**Sample Only (revised 1/23/17) – Cannot be used without IRB Approval**

**Basic Elements of Consent Disclosure Statements**

**for Survey Research**

[*These survey consent elements may only be used 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; and*
* *whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

*Also, remember that if you are collecting PHI and identifiers, 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****: If you are conducting a survey, the following statements should be incorporated into a short introductory paragraph placed directly before the survey questions. Willingness of the subjects to complete the survey will serve as adequate documentation of informed consent.*]

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. 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.
7. 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.
8. 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, [*and choose from the following corresponding phrases if you will be recruiting potential subjects who are patients, and/or students of UT/any school associated with this research, and/or employees of UT/any institution/agency associated with this research*] your medical care, your grade in any course, or your employment status.”
9. Explain how you will maintain the confidentiality of the data.
10. Specifically state, “You may contact Terrence F. Ackerman, Ph.D., UTHSC IRB Chairman, 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.”

**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.*]

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.*]

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.