**INSTRUCTIONS:**

* This protocol template is intended for use with Social/Behavioral focused studies that are non-Exempt. For studies that meet the criteria for Exemption, use HRP-503b – Template – Exempt Protocol.
* When you write a protocol, keep an electronic, clean (all changes accepted, all comments deleted) copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, policies, and manuals can be found in the RAMP Library and on the IRB website.
* As you are writing the protocol, **remove all instructions in italics so that they are not contained in the final version of your protocol.** Depending on the nature of your study, some sections may not be applicable to your research. If so, mark as “N/A”. **Do not delete** the section numbers.
* There are tips and notes throughout this template as comments. Delete those from your final version.

**PROTOCOL TITLE:** << Include full protocol title>>

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:** <<Include the version number and date of this protocol>>

**REVISION HISTORY**

\*This table should only be used during submission of a Modification application to the IRB.

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Contents

[1.0 Study Summary 4](#_Toc199502680)

[2.0 Objectives 5](#_Toc199502681)

[3.0 Background 5](#_Toc199502682)

[4.0 Study Intervention 5](#_Toc199502683)

[5.0 Procedures Involved 5](#_Toc199502684)

[6.0 Data and Specimen Collection 6](#_Toc199502685)

[7.0 Study Timelines 7](#_Toc199502686)

[8.0 Inclusion and Exclusion Criteria 7](#_Toc199502687)

[9.0 Vulnerable Populations 7](#_Toc199502688)

[10.0 Number of Participants 8](#_Toc199502689)

[10.0 Recruitment Methods 8](#_Toc199502690)

[11.0 Withdrawal of Participants 8](#_Toc199502691)

[12.0 Risks to Participants 9](#_Toc199502692)

[13.0 Potential Benefits to Participants or Others 9](#_Toc199502693)

[14.0 Data Management and Confidentiality 9](#_Toc199502694)

[15.0 Provisions to Monitor the Data to Ensure the Safety of Participants 10](#_Toc199502695)

[16.0 Provisions to Protect the Privacy Interests of Participants 10](#_Toc199502696)

[17.0 Compensation for Research-Related Injury 10](#_Toc199502697)

[18.0 Participant Costs and Compensation 10](#_Toc199502698)

[19.0 Consent Process 11](#_Toc199502699)

[20.0 Setting 13](#_Toc199502700)

[21.0 References 13](#_Toc199502701)

# 1.0 Study Summary

1.1Please provide a **brief summary** of the study in the table below. A complete description of the study with detailed information should be provided in the body of the protocol. For sections not applicable to the study, mark them as N/A.

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective/Purpose** |  |
| **Secondary Objective(s)/Purposes** |  |
| **Research Intervention(s)**  |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions**  |  |

# 2.0 Objectives

*2.1* *<<Describe the purpose, specific aims, or objectives.>>*

*2.2 <<State the hypotheses to be tested.>>*

# 3.0 Background (500 Words or fewer)

*3.1 <<Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Include research references in 21.0 of this template.>>*

*3.2 <<Describe any relevant preliminary data (e.g. pilot data).>>*

# 4.0 Study Intervention

*4.1 <<Describe the study intervention that is being evaluated.>>*

# 5.0 Procedures Involved

*5.1 <<Describe and explain the study design.>>*

***Please select the methods that will be employed in this study (select all that apply):***

|  |  |
| --- | --- |
| [ ] Audio/Video Recording | [ ] Psychophysiological Recording |
| [ ] Behavioral Interventions | [ ] Record Review - Educational |
| [ ] Behavioral Observations and Experimentations | [ ] Record Review - Employee |
| [ ] Deception | [ ] Record Review- Medical  |
| [ ] Focus Groups | [ ] Record Review - Other |
| [ ] Interviews | [ ] Specimen (e.g., blood, saliva, etc.) Collection or Analysis |
| [ ] Psychometric Testing | [ ] Other Social-Behavioral Procedures |
| [ ] Surveys and/or Questionnaires |  |

