**Department Name**

**Protocol Title:**

**Introduction of the Principal Investigator/Key Research Personnel: This should be a brief introduction including the names of the key research staff members, their titles, a description of their role in the research, and their contact information so the participant understands who is being referenced in the consent form by the use of pronouns or such terms as research staff/research team or similar terminology. For student projects, the faculty mentor must be included. It is University policy that student researchers cannot be Principal Investigators on research protocols, and they should not be listed as such.**

**NOTE: Federal regulations require the information presented in the consent form strictly adhere to the order as written in this template. You do not need to include the headers if you do not wish to include them, but the order in which the information is presented is imperative. All template instructional information must be removed from the document and the font size and color and spacing should be consistent.**

**Introduction:**

**This paragraph should be included as written in the template.**

**The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete. Your participation is voluntary.**

**What is the purpose for this research study?**

**The description should be consistent with the information included in Section 3 of the application.**

* **Using lay terminology at a reading level appropriate to the targeted population, describe the purpose for the study.**

**What will I be asked to do?**

**The description should be consistent with the information included in Section 4 of the application. If more than one method will be employed each should be described separately.**

* **Describe all research activities, including their purpose and duration. The participant should have a clear understanding of what they will be asked to do and the time commitment for participation from your description.**
* **Describe what types of measures you will use and explain who will administer them. Provide examples of the types of questions you are planning to ask when appropriate.**

**What are the possible risks of participation in this research study?**

**The description should be consistent with the information included in Section 12 of the application. All risks and how they will be mitigated should be described.**

* **Describe any reasonably foreseeable risks and/or discomforts associated with participation in the research consistent and how these risks will be mitigated and/or managed. The description must be consistent with the information regarding risks included in the protocol application.**
* **If support services will be available/provided, this should be described, and a separate list provided to the participant.**

**What are the possible benefits of participation in this research study?**

**The description should be consistent with the information included in Section 13 of the application.**

* **Describe any reasonable benefits expected from participation in the research. The description should distinguish between direct and indirect benefits and be consistent with the information regarding benefits in the protocol application. (e.g.-There may not be any direct benefits to the participant; however, there may be benefits to others, organizations, institutions, etc.).**
* **Describe any key information related to alternatives to participation in the study (when appropriate).**

**How will my privacy be protected?**

**The description should be consistent with the information included in Section 11 of the application. Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.**

* **Describe the provisions in place to protect the privacy interests of the participant. This refers to the participant’s desire to limit interventions or interactions with others and to limit access of others to their private information. This description should include the location of the data collection (i.e.-private location vs. public location, a private space with a closed door, the use of headphones for remote interviews conducted via the Internet, etc.), the method of data collection (focus groups, one-on-one interviews, questionnaires/surveys, via telephone, via identified remote Internet platforms, via email/posted mail communications, etc.), and the type of data that will be collected (i.e.-written vs. oral, recorded, etc.).**
* **If the research will occur in a setting where privacy cannot be guaranteed, the setting must be clearly described (i.e.-laboratory, classroom, public location, etc.). Participants should understand that there are limitations to the protection of their privacy as well as the confidentiality of the data collected in settings where privacy cannot be guaranteed. For example: Because this research will be conducted in a laboratory setting, there are limitations to the protection of your privacy and the confidentiality of the data collected.**

**How will my data be maintained to ensure confidentiality?**

**The description should be consistent with the information included in Section 11 of the application. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of this original disclosure without permission.**

* **Describe the methods you will use to maintain the confidentiality of the data. Include in your description how the data will be maintained (e.g.-paper, electronic, desk or lap top computer or other electronic device, etc.), the method for confidentiality and data security (e.g.-password protected computer, encrypted files, locked cabinet/office, etc.), and the names of the members of the research team or others (listed in Sections 1 or 6 of the application) that will have access to the data.**
* **If data will be shared, describe how data will be transferred or transmitted. If data will be transmitted via electronic networks, describe how you will secure the data during transit. The persons with whom you will share the data should be named.**
* **If data will be coded, describe the method (e.g.-assignment of ID #’s/pseudonyms) and name who will have access to the key to the code.**
* **Describe whether participants’ information or biospecimens will or will not be stripped of identifiers and used for future research and include *one* of the following statements:**

