

Language to be Incorporated into a Non-Clinical Trial Consent Document

This information should follow the CONFIDENTIALITY section:

Protected Health Information (PHI) is any health information through which you can be identified. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). A decision to participate in this research means that you agree to let the research team use and share your PHI for the study explained above.

The following sections are to be customized by the Investigator with a “specific and meaningful” description.

Information that will be used or disclosed:

The research team will look at your _____ (see below for options) and record information needed for the study in your research file.

(HIPAA requires a “specific and meaningful description” of the information. The description should be as specific as possible but should also be broad enough to cover ALL information that you think you will need during this study.

Options: billing records; hospital/medical records (in and out-patient); physician/clinic records; PHI previously collected for research purposes; questionnaires/interviews; lab, pathology and/or radiology samples/results)

Choose one of the following additional sentences as it applies to your research:

Your research file will be coded and the investigator will keep a master list separate from your file. This way only the research team will be able to identify you.

OR

Your research file will contain identifiable information such as your name, patient ID#, or birthdate.

Who may use or disclose the information:

This section is to be customized by the Investigator. Include the name or other specific identification of the person(s) or class of persons authorized to make the requested use or disclosure.

Who may receive the information:

This section is to be customized by the Investigator. Include the name or other specific identification of the person(s) or class of persons who may receive the information.

Purpose of each use or disclosure:

This section is to be customized by the Investigator.

Expiration of the authorization:

This section is to be customized by the Investigator. “End of research study” or “none” is permissible. Possible endpoints include:

Indefinite use – this option is available only when necessitated by the study, i.e. databases/registries. Revise the consent form section as appropriate for the study to explain why identifiers will be retained.

The end of the study

The completion of data collection; specimen processing is complete

Destruction of the database/registry

___ years after closure of the study

FDA approval of the study drug

___ years after approval of the study drug

specific date

Right to revoke authorization:

This section is to be customized by the Investigator. Include a statement of the subject’s right to revoke and a description of how the subject may revoke the authorization.

“You have the right to revoke your authorization to use your PHI. You must notify the Principal Investigator in writing that you are revoking your authorization. From and after the date your notice of revocation is received, you will not be allowed to participate any further in the research and UNTHSC will stop collecting your health information. However, even if you revoke this authorization and your participating in this research study, we may still use and share your health information already obtained as necessary to maintain the integrity of the research study.”

Potential for re-disclosure:

“Some of these people may share your health information with someone else. If they do, the same laws that the Health Science Center must obey may not protect your health information.

Review for the Protection of Participants:

This research study has been reviewed and approved by the UNTHSC Committee for the Protection of Human Subjects on *Insert Approval Date Here*. The UNTHSC IRB can be contacted at (817) 735-5483 with any questions or concerns regarding this study. If you have questions or concerns about your privacy and the use of your PHI, please contact _____.

Research Subject's Rights:

I have read or have had read to me all of the above.

_____ has explained the study to me and answered all of my questions. I have been told the risks and/or discomforts as well as the possible benefits of the study. I have been told of other choices of treatment available to me. I have been told how my health information will be used and disclosed for the study.

I understand that I do not have to take part in this study or authorize use and disclosure of

my health information, and my refusal to participate or my decision to withdraw will involve no penalty, loss of rights, loss of benefits, or legal recourse to which I am entitled. If I decide to withdraw from the study, the study personnel may only use and disclose my health information already collected. If I decide to revoke my authorization to use and disclose my health information, I may not be allowed to continue in the study. The study personnel may choose to stop my participation at any time.

In case problems or questions arise, I have been told I can contact the Principal Investigator at telephone number _____.

I understand my rights as research subject and I voluntarily consent to participate in this study. I understand what the study is about, how the study is conducted, and why it is being performed. I will receive a signed copy of this consent and authorization after it has been signed.

Signature of Subject or Subject's Legal Representative*

Date

*Description of Legal Representative's authority to act on behalf of Subject

Signature of Witness

Date

For the Investigator or Designee:

I certify that I have reviewed the contents of this form with the subject signing above. I have explained the known benefits and risks of the research and the use and disclosure of health information. It is my opinion that the subject understood the explanation.

Signature of Principal Investigator/Designee

Date

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