*5.2 <<Provide a description of all research procedures being performed and when they are performed.>>*

*5.3 <<If accessing or collecting existing data, describe:*

* *The data that will be collected during the study (e.g., demographics, medical history, etc.).*
* How the data will be obtained, including how you have the authority to access the data.
* The source or location of the data>>

5.5 <<If collecting and/or analyzing biological specimens (e.g., blood, saliva, etc.), describe:

* How the biological specimens will be or have been collected.
* How the biological specimens will be stored.
* How long the biological specimens will be stored.
* How the biological specimens will be used.
* The laboratories that will be used.
* Whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS) and whether the data will be forwarded to the NIH dbGaP.>>

5.6 <<If there are plans for long-term follow-up of participants (once all research related procedures are complete), describe what data will be collected during this period.>>

# 6.0 Data and Specimen Storage for Future Research & Sharing of Results

6.1 Storage for Future Research

6.1.1 <<If data or specimens will be banked for **future** **research studies**, describe where the data or specimens will be stored, how long it/they will be stored, how the data or specimens will be labelled and how it/they will be accessed, and who will have access to the data or specimens.

Describe whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS), whether the data will be forwarded to the NIH dbGaP, and attach the NIH-approved Genomic Data Sharing Plan as an appendix to the protocol.>>

6.1.2 <<Once this project has ended, list the data to be stored or associated with each specimen for use in future research.>>

6.1.3 <<Once the project has ended, describe the procedures to release data or specimens, for future research studies including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.>>

6.2 Sharing of Results with Participants

6.2.1<<Describe whether results (study results or individual participant results, such as results of diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g. the participant’s primary care physicians) and if so, indicate whether the lab is CLIA certified, describe under what circumstances results will be shared and how.>>

# 7.0 Study Timelines

7.1 <<Describe the time commitment of the participants (i.e., number of study visits, length of visit, length of participation in months or years, etc.).>>

# 8.0 Inclusion and Exclusion Criteria

8.1 <<Describe the criteria that define who will be included in your study (including age range).>>

8.2 <<Describe the criteria that define who will be excluded from your study. If non-English speakers will be excluded, provide justification here.>>

8.3 << Indicate specifically whether you will include or exclude participants outside of the U.S.>>

8.4 <<Indicate specifically whether you will include or exclude any of the following special populations: (You may not target members of the populations listed below as participants in your research unless you indicate this in your inclusion criteria.)

* Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners
* George Mason University Athletes
* Military>>

8.5 <<Describe screening procedures to assess/confirm that participants meet the inclusion criteria (e.g., participants self-screen based on recruitment/consent materials, screener survey/questionnaire, etc.)

8.6 <<Describe the circumstances that would make the participant ineligible to continue on the study once included (e.g., participant non-compliance with study procedures).>>

8.7 <<Indicate the total number of participants to be enrolled by George Mason University researchers.>>

# 9.0 Vulnerable Populations

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

Additionally, if the research involves any of the following populations, review the associated checklist to ensure you have provided sufficient information

* Pregnant women (HRP-411 - CHECKLIST - Pregnant Women)
* Prisoners (HRP-414 - CHECKLIST – Prisoners)
* Children (HRP-415 - CHECKLIST – Children)
* Cognitively impaired adults (HRP-416 - CHECKLIST - Cognitively Impaired Adults)>>

# 10.0 Recruitment Methods

10.1 Select the methods that will be used to recruit potential participants.

|  |  |
| --- | --- |
| [ ] Email | [ ] Record Review |
| [ ] Flyer | [ ] SONA |
| [ ] Letter | [ ] Research Match  |
| [ ] News Advertisement | [ ] Other |
| [ ] Online/Social Media Advertisement |  |

10.2 <<Describe when, where, and how potential participants will be recruited.>>

10.3 <<Describe how you will minimize undue influence and coercion during recruitment.>>

# 11.0 Withdrawal of Participants

11.1 <<Describe anticipated circumstances under which the principal investigator may withdraw a participant from the study>>

