

AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

IRB Number:

Protocol Title:

Principal Investigator: Dr. James L. Wade III
210 W. McKinley Avenue
Decatur, IL 62526
Telephone: (217) 876-6600

What is the purpose of this authorization?

The privacy of your individually identifiable health information is protected by the federal Health Insurance Portability & Accountability Act (*HIPAA*) of 1996 and its regulations, the Standards for the Privacy of Individually Identifiable Health Information (“*Health Privacy Rule*”), as well as other applicable federal and/or state laws. This identifiable health information about yourself is called “Protected Health Information”. By signing this form, you will be authorizing researchers at Decatur Memorial Hospital and Cancer Care Specialists of Central Illinois to use and disclose your Protected Health Information. This form describes how researchers will use your Protected Health Information.

What protected health information may be used or shared?

All information relating to any examinations, tests, procedures, or questionnaires as outlined in the Patient Information and Consent Form, as well as your medical records which contain your name, address, telephone number, date of birth, race, gender, and government-issued identification numbers.

What will the protected health information be used for?

Your protected health information will be used or shared to determine if you are eligible for this study and to determine what treatment options might work best for you. *Enter purpose of the study from the informed consent form.*

Who may use or disclose my protected health information?

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

- the research base [*give name*]
- the National Cancer Institute (*NCI*)
- the Cancer Trials Support Unit (*CTSU*), a research group sponsored by the National Cancer Institute (*NCI*) to provide patients and physicians greater access to cancer trials
- the Food and Drug Administration (*FDA*)
- the Office for Human Research Protections (*OHRP*)
- the drug manufacturer [*please list*]
- Decatur Memorial Hospital IRB (*which is a group of people who review the research to protect your rights*)
- Decatur Memorial Hospital research staff, pharmacists, compliance officer or designee, administrative staff, or information systems staff for data

- Dr. James L. Wade, III and members of his research team at Cancer Care Specialists of Central Illinois
- Authorized personnel at Cancer Care Specialists of Central Illinois who may need to access your information in the performance of their duties (*for example: to provide treatment, to ensure integrity of the research, or for accounting or billing matters, etc.*)

What about confidentiality?

Information collected about you may be published or presented at scientific meetings, but your name and other personal information will not be used. However, once information is disclosed to others outside of Decatur Memorial Hospital and Cancer Care Specialists of Central Illinois, the information may no longer be covered by the Health Privacy Rule, and we cannot assure you that your information will remain protected.

Will I have access to my research records?

You will not be allowed to review, inspect or copy the information collected for the research until after the study is completed. When the study has concluded, you will have the right to access the information again.

How long does this authorization last?

This authorization does not have an expiration date.

Can I change my mind?

You may withdraw your permission for the use and disclosure of any of your protected health information for research, but you must do so in writing to the Principal Investigator at the address on the first page of this document. If you revoke this authorization, researchers may only use and disclose the protected health information **already** collected for this research study. 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 effect (*bad effect*).

Can I refuse to provide this authorization for research purposes?

Your decision 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.

Whatever you decide, it will have no affect on your current or future medical care at Decatur Memorial Hospital or Cancer Care Specialists of Central Illinois.

Where can I find additional information?

The Notice of Privacy Practices (*a separate document*) describes the non-research procedure(s) used by your physician to protect your identifiable 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 217-876-2128.

You may also visit the HHS web site at: <http://www.hhs.gov/ocr/privacy/index.html>

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

It is my full understanding that the information disclosed may include the following sensitive information:

- AIDS/HIV Information (pursuant to the AIDS Confidentiality Act, 410 ILCS § 305, and the Perinatal HIV Prevention ACT, 410 ILCSC § 335).
- Genetic test information (pursuant to the Genetic Information Privacy Act, 410 ILCS § 513).

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

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: