

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.

Getting Started ✓	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. B I <u>U</u> S
Project Personnel ✓	
Basic Information ✓	
Study Selection	
Study Design	
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Participant Protection	

Experimental Procedures

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

Getting Started ✓	* Identify what procedures are experimental and what are standard of care or established practice for the condition/situation. B I <u>U</u> S
Project Personnel ✓	
Basic Information ✓	
Study Selection	

Conducting Procedures

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).

Basic Information ✓	* 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). B I <u>U</u> S
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If applicable, study instrument permission

If study instruments (e.g. surveys, interview questions, etc.) are not self-created or publicly available, please confirm permission to use each instrument.

Study Design	If study instruments (e.g. surveys, interview questions, etc.) are not self-created or publicly available, please confirm permission to use each instrument.
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If applicable, attach permission to use research instrument(s).

Links to Google docs will not be accepted.

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School-based Research

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.

Project Personnel	✓	* 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.
Basic Information	✓	
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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

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

-Limit attachments to just the recruitment materials.

-Attach Word or pdf only.

-Recruitment examples under [General Guidance](#)

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Compensation

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

Yes/No

If 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?

Sections	<
Getting Started	✓
Project Personnel	✓
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Genetic Testing

Will this study involve genetic testing?

Yes/No If yes, Please describe this in the Study Procedures (above).

Getting Started ✓	* Genetic Testing Will this study involve genetic testing? ☒ Yes Please describe this in the Study Procedures (above). ☐ No
Project Personnel ✓	
Basic Information ✓	
Study Selection	
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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 will appear in the blue left navigation.

* Study Procedures	* 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
Study Products	
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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.

Study Design	* Participant Duration Describe the duration of study participation, the length and number of study visits, and the timetable for study completion. B I U S ≡ ≡ ↺ ↻
* Study Procedures	
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Study Instruments

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

-Limit attachments to just the study instrument.

-Attach Word or pdf copies only.

Study Selection	Study Instruments <i>Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, data variables for secondary data analysis, etc.) to be used in the study.</i> <i>-Limit attachments to just the study instrument.</i> <i>-Attach Word or pdf copies only.</i> ATTACH
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Data & Specimens

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

Project Personnel ✓	* Data & Specimens * How will the results be shared, with whom, and in what form? B I U
Basic Information ✓	
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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 through 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.

Study Selection	* 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, two additional questions

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/NA

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.

Sections

- Getting Started ✓
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☒ Yes
☐ No

*** 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.

B I U S L I O A

Data/Specimen Banking & Future Research

Will any data and/or specimens from this project may be used for future research?

Yes/No, If yes, two additional questions

Future Genetic Research

Is it possible that the future research may include genetic research?

Data & Specimen Banking Procedures

Describe what data and/or specimens from this project will be banked for future use. Be sure to address:

- If the data/specimens will be banked in a separate, shared repository or a repository within this study.
- Where the data/specimens will be stored.
- How long they will be stored.
- How they may be accessed, and who will have access to the data/specimens.
- Describe the procedures to release data or specimens, 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.

Sections	* Data/Specimen Banking & Future Research Will any data and/or specimens from this project may be used for future research? ☒ Yes ☐ None at this time * Future Genetic Research Is it possible that the future research may include genetic research? ☒ Yes ☐ No * Data & Specimen Banking Procedures Describe what data and/or specimens from this project will be banked for future use. Be sure to address: • If the data/specimens will be banked in a separate, shared repository or a repository within this study. • Where the data/specimens will be stored. • How long they will be stored. • How they may be accessed, and who will have access to the data/specimens. • Describe the procedures to release data or specimens, 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.
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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.

Project Personnel	✓
Basic Information	✓
Study Selection	
Study Design	
* Study Procedures	* 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.