**AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE HEALTH INFORMATION**

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

You authorize [PI’s name] and study staff to access/share your information for the following study [add title and IRB number]

**Your health information will be used for** [Study Title]

**Your health information that may be accessed, used and/or released includes:**

* Demographic information
* Results of physical exams
* Blood tests
* X-rays
* Other diagnostic and medical procedures related to the study
* Medical Record Number
* Social Security Number

**The Researchers may use and share your health information with:**

*Note: The information listed in this section should include all the agencies/researchers included in the consent form; however, the authorization may require additional information or more specific information than the consent form.*

* The University of Kentucky’s Institutional Review Board/Office of Research Integrity;
* Law enforcement agencies when required by law;
* University of Kentucky representatives;
  + - * + UK Hospital *{if applicable. You must include this item if you are providing financial compensation for study participation or obtaining lab results from UKMC}*;
        + UK Health systems (EPIC, the electronic medical records) and health systems outside of UK that you have a patient relationship with;
* *If your research falls under the purview of a government agency (e.g. FDA, NIH, etc.), list them in this section of the authorization form.*
* Investigational Drug Service (IDS) *{if investigational drugs are dispensed through IDS}*;
* Center for Clinical and Translational Science (CCTS) *{if CCTS staff are involved in the study}*;
* National Cancer Institute (NCI) *for cancer-related studies only*;
* *List any collaborators, outside laboratories, etc.*
* *If applicable – list the sponsor’s name and its agent(s) or government agency funding your research.*
* *List any other groups with whom the information may be shared.*
* *If the participant’s primary physician will be contacted by the researcher, if in the course of the project, the study team learns of a medical condition that needs immediate attention.* Your primary physician will be contacted if we learn of a medical condition that needs immediate attention.

*If reporting pregnancy is required by the Sponsor add the following language to the authorization form.*: If you become pregnant anytime during the study or within \_\_\_ days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

***OR***

*IF a separate authorization to release pregnancy information to the Sponsor may be required:* A separate authorization to release pregnancy information to the Sponsor may be required.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

* Current or future healthcare at the University of Kentucky;
* Current or future payments to the University of Kentucky;
* Ability to enroll in any health plans (if applicable); or
* Eligibility for benefits (if applicable).

**After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:**

* Send a written letter to: {*name and contact information of PI}* to inform *{him/her}* of your decision.
* Researchers may use and release your health information **already** collected for this research study.
* Your protected health information may still be used and released should you have a bad reaction (adverse event).

*Optional item - include if participant will be able to access the information collected for the research study after the study is complete:* You will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you may have the right to access the information.

The use and sharing of your information has no time limit.

**If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky’s Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184**

**You will receive a copy of this consent form after it has been signed.**

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| *Remove this shaded section if not seeking IRB approval to obtain consent from a legally authorized representative*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *\*Printed name of research subject’s legal representative*  *\*If applicable, please explain Representative’s relationship to subject and include a description of representative’s authority to act on behalf of subject:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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