification key or code? Code = assigned numbers/pseudonyms, identification key = link between code and subject identifiers (ie. name).** B. What individually identifiable information will be collected as part of the study data and who will have access to that information? **Only researchers should have access to identifiable information. Anyone who will have access to identifiable information needs to be listed as part of the study team and complete the CITI training. All identifiers that will be collected should be included in this section. Recordings (audio and/or video) are considered identifiable and should be deleted upon transcription unless there is a valid justification for why they need to be retained. If there are no identifiers being collected, state that instead.** C. When will identifiable information/the identification key be destroyed (if applicable)? *Please note that when feasible, the IRB recommends that personal identifiers be destroyed as soon as possible, though research data must be stored for 5 years.* **Identifiable information can and should be deleted as soon as it is no longer needed. Only the de-identified data has to be stored for five years after the study ends.**  D. Where will the data be stored? (*Copies of records must be stored on Mason property—for example, in the PI’s office, Mason owned servers, Mason owned desktops and/or laptops, Office of Research Computing resources, etc.)* **A copy of the data must be stored on Mason property (i.e., a Mason-owned computer, locked office, M-Drive, etc.).** E. How long will the data be stored (*data must be retained for at least 5 years after the study ends*)?  **The data must be stored for at least five years after the study ends. Avoid listing specific dates.**  F. What, if any, are the final plans for disposition/destruction of the data? **Make sure to include details for both electronic and paper copies of data, if applicable. If there are no plans to destroy data after 5 years, state that instead.** G. Will results of the research be shared with the participants? [ ] Yes [ ] No If yes, describe how this will be accomplished: **If yes, explain how the results will be shared with participants.**  H. Will individually identifiable information be shared with anyone outside of the research team (*If yes, please explain and be sure to include this information in the consent form*)?  [ ] Yes [ ] No If yes, please explain: I. Does the research involve possible disclosure by participants of intent to harm themselves or others or possible disclosure of child abuse or neglect?(*If yes, please explain and be sure to include this information in the consent form*)? [ ] Yes [ ] No If yes, please explain: If this response is yes, be sure to include the relevant mandatory reporting statement in the consent form: “There is one exception to confidentiality. It is our legal responsibility to report situations of suspected child abuse or neglect to appropriate authorities. Although we are not seeking this type of information in this study nor will you be asked questions about these issues, we will disclose them as required under the law if discovered.” OR “If your responses indicate intent to commit suicide, intent to kill or cause serious bodily harm to another person, and/or knowledge of past, current, or future unreported child abuse or elder abuse such responses must be reported under the Virginia Code of Law.” |
| 1. **Risks**

 A. Summarize the nature & amount of risk if any (*include side effects, stress, discomfort, physical risks, psychological and social risks*): **Answer this question in full regarding any potential risks outside what one would encounter in every day life. This section should also match the Risks section in the consent form.** B. Estimate the probability if any (e.g. not likely, likely, etc.) that a given harm may/will occur and its severity: **Answer this section regarding how likely it is that a participant will experience risks associated with the study and how severe it may be.** C. What procedure(s) will be utilized to prevent/minimize any potential risks? **Providing mental health resources, reminding participants that they can skip any question they do not want to answer, reminding participants that they can withdraw from the study at any time, etc.** |
| 1. **Benefits**

 A.Describe any probable benefits (if any) of the research for the subject(s) (*Do not address compensation in this section*): **This section refers to direct benefits that the participant will get only due to their participation in the research. The majority of research will not have any direct benefit to participants. Benefits can also not be guaranteed. Compensation is NOT a benefit.**  B. Describe the benefits to society and general knowledge the study is likely to yield: **This section must be completed in full for the project to be considered research. Include the generalizability of the potential findings. If this is for quality improvement purposes or not generalizable, state that instead. Note: if this is not generalizable, you can complete the Human Research Determination form instead to receive a Not Research letter.** |
| 1. **Financial Information**

 A. Is there any internal or external funding or proposed funding for this project? [ ] Yes [ ] No  If yes, funding agency  and OSP # (if external funding)  **(if funded, IRB study title must match title on the funding application)** B. Are there financial costs to the subjects? [ ] Yes [ ] No If yes, please explain: **If the participant has to pay to park at a research site, this would be considered a cost.** C. Will subjects be paid or otherwise compensated for research participation? [ ] Yes [ ] No  If yes, please respond to the following questions: 1. Describe the nature of any compensation to subjects (cash, gifts, research credits, etc.): **Payment cannot be so high as to cause undue influence on participants. The compensation should match the time and effort required for someone to participate.**  2. Provide a dollar amount/research credit amount, if applicable: **Note: SONA credits are 0.5 credits per 30 minutes, 1 credit per hour.** 3. When and how is the compensation provided to the subject?  4. Describe partial compensation if the subject does not complete the study:  5. If research credit, what is the non-research alternative to research participation? **A non-research alternative way to get credit is required to be listed for any study that provides research credit as an incentive that matches the time and effort required for the study. This information is also required to be listed in the consent form.** |
| 1. **Special Topics**
2. Will the study involve minors? [ ] Yes [ ] No

*If yes, complete addendum A*1. Will the study involve prisoners? [ ] Yes [ ] No

*If yes, complete addendum B*1. Will the study specifically target pregnant women, fetuses, or neonates?[ ] Yes [ ] No

*If yes, complete addendum C*1. Will the study involve FDA regulated drugs (other than the use of approved drugs in the course of medical practice)? [ ] Yes [ ] No

*If yes, complete addendum D*1. Will the study involve evaluation of the safety or effectiveness of FDA regulated devices? [ ] Yes [ ] No

*If yes, complete addendum E*1. Will false or misleading information be presented to subjects (deception)? [ ] Yes [ ] No

*If yes, complete addendum F*1. Will participants be audio or videotaped?[ ] Yes [ ] No

*If yes, complete addendum G*1. Will the research involve other potentially vulnerable participants (e.g. disabled or addicted individuals, populations engaging in illegal behavior)? [ ] Yes [ ] No

*If yes, complete addendum H*1. Will the research be conducted outside of the United States? [ ] Yes [ ] No

*If yes, complete addendum I*K.  Are you requesting a reliance agreement for a collaborating site to rely on GMU’s IRB or for GMU to rely on the IRB of the collaborating site? [ ] Yes [ ] No *If yes, complete addendum K* |
| 1. **Investigator Certification**

**I certify that the information provided in this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request and receive approval from the IRB for changes prior to implementing these changes. I will comply with all IRB policies and procedures in the conduct of this research. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol. I understand that I am ultimately responsible for the entire conduct of this research.** |