Informed Consent Guidance for Repositories

**Repository Consent**

**Research Study contributing to another repository. If the Repository is:**

* Local (under UTHSCSA IRB oversight): Use currently approved consent from original repository study
* External (not under UTHSCSA IRB oversight):
1. Submit [Form D](https://www.uthscsa.edu/sites/default/files/Services/forms/form_d.docx) or [Form D-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_d-1.doc) for the research study; and also submit [Form E](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e.doc) to explain the repository collection, storage and distribution procedures.
2. When submitting Form D or D-1, incorporate Sponsor’s optional sub-study language into the consent. If the sponsor has not provided language, you may use the following language:

**Optional Sub-Study:**

In addition to the main study, you are being asked to volunteer for an optional sub-study that involves collection and storage of materials (tissues and/or data) for a repository. A research repository is a special type of research also known as a tissue bank or data registry. A repository provides a way for researchers to store samples of tissues (for example, blood, tissue specimens obtained from biopsies, and tissues or organs removed during surgery) and information (for example, information from your medical record about your condition) about a person for future use in research studies.

The following materials will be collected and stored in the repository: [list type of data/information being banked]

After reading and considering the above information, indicate below if you give permission for (*insert investigator or sponsor)* to keep your \_\_\_\_\_\_\_\_\_\_\_\_(specify - *tissue/blood sample, DNA and/or medical/health information*) at \_\_\_\_\_\_\_\_\_\_\_\_\_\_*[insert name and location of repository]* until they are used up but no longer than\_\_\_\_\_\_\_\_\_\_\_\_\_\_(insert time frame) years for use in future research to learn more about how to prevent, detect, or treat \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*insert name of disease*).

Remember your participation in this sub-study is optional. You can still be in the main study even if you do not wish to participate in this sub-study.

If you answer yes, you also give your authorization for your accompanying health information to be used and disclosed along with the materials.

Yes, I choose to participate in the optional banking sub-study. \_\_\_\_Initials

No, I choose not to participate in the optional banking sub-study. \_\_\_Initials