Study Procedures Section

Depending on your responses, additional questions may appear.

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Study Procedures

* **Study Procedures**

Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

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* Identify what procedures are **experimental** and what are standard of care or established practice for the condition/situation.

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* **Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).**

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* Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.

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* **For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and non-subjects will be located during the activities.**

There should be an equal opportunity for non-participants to earn a benefit, such as extra credit, comparable to those participating.

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* **Recruitment Process**

Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- List any specific agencies or institutions that will provide access to prospective subjects.
- Identify who will contact prospective subjects and how.

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* **Recruitment Documents**

Upload all recruitment materials used in the study (e.g, flyers, advertisements, telephone scripts, etc.).

ATTACH

* **Compensation**

Will subjects be given any compensation/material inducements for participation?

Yes

* **Describe the amount, method, and timing of any payments to subjects, including how payments will be prorated for subjects who partially complete the study.**

- Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether W 9's will be collected.) UMS W9 Policy
- For raffles include the number of prizes, nature and value of each prize. Guidance
- If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.
- Who is responsible for costs incurred due to injury/harm?

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* **Genetic Testing**

Will this study involve genetic testing?

- (●) Yes
  Please describe this in the Study Procedures (above).
- ( ) No

* **Study Products**

Will the study involve any study products that may be FDA-regulated? For example, drugs, biologics, devices, diagnostics, dietary supplements, or food additives.

- (●) Yes
- ( ) No

If yes, Study Products section appears.

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* **Participant Duration**

Describe the duration of study participation, the length and number of study visits, and the timetable for study completion.

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Study Instruments

Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.

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Data & Specimens

How will the results be shared, with whom, and in what form?

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* **Identifiable Data/Specimens**

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or throug identifiers linked to these individuals (coded data with access to the key)?

- ( ) Yes
- (●) No

* **Collection & Handling**

Describe the information to be gathered and the means for collecting and recording data/specimens. Be sure to address:

- *Where and how will data or specimens be stored?*
- *What information will be included in that data or associated with the specimens?*
- *How long will the data or specimens be stored?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data and specimens be transported?*
- *If previously collected data is to be used, describe both the previous and proposed uses of these data.*

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* **Data & Specimen Security**

Describe the steps that will be taken to secure data and specimens during storage, use, and transfer (e.g., restricting staff access, password protection, encryption, physical security, separation of identifiers from data and specimens, certificates of confidentiality, etc.).

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* **Sharing Results with Subjects**

Will study results or individual subject results be shared with subjects or their providers (e.g., incidental findings, results of standard or research lab tests, genetic test results, etc.)?

- (●) Yes
- ( ) No

If yes, CLIA and Procedures for Sharing appear.

* **CLIA Certified Laboratory Results**

If laboratory results will be shared with subjects or their healthcare providers, confirm if the laboratory conducting the test is CLIA certified.

- ( ) Yes
- ( ) No
- (●) N/A

* **Procedures for Sharing Results**

Describe what results may be shared and how. If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

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* **Data Analysis**

Describe the data analysis plan, including any statistical procedures and a power analysis (if applicable). Describe any procedures that will be used for quality control of collected data.

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