FAIRMONT STATE UNIVERSITY™

CONSENT TO BE PART OF A RESEARCH STUDY

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study, and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Project Information

Study Title: Include title from IRB protocol.

Researcher: Include PI Name. *When applicable also include degree and title of PI; and name, degree, and title of advisor/co-investigator.*

Organization: Include affiliation of PI. *When applicable include collaborating organizations.*

Sponsor: Include name of agency or company. *If not applicable, you can delete the Sponsor item.*

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1. **BRIEF SUMMARY**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Include **brief** descriptions of the nature of the study that would help a potential participant decide whether to participate (e.g., discuss degree of risk, potential benefits, and main purpose of research). Exclusion criteria (if applicable) and voluntary nature must be included. Keep everything concise – details can be provided in later sections. **Do NOT** list any form of compensation (e.g., extra credit, money) as a benefit.

   - ADDITIONAL REQUIREMENT FOR CLINICAL TRIALS OR EXPERIMENTAL INTERVENTIONS: Disclose that the study involves clinical or experimental procedures and include the approximate number of participants involved.

2. **PURPOSE OF THIS RESEARCH STUDY**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Include 3-5 sentences written in nontechnical language. Where appropriate, explain what is being investigated, what the researcher is hypothesizing, what knowledge is being sought, and why.

   - EXCEPTION TO REQUIREMENT IF USING INCOMPLETE DISCLOSURE OR DECEPTION: The purpose section may be modified so as not to reveal the true purpose of the study. E.g., "*At the end of the study, we will explain in greater detail what we hope to learn from this research.*" Use of deception, alteration of consent and method of debriefing must be reviewed and approved by the IRB.

3. **PROCEDURES**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe procedures in chronological order and indicate the expected duration of subject's participation (per session and in total).

4. **POSSIBLE RISKS OR DISCOMFORT**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe known or anticipated risks of personal harm. If unknown, state so. Also indicate any steps researchers have taken to minimize risks and describe what the participants should do if they experience discomfort or side-effects.

5. **POSSIBLE BENEFITS**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.

6. **COMPENSATION AND COSTS**
   - GENERAL REQUIREMENT FOR ALL STUIDIES: Describe compensation or lack of compensation.
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe costs to the subject that might result from participation in this study.

7. **PRIVACY AND CONFIDENTIALITY**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe the extent to which confidentiality of records identifying the subject will be maintained before, during and after the study. Indicate whether data is anonymous, confidential, or linked to identifiers. Describe storage, coding, and de-identifying procedures when applicable. If applicable, extend discussion of privacy and confidentiality to concurrent or future sharing of data across researchers, organizations or studies.

8. **RESEARCH RESULTS AND FUTURE RESEARCH**
   - REQUIREMENT IF STUDY COULD INVOLVE CLINICALLY RELEVANT RESEARCH RESULTS: Indicate whether research results will be disclosed to subjects, and if so, under what conditions.

9. **TERMINATION OF RESEARCH STUDY**
   - GENERAL REQUIREMENT FOR ALL STUDIES: Describe the voluntary nature of participation and the right to withdrawal from the study at any time. Describe potential consequences of early withdrawal. If applicable, describe when the researcher may terminate the subject's participation and indicate potential consequences of early termination.

10. **CONTACT INFORMATION**
    - GENERAL REQUIREMENT FOR ALL STUDIES: Provide contact information for the Principle Investigator the IRB Chair.

11. **AUTHORIZATION AND RECORD OF INFORMATION PROVIDED**
    - GENERAL REQUIREMENT FOR ALL STUDIES: Indicate consent to participate written from the perspective of the participant.

"I have read and understand this consent form, and I volunteer to participate in this research study. I understand that my participation is voluntary and that refusal to participate or withdrawal from the study involves no penalty to me and will not alter future care. I have discussed this study, its risks and potential benefits, and my other choices with ***(Study Team Member Name/s)****. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in the previous section. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative*

may be asked to re-consent prior to my continued participation in this study. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws."

Participant Name (Printed or Typed): _____

Participant Signature: _____

Date: _____