11.2 <<Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.>>

# 12.0 Risks to Participants

12.1 <<List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research.>>

12.2 <<If applicable, describe risks to others who are not participants (e.g., group harms).>>

12.3 <<Describe the procedures performed/steps to be taken to lessen the probability or magnitude of risks.>>

12.4 <<If you are using surveys/questionnaires/interviews/focus groups and any portion thereof could be upsetting to participants, describe the nature of the questions and how you will refer participants for counseling or other assistance. Include a plan for the study team developing criteria for which answers indicate distress, reviewing the answers before the participant leaves the study visit, and a plan for treatment or referral.>>

# 13.0 Potential Benefits to Participants or Others

13.1 <<Describe the potential benefits that individual participants may experience from taking part in the research. Note: incentives/compensation for participation are not considered benefits.>>

13.2 <<Describe benefits to society or others, if any.>>

# 14.0 Data Management and Confidentiality

14.1 <<Describe the data analysis plan, including any statistical procedures or power analyses, if relevant.>>

14.2 <<Describe the physical and electronic location where the data, including the informed consent document, will be stored (e.g., on GMU property such as PI office, Mason issued computer, OneDrive) and the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.>>14.3 <<Describe any procedures that will be used to ensure the accuracy and quality of collected data (e.g, attention checks in online surveys).>>

14.4 <<Describe how data will be handled study-wide:

* What identifiable information will be included in the data or associated with the specimens (e.g. names, dates, zip codes, accession numbers, etc.)?
* How long the data will be stored? Please refer to the Investigator Manual for data retention requirements.
* How the data will ultimately be destroyed?
* If you plan to share confidential data with anyone outside of the research group (e.g., those described in the consent), describe:
* With whom you will share the confidential data, under what circumstances this will occur, and explain how/whether participants will be informed.>>

14.5 If you will review/access and/or collect/obtain Protected Health Information (PHI) during recruitment or the main study, select all that apply.

|  |  |
| --- | --- |
| [ ]  Obtaining Signed Authorization | [ ]  Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only |
| [ ]  Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | [ ]  Waiver of HIPAA Authorization for Entire Study |
| [ ]  Data Use Agreement | [ ]  Business Associate Agreement |

* <<Describe the PHI that will be disclosed to or received from individuals outside of the research group (e.g., those not described in the consent), and your plan to maintain an accounting of disclosures.>>
* <<If you have selected an alteration or waiver in the table above, describe:
	+ - The inclusion criteria you will utilize to identify the records (e.g. diagnosis codes, treatments received, etc.).
		- The time interval of the charts/records involved, if applicable.
		- The plan to protect identifiers collected under the waiver or alteration from improper use and/or disclosure.
		- The plan to destroy the identifiers collected under the waiver or alteration at the earliest opportunity consistent with the conduct of the research.
		- Provide written assurance that the PHI will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.
		- Why it is not practicable to obtain signed HIPAA Authorizations from the participants before using or disclosing their PHI in your study.
		- Why your study cannot be conducted without access to and use of participants’ PHI.>>

14.6 NIH Data Sharing Plan

<<If this is a NIH funded study, copy and paste the data sharing plan accepted by the NIH sponsored grant.>>

# 15.0 Provisions to Protect the Privacy Interests of Participants

15.1 <<Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.>>

15.2 <<Indicate how the research team is permitted to access any sources of information about the participants.>>

# 16.0 Compensation for Research-Related Injury

16.1 <<If the research involves more than minimal risk to participants, describe the available compensation in the event of research related injury.>>

# 17.0 Participant Costs and Compensation

17.1 <<Describe any costs that participants will incur because of participation (e.g. travel costs, parking fees, purchase of special materials, etc.). Indicate whether these costs will be reimbursed. In addition, describe any support that may be available to help defray costs to participants.>>