**A statement that identifiers might be removed from the identifiable private information/identifiable biospecimens and that, after such removal, the information/biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional consent from the participant or the legally authorized representative is not included. *OR***

**A statement that the participant’s information/biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies is not included.**

**ONLY when appropriate include the following headers:**

**Will photographs, audio, video, or film recording be used?**

**The description should be consistent with the information included in Section 11 of the application.**

* **If participants will be recorded/photographed in any manner, you must include a description of the purpose for them, how they will be used, who will have access to them and the disposition of them once the research study is complete.**
* **If recording is an option, checkboxes must be included at the end of the consent form for participants to indicate agreement for the recording. A separate checkbox for each type of recording should be created (e.g.- I agree to be audio recorded.**  **Yes  No; I agree to be video recorded.  Yes  No, etc.).**
* **If recording is not an option, include a statement at the end of the consent that verifies the participant’s understanding that by participating they will be recorded in some manner (specifying the type of recording/s as appropriate). For example: I understand the interview will be audio recorded.”**

**Will I receive compensation for participation?**

**The description should be consistent with the information included in Section 8 of the application and should only be included if participants will receive compensation.**

* **Describe the method of compensation (e.g.-cash, gift card, course credit, etc.), and how it will be awarded (e.g.-per task, per session, etc.).**
* **If you will hold a raffle/drawing, the odds of winning must be described.**
* **With the understanding that compensation cannot be contingent upon full participation, describe how compensation will be pro-rated awarded if a participant withdraws prior to completion.** **Compensation should be pro-rated in a manner that recognizes the time and effort of the participant prior to withdrawal. The amount the participant will receive should be specified. Participants should have a clear understanding of the way compensation will be awarded and how much they should expect to receive should they withdraw prior to completion.**

**Will clinically relevant research results will be returned to the participant?**

**Will research activities include whole genome sequencing?**

**Information about possible commercial profit.**

**Information regarding Certificates of Confidentiality:**

**If your research includes a Certificate of Confidentiality (CoC) you must include the following:**

**A Certificate of Confidentiality (CoC) protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside of this research.**

* **No one can be forced to share your identifiable information/biospecimens for a lawsuit.**
* **Your information cannot be used as evidence even if there is a court subpoena.**

**If you consent, your information/biospecimens could be shared for (restate what will be disclosed if there are other purposes listed in the consent form):**

* **other scientific research; and/or**
* **(explain the other purposes) not connected with this research.**

**The CoC does not prevent some disclosures:**

* **You can still share information about yourself. You can also freely discuss your involvement in this research.**
* **The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.**

**Information regarding situations of abuse/risk/harm if/when mandated reporting is indicated.**

* **Under Syracuse University policy, faculty and researchers are considered mandated reporters. Because of this, please make the following addition to your informed consent regarding situations of abuse/risk/harm if/when mandated reporting is indicated: *We will keep your study data as confidential as possible with the exception of certain information we must report for legal or ethical reasons such as child abuse, elder abuse, sexual misconduct, or intent to harm yourself or others.***

**Information regarding legal subpoena.**

* **Researchers who plan to ask participants about their or others' illegal activities (underage drinking, drug use, etc.) must clarify this on the consent and include the following sentences: "*The researcher is not immune to legal subpoena about illegal activities. Although it is very unlikely, if law enforcement officials asked to see my data, I would have to give it to them."***

**What are my rights as a research participant?**

**This information should be included as written in the template.**

* **Your participation is voluntary.**
* **You may skip and/or refuse to answer any question for any reason.**
* **You are free to withdraw from this research study at any time without penalty.**

**Whom may I contact with questions now, during, or after the research is complete?**

**This information should be included as written in the template.**

* **For questions, concerns or more information regarding this research you may contact *include the names and contact information of the Principal Investigator and key research personnel.***
* **If you have questions or concerns about your rights as a research participant, you may contact the Syracuse University Institutional Review Board at (315) 443-3013.**

**The following paragraph should be included as written in the template.**

**All of my questions have been answered, I am 18 years of age or older, and by signing this consent form, I agree to participate in this research study. I have received a copy of this form for my personal records.**

**­­­­­­­­­­­­­­­­­------------------------------------------------------------ Date: ­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of the Participant**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of the Participant**

**------------------------------------------------------------ Date: ­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of the Researcher**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of the Researcher**