HIPAA Template Language Instructions

Use if: Your research involves the disclosure or use of Protected Health Information (PHI)

Before you start: Read these tips to avoid delays!

1. You will need to insert the template language into the informed consent document after the **Confidentiality** section.
2. **Customize this template to reflect the specifics of your study**. Modify the text in **blue**, **red** and **green** as they apply to your study. Some items may not be applicable to your research.
   - Keep all language and formatting, including bolding, shown in **regular black text** unless otherwise noted.
   - **Blue** text identifies required elements and includes issues to consider when developing your version of the document.
   - **Red** text identifies required elements to be included when applicable to the research.
   - **Green** text provides examples or suggested language for the elements indicated by the blue and red text.

   Color Code Key:

   Black: Required template text

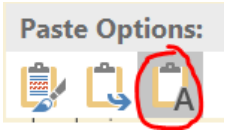
   Blue: Required Element of Informed Consent

   Red: Required Element when applicable

   Green: Suggested language/examples

   Highlighted Text: Instruction

3. **Use the "Paste Special" command** instead of "Paste" when inserting the template language into your informed consent document. We recommend selecting the Keep Text Only option as shown in this screen shot.

4. 

5. **Before submitting the consent document to the IRB:**
   - **If using suggested language shown in green text**, change the text color to black.
   - **Remove all instructional text** (**red** and **blue**) before submitting this form to the IRB. Failure to do so will result in return of your application without review.

Use of Your Identifiable Health Information

A law, called the Health Information Portability and Accountability Act (HIPAA), protects your health information. When choosing to take part in this study, you are giving us permission to obtain and use your health information. This health information includes information in your medical records and information that can identify you (like your name, or phone number), so generally this information cannot be used in research without your written permission.

If you give your permission, your health information that will be shared with us and used in the study includes:

Your name and phone number.

Your health information above will be shared with us by your health care providers listed below.

[List below all health care providers (persons, groups or organizations – or health plans and health care clearinghouses, if used) that will share health information about their patients with the researchers.

- Delete any providers listed that do not apply to your study.
- Add providers applicable to your research.
- If the providers are not yet known, include one or more spaces below to allow the research participant to write-in their provider(s) name(s)].

- The University of Tennessee Hearing and Speech Center
- The University of Tennessee Health Science Center, Memphis
- The University of Tennessee Medical Center, Knoxville
- The University of Tennessee, Knoxville – [**list the specific UTK component(s) providing the PHI:**] Psychological Clinic, Vine School Health Center, Student Health Center, Veterinary Social Work
- East Tennessee Children's Hospital
- Tennessee Orthopaedic Clinics
- Other: _____

We may need to share your health information with other people or organizations. Below is a list of those people and organizations and the reasons why they may see or get your health information.

- Members of the research team and other authorized staff at the University of Tennessee, Knoxville [If collaborative or multi-site study, include name(s) of the other institution(s)] who make sure it is safe for you to be in this study, conduct the study and analyze the research data.
- People at the University of Tennessee, Knoxville [If the research is a collaborative or multi-site study, add the name(s) of the other institution(s)] who oversee and evaluate research. This includes the ethics board and quality improvement program that work to ensure research is conducted properly.
- People from and agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- [If participants will be paid:] Business offices at the University of Tennessee, Knoxville may be given your name, address, Social Security Number, payment amount and related information to issue your payment and report tax information.

- [If funded, include the name of agency/sponsor] who is the study sponsor paying or providing equipment for this research.
- [If applicable:] Information about your study participation may be included in your medical record.
- [If a data safety monitoring board is involved with the study:] Groups monitoring the safety of this study.
- [If the research is regulated by the FDA:] The Food and Drug Administration (FDA).
- [If study involves the delivery of treatment or other health care for which participants might be billed] Your medical insurance provider or other organizations that may need the information in order to pay your health care costs or other costs related to your participation in the study.
- [If applicable, list any other organizations or class of persons to whom the participant's information might be disclosed: e.g., others who will conduct data analysis, data coordinating center, outside laboratories that will analyze specimens/data:]

Some of these people or organizations that may see or get your health information may not have to follow the same privacy laws and protect your information in the same way that we will. Your health information will not be shared with anyone else without your permission unless all information that can identify you is removed.

[Select one of the options below.]

[**Option 1**] Your permission for us to use and share your health information for this study will last until [Include an expiration date or event that relates to the participant or the research], unless you cancel it sooner.

[**Option 2**] Your permission to use and share your health information for this study will continue until the research study ends and will not expire, unless you cancel it sooner. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

[NOTE: HIPAA requires that consent forms be maintained for 6 years after the study is completed.]

Can I change my mind about the use of my health information?

At any time you may change your mind and withdraw your permission for your health care provider(s) to share or use your health information for the research; however you cannot get back information that was already shared.

To takeback your permission, you must write the researcher and tell him or her of your decision. You should also send a copy of this written notification to your health care providers. In the letter, state that you changed your mind and do not want any more of your health information shared or collected.

[Insert the investigator's name, address and email address here].

Once you take away your permission, no new health information will be shared with us. However, health information that has already been collected or shared with us may still be used as necessary to maintain the integrity of the research and as required by law. Also, if you take away your permission, you may not be able to stay in the research study.

You do not have to allow use of your health information, but if you do not sign this form to allow its use, you cannot take part in the research study. If you do not allow use of your health

information, it will not affect your relationship with the researchers, the University of Tennessee, your health care provider(s) or any of the services and benefits you and your family receive from them in any way.

You have the right to see and copy your health information that is shared or used in this study. However in order to complete the research, your access to this information may be restricted during the conduct of the study to maintain the integrity of the research. When the study is completed, you will be able to access to this information.