*Italicized text and blanks should be deleted or replaced as appropriate with information specific to your study.*

**Statement of Informed Consent**

*You must have the wording above (or something very similar) as your title. You may add a more specific subtitle here if you which to do so.*

**Key Information:** (*the first four of the five key elements below must be presented in clear and concise language. The fifth must be presented only when appropriate. You cannot change the first element except to adjust the pronoun and verb as appropriate. All other bullet points should be filled in with study-specific information)*

1. I(we) am(are) seeking your consent to participate in research. Your participation in voluntary and you may refuse to participate or withdraw from participation at any time without consequence.
2. *Purpose of research, expected duration of prospective subject’s participation, and procedures to be followed in the research*
3. *The reasonably foreseeable risks or discomforts to the prospective subject*
4. *The benefits to the prospective subject or others that may reasonably be expected from the research*
5. *Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject*

**Detailed Study Description:**

If you choose to participate, you will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*Describe here each activity the subject will be involved in. Be sure to include information about the type of intervention to be performed or information/specimen to be collected at each step )*.

**Risks and Benefits of Participation:**

This study involves the risk that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Describe any foreseeable risks of participation, including both physical risks and non-physical ones such as social or psychological harm, risk of criminal liability, or damage to financial standing, employability, or reputation. DO NOT say that there is no risk; if you cannot foresee any risks, describe the risk as minimal, or as no more than those encountered in daily life. Be sure to consider risks that might occur if confidentiality were accidentally breached.)*

There may also be other risks that we cannot predict.

It is reasonable to expect the following benefits from participation in the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Give here any reasonable expectations of benefit to the subject)*. However, we can’t guarantee that you personally will experience benefits from your participation. Others may benefit in the future from the information we gather in this study.

**Confidentiality:**

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Tell what identifying information will be collected, if any, how it will be stored, and who will have access to it. Explain how the data will be shared or published, whether it will be aggregated or direct quotes will be used, for instance. If aggregated, describe how participants will be protected from re-identification – for instance, by excluding aggregate information about groups with a small number of members)*

**Withdrawal from the Study:**

Your participation in this research is completely voluntary. If you decide to participate, you may change your mind and cease participating at any time (*Describe how the subject can withdraw from the study if desired). (if there is a point at which withdrawal is no longer possible—such as after submitting an anonymous survey or known/ approximate date when data analysis will be complete, explain that here.)* If you stop participating, you will not be penalized in any way or lose any benefits, and it will not harm your relationship with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Whoever is involved, for instance, a professor or employer)*.

**Other Information:**

*If there is an incentive for participation, explain it here.*

*If the subject’s information or biospecimens may be used for commercial profit, you must state that here and explain whether subjects will receive any of those profits)*.

*If clinically-relevant research results are obtained, including individual results, you must state here whether those results will be disclosed to participants and under what circumstances.*

*For research involving biospecimens, you must state whether research will or might include whole genome sequencing*.

*For studies involving identifiable private information or identifiable biospecimens, one of the following statements must be included:*

* *Identifiers might be removed from your private information or biospecimens and, after such removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent.*
* *The identifiable private information or biospecimens collected as part of this research will not be used or distributed for future research, even if identifiers are removed.*

*If you wish to seek broad consent for storage, maintenance, and secondary research use of any data collected as part of this research, you must explain that here and offer a mechanism for participant to document their consent (e.g. a separate signature/date line). You must provide a general description of the data to be stored/maintained and the types of research that may be conducted how you will prevent their data from being used in any future research if they choose not to consent. If the data is anonymous or is de-identified as part of the process of storage and maintenance, you should state that here and mention that withdrawal of broad consent at that point is not feasible)*

**Contact Information:**

If you have any questions about this study, or experience any problems, unexpected physical or psychological discomfort or injury, or think that something unusual or unexpected is happening, call \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Most likely contact information for the Principal Investigator, but other designate could be here)*

If you have any unanswered questions or concerns about your rights as a research participant, contact the Institutional Review Board at [irb@semo.edu](mailto:irb@semo.edu) or call Jennifer Bengtson, IRB chair, at (573) 651-2354.

*If you are requesting a waiver of documentation of informed consent, the signature lines below can be deleted.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Subject or Representative                        Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Subject or Representative

*The signed document should be stored appropriately by the investigator, and a copy should be provided to the research subject. In cases where consent is obtained electronically, an option to save or print the document must be available.*