

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Protocol Title:

Principal Investigator:

Sub-Investigator(s):

What is the purpose of this form?

Federal Privacy Regulations provide safeguards for privacy and security of health information that may identify you. Health information through which you can be identified is called "Protected Health Information". This authorization (*permission*) form gives more detailed information about how your personal health information will be protected and includes:

- What protected health information about you will be collected in this study
- Who will use your information within this Decatur Radiology Physicians and Decatur Memorial Hospital and why
- Who may disclose (*release*) your protected health information and to whom
- Your right to access research information about yourself
- Your right to withdraw your authorization for any future use of your protected health information

By signing this document, you are permitting Decatur Memorial Hospital to use protected health information collected about you for research purposes within Decatur Memorial Hospital. You are also allowing Decatur Memorial Hospital to disclose that protected health information to outside organizations or people that participate in this research study.

What protected health information is collected and used in this study and might also be disclosed?

The following protected health information will be collected, used for research and may be disclosed or released during your involvement with this research study. Your entire medical record, including but not limited to the following:

- Name
- Address
- Telephone number
- Social security number
- Medical record number
- Race
- Gender
- Date of birth
- History and diagnosis of your disease
- Family medical history
- Current and past medical records
- Prior medical history
- Current and past medications

- Current and past therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, temperature, height and weight
- Medical data, including laboratory tests results, tumor measurements, CT scans, MRIs, x-rays, operative reports and pathology results
- Information on side effects (*adverse events*) you may experience and how these were treated
- Data that may be related to [blood and/or urine]that will be collected from you

You may request a blank copy of the data forms from the research physician or his/her research staff to assist you in understanding what information will be used and disclosed.

Why is your protected health information being used?

Your personal contact information is important for Decatur Memorial Hospital to contact you during the study. Your protected health information is being collected and used to determine if you are eligible for this study, to conduct this research study and for the advancement of medicine and clinical care. The purpose of this study is

The Principal Investigator and/or sub-investigator(s) may also use some of the results of these tests and procedures to treat you.

Which of our personnel may use or disclose your protected health information?

The following individuals and organizations may use or disclose your protected health information for this research project:

- The Principal Investigator and the Investigator's study team (*other Decatur Radiology Physicians and Decatur Memorial Hospital staff associated with the study*)
- Authorized members of the Decatur Radiology Physicians and Decatur Memorial Hospital workforce who may need to access your information in the performance of their duties (*for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.*)

Who, outside of Decatur Memorial Hospital might receive your protected health information?

As part of the study, the Principal Investigator and study team may disclose your protected health information, including the results of the research study tests and procedures to the following:

- the Food and Drug Administration (*FDA*)
- the Office for Human Research Protections (*OHRP*)
- Decatur Memorial Hospital IRB (*which is a group of people who review the research to protect your rights*) appropriate research study staff and physicians with Decatur Memorial Hospital (*DMH*)
DMH appropriate research staff, compliance officer and/or his/her designee, administrative staff, information systems staff for data compilation and study oversight
- Bradley University IRB, and faculty sponsor, **insert name**, for study oversight
- Millikin University IRB, and faculty sponsor, **insert name**, for study oversight

If your research record is reviewed by any of the groups listed above, your medical record may also need to be reviewed in order to confirm and/or clarify the information in your research record.

The Principal Investigator or study staff will inform you if there are any changes to the list above during your participation in the trial.

Once information is disclosed to others outside of Decatur Memorial Hospital, the information may no longer be covered by the federal privacy protection rules and we cannot assure you that the information will remain protected.

In all disclosures outside of Decatur Memorial Hospital, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

In records and information disclosed outside of Decatur Memorial Hospital and [insert name] University, you will be assigned a unique code. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at [list end point—e.g. the end of the research study].

How long will Decatur Memorial Hospital be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study will be used until [insert end point - such as: the study closes; the data collection is completed; the database/registry is destroyed; years after closure of the study; FDA approval of the study drug; years after FDA approval of the study drug; ___(supply specific date) or indicate that the authorization will not expire]. This information may be maintained in a research repository (*database*). However, the Principal Investigator may not re-use or re-disclose your protected health information collected in this study for another purpose other than the research described in this document unless:

- The Decatur Memorial Hospital Institutional Review Board has granted permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

Will you be able to access your records?

[If applicable, for the majority of blinded studies or other studies where access will be denied:] During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your research physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over. However, the investigator is not required to release to you research information that is not part of your medical record.

[If applicable for open label studies and other studies for which access will not be denied:]

During your participation in this study, you will have access to your medical record and any study information that is a part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Can you refuse to provide authorization for the use of your protected health information for the purpose of this research study?

Your decision whether to allow the use and disclosure of your identifiable health information for the purpose of this research study is completely voluntary. However, since sharing information is essential to the research, if you do not provide your written authorization for the use and disclosure of your identifiable health information, you will not be allowed to participate in the research study.

Whether or not you provide your authorization to use and disclose your identifiable health information will have no affect on your current or future medical care at Decatur Memorial Hospital.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but **you must do so in writing** to the Principal Investigator at the address on the first page of this document. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, in order to maintain the integrity of the research, researchers may continue to use the health information that was provided before you withdrew your permission. In addition, even if you change your mind and withdraw your permission, your protected health information may still be used and disclosed should you have an adverse event (*bad effect*).

Since sharing information is essential to this research, if you withdraw your permission to use and disclose your protected health information that means you will be withdrawn from the research study at that time.

Your decision to withdraw your authorization for the research use and disclosure of your protected health information will have no affect on your current or future medical care at Decatur Memorial Hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Who do I contact for additional information?

The Notice of Privacy Practices (*a separate document*) describes the procedures used by the researcher to protect your protected health information. If you have not already received the Notice of Privacy Practices, the research team will make one available to you.

If you have any questions or concerns about your privacy rights, contact the Privacy Officer for Decatur Memorial Hospital at 217-876-2115, Beth Paul, RN.

You will be given a copy of this signed and dated Authorization Form.

If you sign this form, will you automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and a separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

DOCUMENTATION OF AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

You are voluntarily making a decision to allow the use and disclosure of protected health information collected and generated about you for research purposes as described above. Your signature means that you have read and understood the information presented and have decided to authorize the use and disclosure of your protected health information. Your signature also means that the information on this authorization form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during this study, you should contact the researcher(s).

I agree to permit the use and disclosure of my protected health information for research purposes as described above.

Signature of Participant or Legally Authorized Representative*	Date
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Printed Name

*Please explain Representative's Relationship to Patient and include a description of Representative's Authority to act on behalf of Participant:

IRB Approved: xx/xx/xx