**Sample Only (revised 02/23/21) – Cannot be used without IRB Approval**

**Consent Disclosure Statement**

[*for Survey Research, Exempt Benign Behavioral Interventions, and other projects where an alteration of consent request may be approved by the IRB*]

[*The consent disclosure statement may only be submitted to the IRB if you are requesting an alteration of informed consent in the Form 1 IRB electronic application. A request for an alteration of consent must satisfy the following conditions:*

* *the research involves no more than minimal risk to the subjects;*
* *the alteration will not adversely affect the rights and welfare of the subjects;*
* *the research could not practicably be carried out without the alteration;*
* *if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and*
* *whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

*Also, remember that if you are collecting individually identifiable health information protected under HIPAA, you must request a waiver of the subject authorization for the HIPAA requirements in the Form 1 IRB electronic application.*]

[*Be sure to use the UTHSC header and to insert a ‘preparation date’ on the document.*]

[***NOTE****: Willingness of the subjects to complete the research activity after reading this consent disclosure statement will serve as adequate documentation of informed consent (versus requiring a subject’s signature*). *Remember, however, that when you secure the prospective verbal agreement of subjects on the phone or in person, this should be documented in each subject’s research record.*]

1. Provide the title of the research study at the top of the page.
2. Specifically state that this is a “research study”, or that this survey is part of a “research study.”
3. Indicate who is performing the research (i.e., the Principal Investigator’s name), and provide a phone number, indicating that they should contact you (or name the designee) “if you have questions about this research study.”
4. State the purpose of the research in lay terms.
5. Explain the research procedures in lay terms and how long the subject will participate. For example, explain that the study involves answering a series of questions and that it should take about 20 minutes to answer the questions.
6. If you will conduct an **exempt benign behavioral intervention** and it will involve deceiving subjects regarding the nature or purposes of the research, you must state that the subject will be unaware of or misled regarding the nature or purposes of the research. In addition, explain whether and if so, when, subjects will be debriefed regarding the nature of the deception and the reason it was used.
7. List any foreseeable risks. These might include tiring from answering questions; being uncomfortable when answering sensitive questions; the subject’s private, identifiable information being seen by people not involved in the research; etc. If there are no foreseeable risks, this should be clearly stated.
8. Explain the anticipated benefits for society (i.e., what knowledge could be gained?) and any anticipated direct benefits for subjects. If there will be no direct benefits to subjects, this should be clearly stated.
9. Specifically state, “Your participation is voluntary and if you choose to not participate or to stop participating at any time, your decision will not result in a penalty or affect your rights.”

If you will be recruiting potential subjects who are students, residents, or fellows (of UT/any school associated with this research) and/or employees (of UT/any institution/agency associated with this research), include the following statement(s):

“If you are a student of [*school name*], participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of [*school name*], participating or not participating in this study will in no way influence your academic standing. If you are an employee of [*name of institution/agency*], participating or not participating in this study will not affect your employment status.”

1. Explain how you will maintain the confidentiality of the data.
2. Specifically state,

“You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.”

12. If you are conducting a clinical trial with (i.e., administering for research purposes and evaluating) a drug, biologic, and/or device, the following sentences must be included:

 A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**FUTURE CONTACT:**

[*Include this section and EDIT the following paragraph if you wish to retain subjects’ contact information (and PHI) in order to contact them in the future regarding participation in other studies- you must also indicate this in your application.*]

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN keep your contact information and health information to ask you about participating in future studies.

\_\_\_\_\_\_\_We MAY NOT keep your contact information and health information to ask you about participating in future studies.

[*Include this section and EDIT the following paragraph if you wish to attempt to find subjects lost to follow up- you must also indicate this in your application.*]

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

* The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
* Certified mail will be sent to you requesting that you call us.
* A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
* [*list any other ways that you stated in your application*]

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN attempt to find/contact you in the above ways.

\_\_\_\_\_\_\_We MAY NOT attempt to find/contact you in the above ways.