17.2 If you will provide compensation to participants, select all that apply:

|  |  |
| --- | --- |
| [ ]  No Compensation | [ ]  Tokens (pens, food items, etc.) |
| [ ]  Financial Compensation (cash, gift cards) | [ ]  Other  |
| [ ]  Course Credit (i.e. extra credit, SONA points) |  |

<<Describe the amount and timing of any payments/incentives to participants. Please note, if providing extra credit to students an alternative non-research assignment of equivalent extra credit points/percentage must be offered to students – and mentioned here.>>

# 18.0 Consent Process

18.1 Select the consent options you will use during the course of the study. Each selection below must have a description in the subsequent section(s). Choose all that apply:

|  |  |
| --- | --- |
| [ ]  Obtaining Signed Consent (Participant or Legally Authorized Representative) | [ ]  Obtaining Consent Online (Waiver of Written Documentation of Consent) |
| [ ]  Obtaining Signed Parental Permission | [ ]  Obtaining Verbal Consent (Waiver of Written Documentation of Consent) |
| [ ]  Obtaining Signed Assent for Children or Adults Unable to Consent | [ ]  Waiving Consent and/or Parental Permission (Waiver of Consent Process) |
| [ ]  Obtaining Verbal Assent for Children or Adults Unable to Consent | [ ]  Waiving Assent/Assent is Not Appropriate |

18.2 <<If you will be obtaining signed consent or electronic consent (eConsent) from the participant or legally authorized individual (LAR), or will be obtaining signed parental permission, describe:

* *Where the consent process will take place.*
* Specify the platform used for eConsent, if applicable (i.e., RedCap, DocuSign).
* *The process to ensure ongoing consent (e.g., in longitudinal studies or studies with multiple interactions over time)*
* *Describe:*
	+ The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
	+ The time that will be devoted to the consent discussion.
	+ Steps that will be taken to minimize the possibility of coercion or undue influence during the consent process.
	+ Steps that will be taken to ensure the participants’ understanding.>>

18.3 <<If you will be obtaining consent online or verbally (no signature), review HRP-410 - CHECKLIST - Waiver of Written Documentation of Consent and provide justification for the requested waiver. Also, please describe:

* Where and/or how the consent process will take place
* Any waiting period available between informing the prospective participant and obtaining the verbal or online consent.
* The process to ensure ongoing consent (if applicable; e.g. for studies involving multiple visits).
* The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
* The time that will be devoted to the consent discussion.
* Steps that will be taken to minimize the possibility of coercion or undue influence.
* Steps that will be taken to ensure the participants’ understanding.>>

18.4 <<If you will enroll minors (children) as participants:

* *Describe how you will determine whether a prospective participant has not attained the legal age for consent under the applicable law of the jurisdiction in which the research will be conducted.*
* Describe how parental permission will be obtained. NOTE: Opt-out consent is not permitted.
* Describe the process for obtaining assent from the participants. Indicate whether:
	+ Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.
		- If assent will not be obtained from some or all participants, provide an explanation of why not.
	+ Assent of the participants will be documented and the process to document assent.>>

18.5 <<If you will enroll individuals who are unable to provide legal consent (e.g. cognitively impaired individuals or individuals requiring a LAR), describe:

* The criteria that will be used to determine whether a prospective participant is unable to provide legal consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.
* For participants with a LAR, list the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)>>

18.6 <<If you will obtain consent from non-English speaking participants, indicate the different language(s) of the prospective participants and describe the process to ensure that the oral and written information provided to those participants will be in their primary/native language, including who will act as translator>>

# 19.0 Setting

19.1 <<Describe the sites or locations where your research team will conduct the research.

* Identify where research procedures will be performed.
* For research conducted outside of the organization and its affiliates, including research conducted internationally, describe:
	+ Site-specific regulations or customs affecting the research for research outside the organization.
	+ Local scientific and ethical review structure outside the organization.
	+ The composition and involvement of any community advisory board.
	+ Upload a letter of support/other committee approval/host country approval on the Local Documents page of the IRB application.>>

# 20.0 References

20.1 <<*Provide your references>>*