

Research Participant's Name (last, first, middle and SSN):

Date:

Title of Study: *(enter title here on page 1)*

Principal Investigator: *(enter name of PI here on page 1)*

VAMC: John D. Dingell
VA Medical Center

The following elements must be included:

PURPOSE OF RESEARCH STUDY:

DESCRIPTION:

RISKS:

BENEFITS:

ALTERNATE COURSES OF ACTION:

STATEMENT OF RESEARCH RESULTS:

SPECIAL CIRCUMSTANCES:

COMPENSATION:

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REQUEST FOR PATIENT AUTHORIZATION FOR ACCESS TO PROTECTED HEALTH INFORMATION

1. By signing this document, you authorize the Veterans Health Administration (VHA) to provide **(insert name of Principal Investigator)** and his or her research team to access your Protected Health Information (medical chart data) for research purposes. This information may include the following: Hospital records and reports; admission history, and physical; X-ray films and reports; operative reports; laboratory reports; treatment and test results; psychotherapy notes; dental notes; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical records needed by the research team. *(This list may be edited by the research PI, please delete this line)*

2. Your Protected Health Information will be stored in a secure location and will be used for the following research purposes: *(Brief description to be completed by research PI, please delete this line)*

3. I understand that the information to be released may include information regarding the following condition(s): sickle cell anemia, drug abuse, alcoholism or alcohol abuse, testing for or infection with human immunodeficiency virus (HIV)

4. You may refuse to sign this authorization and refuse to allow the disclosure of your Protected Health Information. Your refusal will not affect your ability to receive medical care or benefits at the Detroit VAMC.

5. *(PI must select one of the following choices and delete the rest)*

This authorization will expire at the end of the research study;

This authorization will expire at this date_____;

This authorization will expire at this event_____;

or This authorization has no expiration date.

6. This authorization may be revoked at any time by sending a written request to **(PI name and address here)** If you revoke this authorization, **(insert name of Principal Investigator)** and his or her research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

7. The Detroit VAMC complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

8. *Insert the following if the study has a sponsor outside the VHA (i.e., pharmaceutical company):*

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As part of the study, we may disclose your information to **(insert name of sponsor)**, the sponsoring company for this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for the purposes related to the study. Any information shared with the sponsor may no longer be protected under federal law. If appropriate insert the following: Because this study involves material regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect records identifying you as a subject in this research.” If appropriate insert the following: Payments to research participants will be issued by Metropolitan Detroit Research & Education Foundation (MDREF). MDREF administrators will access your name, address and social security number to process payments.

9. *(Insert the following if the study includes the creation of a database or tissue repository):*

This study includes the creation of a database of information or specimens such as blood, tissue, or other bodily fluids that will be used in future research. By signing this authorization, you agree to allow the information collected in this study to be added to that database.

RESEARCH PARTICIPANT'S RIGHTS:

I have read or have had read to me all of the above. Dr. *[insert name of PI]* has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

If you have any questions, concerns or complaints about this study now or in the future, you may contact *[insert name of PI]* or one of *[his/her]* research team members at the following phone number *[insert telephone number]*. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, call the Research Office at (313) 576-1000, ext. 61046 to ask questions or voice concerns or complaints or the Patient Advocate at (313) 576-1000, ext. 65158.

The results of this study may be published, but my records will not be revealed unless required by law. In case there are medical problems or questions, I have been told I can call Dr. *[insert name of PI]* at *[insert telephone number]* during the day and *[insert name]* at *[insert telephone number]* after hours.

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no additional compensation is available. No reimbursement, compensation or free

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medical care is offered by Wayne State University. (You can also add, if applicable, DMC hospitals, NIH, etc.)

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

(Note: If this study will be enrolling only patients who are capable of consenting for themselves, delete all references to the Subject's Legally Authorized Representative.)

X _____ X _____
Research Participant's Signature Date

X _____ X _____ X _____
Signature of Participant's Representative Representative (Print Name) Date
(Only required if subject is not competent.)

X _____ X _____ X _____
Signature of Witness Witness (Print Name) Date
(Participant's signature **MUST** be witnessed. If subject cannot read, independent witness must observe consent process.)

X _____ X _____ X _____
Signature of person obtaining consent (Print Name) Date
(Study personnel must be approved by VA IRB.)