Instructions: **ALL RED TEXT IS INSTRUCTIONAL. PLEASE DELETE FROM YOUR FINAL DOCUMENT.** This template may be used to help you build your consent document. The 2018 Final Rule has implemented numerous changes to the consent document requirements. Please contact ORSP at orsp@acu.edu if you have any questions about these changes. Use the template to build your consent document as appropriate for your study. You may delete sections that are not appropriate for your study, although the IRB may recommend reinserting in some cases.

PLEASE NOTE THE FOLLOWING REQUIREMENTS of consent: the individual or their legally authorized representative must provide consent, they should be given time to discuss and consider their participation, the language should be understandable to the individual/representative, they must be provided with the information that a "reasonable person" would want in order to make an informed decision, the presentation must be concise and focused in a manner that facilitates understanding for the individual/representative, and there must not be any exculpatory language (language that appears to remove someone's legal rights.)

Introduction: [insert title of study]

The introduction of the study must be a concise presentation of key information designed to facilitate understanding so that the potential participant can make an informed decision about their participation. Use simple, clear language. Avoid jargon specific to your field of study. Use active voice. Do not simply list facts. This may be somewhat flexible but generally includes the basic requirements of consent. The informed consent form should be brief and help the potential participant understand what you are asking them to do, and what they need to know about your research.

You may be able to take part in a research study. This form provides important information about that study, including the risks and benefits to you as a potential participant (Please note that if you are providing consent for another person, such as a child, "you" refers to the person for whom you are consenting) **[include in the form if study involves any kind of surrogate consent]**. Please read this form carefully and ask the researcher any questions that you may have about the study. You can ask about research activities and any risks or benefits you may experience. You may also wish to discuss your participation with other people, such as your family doctor or a family member.

Your participation in this research is entirely voluntary. You may refuse to participate or stop your participation at any time and for any reason without any penalty or loss of benefits to which you are otherwise entitled.

PURPOSE AND DESCRIPTION: [provide a brief explanation of the research and WHY it is being conducted, what is this a study of, and what you hope to learn. Must be in lay person's terms.]

If selected for participation, you will be asked to attend [##] visits with the study staff over the course of [## days/weeks/months/years]. Each visit is expected to take [## minutes/hours]. During the course of these visits, you will be asked to participate in the following procedures: [insert a concise, yet complete description of your study procedures, noting any group assignment procedures and any experimental

procedures, if applicable; be sure to state if there will be any recording, and specify audio only, or audio/video]

[If technology will be used capable of generating identifiable private information/biospecimens, include in description of research]

RISKS & BENEFITS: There are risks to taking part in this research study. Some of these risks may be serious. [delete this statement if the study is minimal risk]. Below is a list of the foreseeable risks, including the seriousness of those risks and how likely they are to occur:

- Breach of confidentiality; [Rare; Less likely;][Serious. Not serious.]

[insert a bulleted list of the risks identified in your study application, including physical, social, psychological, legal, and economic (*risk of Breach of Confidentiality should **always** be included on this list*). **State whether they are likely, less likely, or rare, and whether they are serious or not serious.**]

There are potential benefits to participating in this study. Such benefits may include [insert list of benefits as appropriate]. The researchers cannot guarantee that you will experience any personal benefits from participating in this study. [OR if no expected benefits: You may not experience any personal benefits from participating in this study.]

ALTERNATIVE PROCEDURES: [If appropriate, include a description of any alternative procedures or treatments that may be advantageous to the participant. If none are known, you may state that. If it is not applicable to your study, you may delete this section] There may be other options available to you, which include:

PRIVACY & CONFIDENTIALITY: Any information you provide will be confidential to the extent allowable by law. Some identifiable data may have to be shared with individuals outside of the study team, such as members of the ACU Institutional Review Board [or individuals affiliated with the granting agency]. Otherwise, your confidentiality will be protected by [insert a description of steps being taken to protect participant identity and personal information].

[For Focus Groups: The researchers cannot guarantee your confidentiality outside of this focus group. While the researchers will take measures to protect your identity and responses as outlined above, we cannot guarantee that other focus group participants will do the same. We encourage all participants to maintain the confidentiality of other participants in the group. The researchers request that you do not share any private information obtained during your participation or any other information that may identify the other participants unless you are legally required to do so.

Participants are encouraged to consider the limitations of confidentiality in the focus group setting. Participation is voluntary. At any time, you may decide not to share information or you may discontinue participating in the group altogether.]

I will adhere to ACU's data storage policies; that is -- data will be securely stored on campus for a period of at least 3 years following the completion of my study, after which it may legally be destroyed.

[For electronic surveys involving Qualtrics] The primary risk with this study is breach of confidentiality. However we have taken steps to minimize this risk. We will not be collecting any personal identification

data during the survey. However, Qualtrics may collect information from your computer. You may read their privacy statements here: https://www.qualtrics.com/privacy-statement/.

COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS: [include/edit as appropriate, otherwise delete section]: After identifying information is removed, your data [or biospecimens] may be used for future research, including by other researchers, without contacting you again. [OR Your data [biospecimens], with or without identifiers, will **not** be used for any other research purposes other than those described herein]

COMPENSATION FOR INJURY: [only if research is more than minimal risk, otherwise delete section] The researchers and ACU do not have any plan to pay for any injuries or problems you may experience by participating in this research. OR [insert statement of what compensation or treatments ARE available, if applicable]

CONTACTS: If you have questions about the research study, the lead researcher is [Name, credentials] and may be contacted at [provide telephone #, email, and/or mailing address]. If you are unable to reach the lead researcher, or wish to speak to someone other than the lead researcher, you may contact [name, credentials, and contact information of alternate contact person. **Students should include their Faculty Advisor here**]. If you have concerns about this study, believe you may have been injured because of this study, or have general questions about your rights as a research participant, you may contact ACU's IRB Chair, Raquel Ellis, at raquel.ellis@acu.edu.

Additional Information

HIPAA [FERPA] AUTHORIZATION: [Include/edit this section if it is relevant to your study, otherwise delete section] [when HIPAA or FERPA protected data is being accessed, the disclosure authorization may be included as part of the overall consent document, when it is clearly identified as such. Authorizations should include the following: What is being accessed (what protected information will be viewed and/or collected), Who is accessing the information and/or to whom is it being given, Why– for what purpose, How Long– for how long will access to (or retaining of) identifiable protected information be required, A statement of the right to refuse or revoke authorization, If any treatments or benefits are conditional on authorization, A statement regarding risk of accidental disclosure]Additional information should be provided to the extent that it is applicable to the study and provides important information to aid in decision-making. Non-essential information should be placed toward the end so as not to impede the basic understanding of the elements needed for consent. Remember, concise and focused

[expected # of participants to be enrolled in study]

There may be unexpected risks associated with your participation in this study and some of those may be serious. We will notify you if any such risks are identified throughout the course of the study which may affect your willingness to participate. [include if study is greater than minimal risk and has the potential for serious events]

[If applicable, include a statement about any risks or consequences that may be associated with early withdrawal from the study.]

[If applicable, identify any conditions under which the participant may be withdrawn by the investigators and what procedures to expect in these circumstances.] Your participation may be ended early by the researchers for certain reasons. For example, we may end your participation if you no longer meet study requirements, the researchers believe it is no longer in your best interest to continue participating, you do not follow the instructions provided by the researchers, or the study is ended. You will be contacted by the researchers and given further instructions in the event that you are removed from the study.

[If applicable, please describe any costs that the participant may incur as a result of participating in the study.]

[in studies involving biospecimens, a statement that the biospecimens may be used for commercial profit (if applicable), and whether the participants will share in profit.]

[when applicable, a statement regarding whether clinical results will or will not be provided to the participants, and if provided, under what circumstances.]

[when involving biospecimens, a statements as to whether whole genome sequencing will (if known) or might occur (if specimens will be shared/stored for future research, with or without identifiers)]

Please let the researchers know if you are participating in any other research studies at this time. [include if it is important for you to know this information]

[If applicable, please describe any payments that will be made to the participants, including how much, how it will be distributed (cash, check, gift card etc), when it will be paid, and what, if anything, they will receive if they choose to withdraw from the study prior to completion.]

Consent Signature Section

Please sign this form if you voluntarily agree to participate in this study. Sign only after you have read all of the information provided and your questions have been answered to your satisfaction. You should receive a copy of this signed consent form. You do not waive any legal rights by signing this form.

[For ***electronic consent*** to complete an online survey: Please click the button below if you voluntarily agree to participate in this study. Click only after you have read all of the information provided and your questions have been answered to your satisfaction. If you wish to have a copy of this consent form, you may print it now. You do not waive any legal rights by consenting to this study.][**PLEASE NOTE: ELECTRONIC SIGNATURES ARE NOW CONSIDERED AN ACCEPTABLE FORM OF DOCUMENTATION. PLEASE CONSIDER USING THIS WHEN DEVISING ELECTRONIC CONSENTS.**]

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date
_____	_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

[As appropriate, add lines for signatures of parent/guardian/legally authorized representative and/or witness. When surrogate consent is given, the signature of the participant above should represent assent, when appropriate. DELETE THIS BOX IF NO SURROGATE SIGNATURE IS SOUGHT]

_____	_____	_____
Printed Name of Surrogate	Signature of Surrogate	Date

Role of Surrogate: ☐ Parent ☐ Guardian ☐ Legally Authorized Representative

_____	_____	_____
Printed Name of Witness	Signature of Witness	Date