APPENDIX D

Institutional Review Board Full Review Form
(Revised May 20221

Clear Form

***If additional space is needed for description/information, please provide attachment(s).*

Information needed to properly complete this document is contained in the Rhodes State College. Institutional Review Board Charter and Standard Operating Procedures (IRB SOP) (12/15/2018 Revision). Questions about whether a research activity may be exempt from human subjects review or any other IRB issue should be directed to the Institutional Research Coordinator who serves as the IRB Chairperson.

Rhodes State College's IRB will determine whether your request is approved based on the Federal guidelines for review of eligible research activities as contained in the IRB Charter. If a question does not apply to your research project, please indicate this by typing "N/A" in the answer area.

Principal Investigator	**Phone**	**Email**
Additional Investigator	**Phone**	**Email**
Faculty Sponsor Name (for student PIs):		**Email**

Project Activity Status:

- ☐ **New Project**
- ☐ **Periodic Review of Continuing Project**
- ☐ **Revision to Previously approved Project**

A. Research Overview:

1. **Title of Project:**
2. **State the purpose/objective aims of your research:**
3. **If relevant, include your major hypotheses.**
4. **Source of Funding for Research (if any):**
5. **Projected Duration of Research:** **Projected Start Date:**
6. **Expected participants in research study will include:**

B. Research Procedures:

1. **Describe in detail the activities in which participants will participate, including any equipment that will be used. The IRB should be able to imagine every step the participant goes through.**

2. **Describe the amount of any biospecimens you are collecting and the mode of collection.**

3. **Specify the length of time each participant will be involved.**

4. **How are you obtaining informed consent from your participants? Specify if you are obtaining broad consent**. (Broad consent is required only when participants are identifiable, which can be done through demographic data in some cases. See Guidelines document for more information about broad consent.)

5. **If you believe that consent is not required, if you plan to obtain consent without using a consent form (e.g., verbal consent by illiterate adults), describe your justification. Explain how you will be sure that you have obtained consent.**

6. **Specify the location(s) of the study.**

7. **If you plan to use deception (misleading participants about the purpose of or procedures in a study), provide your rationale for using it.**

8. **If you plan to use deception or incomplete disclosure (withholding more information than your hypotheses in order to conduct an unbiased study), explain how you will debrief participants (e.g., written debriefing document, script for verbal debriefing).**

9. **How will you assure that participants are not coerced, in any way, to participate?**

C. Participant Information

1. **State the source of the participant population and how they will be recruited. Include any information about the use of incentives, if relevant.**

2. **State the total number of participants.**

3. **Does your research primarily include participants vulnerable to coercion or undue influence (children, prisoners, individuals with impaired decision-making ability, or members of economically/educationally disadvantaged groups)?**

4. **If your research includes vulnerable participants, state the rationale for their inclusion.**

5. **If your research includes non-English speaking participants, explain how participants will understand their rights and the research you plan to conduct. Include contact information (name, address, phone, and email) for the person translating for participants and explain this person's level of proficiency in the language of your participants.**

D. Participant Harms and Benefits

1. **Describe any potential risks of physical, emotional, financial, or social harm to participants.**

2. **Describe your methods for minimizing the risk of any potential harm.**

3. **Specify any factors that would cause you to stop this research due to participant stress (physical, emotional, etc.). Explain how you would halt the research for individual participants and the research as a whole.**

4. **Describe how you would report any incident of harm if such an incident occurred during this research.**

5. **State any anticipated direct benefits to your participants.**

6. **State any anticipated benefits to society-at-large or others (e.g., your academic field). Benefits to the self are not included in this section.**

E. Data Storage/sharing – Only answer one set of questions.

E.1 For projects where data is protected/anonymous (must be used for biospecimen research)

1. **Describe your methods for protecting the identity of individual participants.**

2. **Describe your plans for keeping and disposal of the original data in a way that keeps the data private.**

3. **Describe how biospecimens are labeled and how documentation matching them to participants is secure.**

4. **Describe how biospecimens will be stored after collection, for what length of time, and procedures for destruction.**

E.2 For projects where participant identities are shared (not appropriate for biospecimen research):

1. **Describe how biospecimens will be stored after collection, for what length of time, and procedures for destruction.**

2. **Indicate how individual data will be shared and stored (e.g., location, length of time, format, etc.).**

F. **For projects where participant identities are shared (not appropriate for biospecimen research)**

1. **Explain how you will ascertain whether or not participants agree to share their identity and procedures to be followed if a participant does not want her/his identity shared.**

2. **Indicate how individual data will be shared and stored (e.g., location, length of time, format, etc.).**

G. **Research Data and Surveys**

1. **Do you intend to use campus email lists (student, faculty, staff, employee) to send a request to complete the survey?** ☐ **Yes** ☐ **No**

2. **If yes, have you communicated with the Rhodes State Institutional Research Coordinator (or similar position if you are from another college)?** (Please be aware that there are strict guidelines that must be followed to send research surveys out via institution email lists, and it must be approved by the Institutional Research Coordinator. Without such approval, you may NOT send your survey out via those email lists). ☐ **Yes** ☐ **No**

3. **Method(s) of Data Collection (check all that apply):**
☐ **In Person** ☐ **Phone** ☐ **Email** ☐ **Surveys** ☐ **Other:**

4. **Method of removing all personal and/or identifiable information from research data:**

5. **Indicate how data will be shared and stored (e.g., location, length of time, format, etc.):**

H. Additional Documents - All documents should be submitted as one additional file (Word or PDF) in the same email as a complete IRB form.

1. Informed consent document or script
2. Recording consent document, if necessary
3. All materials (e.g., questions to be asked, images to be shown, links to videos, etc.)
4. Debriefing document or script, if necessary
5. Survey Request Form, if necessary

Your signature below affirms that:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

Investigator/Project Director Signature	**Date**	**Co-Investigator Signature (if applicable)**	**Date**

FOR IRB USE ONLY:

Signature of IRB Committee Chair **Date**

IRB Chair Exempt Requirements Approval: ☐ **Approved** ☐ **Approved with Conditions** ☐ **Refer to Full Committee Review**