**RESEARCHER:** Click or tap here to enter text.

**PROJECT TITLE:** Click or tap here to enter text.

**FILE #:** Click or tap here to enter text.

**REVIEWER:** Click or tap here to enter text.

**Project Information is Complete and Sound**

All required documents are included with the submission. Yes No

*(Documents may include: debriefing letter or script, external IRB approval*

*letter, questionnaire(s), test(s) or other instrument(s), recruitment materials)*

The investigator has adequately described sound methods/procedure. Yes No

The **inclusion/exclusion** criteria are appropriate. Yes No

Participant **vulnerability** is adequately addressed. Yes No

Potential **coercion** is adequately addressed. Yes No

If there is **deception**, it has been adequately addressed. Yes No

Participants’ **privacy** is adequately protected. Yes No

Participants’ **confidentiality** is adequately protected. Yes No

Compensation is commensurate with study demands. Yes No

**Study is Minimal Risk**

This study has only minimal risk(s). Yes No

(i.e., the risks of the proposed study are **not** considered to be greater than

those encountered in the participant’s daily life or during routine physical

or psychological examinations.)

If more than minimal risk, are there any safeguards needed? Yes No

*If safeguards are needed, this study will need to go to full review.*

**Confidentiality of Data**

Has the researcher adequately address who will have access to the data? Yes No

Is the data storage plan acceptable? Yes No

**COMMENTS:**

**Informed Consent Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Key Elements – These MUST be included in the consent statement*** | | | |
| **Included** |  | **Needs revision** | **Abbreviated Description of Informed Consent Element** |
|  |  |  | Consent for voluntary research participation |
|  |  |  | Purpose of research [1] |
|  |  |  | Research procedures [2] |
|  |  |  | Duration of research participation [3] |
|  |  |  | Appropriate alternative procedures available (including when course/extra credit is offered for other studies/activities) [4] |
|  |  |  | Reasonable foreseeable risks/discomforts [5] |
|  |  |  | Benefits to participants/others [6] |
| ***Basic Elements*** | | | |
| **Included** | **n/a** | **Needs revision** |  |
|  |  |  | Extent of confidentiality [7] |
|  |  |  | Compensation or remuneration if injury occurs [8] |
|  |  |  | Who to contact for questions about the research or to report an adverse experience |
|  |  |  | Statement that participation is voluntary, there is no penalty for decision to participate or not, and that the research can be discontinued at any time |
|  |  |  | * For any research involving the collection of private information or identifiable biospecimens, the consent MUST INCLUDE one of these statements: “Identiﬁers might be removed and your de-identiﬁed information or biospecimens used for future research without additional informed consent from you” or “Your information or biospecimens will not be used or distributed for future research studies even if identiﬁers are removed.” |
| ***Additional Elements*** | | | |
| **Included** | **n/a** | **Needs revision** |  |
|  |  |  | Some treatments may involve risks if the participant becomes pregnant |
|  |  |  | Circumstances under which participant’s participation may be terminated by the researcher |
|  |  |  | Additional costs that may result from participation |
|  |  |  | The consequences of withdrawing from the research (including implications when course/extra credit is offered in exchange for participation) |
|  |  |  | A statement that new findings that may impact participants’ willingness to continue will be reported to participants |
|  |  |  | The approximate number of participants involved in the study |
|  |  |  | That biospecimens may be used for commercial profit and that the participant will/will not share in this profit |
|  |  |  | Whether clinically relevant results will be disclosed to participants and under what conditions |
|  |  |  | Whether research with biospecimens may include whole genome sequencing in the future |
|  |  |  | If you plan to audiotape and/or videotape, request permission to do so, in writing and indicated how you will be using the information. |
|  |  |  | If DECEPTION IS USED, include a statement to the effect that the research cannot be fully described at this time, but at the conclusion of the participation, an explanation will be provide. (Debriefing statement included.) |
|  |  |  | Any costs to the participant that may result from participation |

The consent form contains all required element (see checklist, above). Yes No

Describe any revisions needed:

Are there additional elements that should be included in consent? Yes No

If yes, please specify:Click or tap here to enter text.

The process of informed consent is appropriate (i.e., not coercive). Yes No

The informed consent form is free of spelling and typographical errors. Yes No

**COMMENTS ON CONSENT PROCESS:**

**Summary of Review:**

**Approve**

**Approve, pending revisions**

**Reject** *(please provide rationale for rejection below)*