# RICHARD L. ROUDEBUSH VETERANS AFFAIRS MEDICAL CENTERINFORMED CONSENT STATEMENT FOR RESEARCH

**[Insert Protocol Title]**

**[Insert IRB Protocol Number]**

**[Insert Sponsor Name and Sponsor Protocol Number]**

**[Insert name of PI]**

**[Insert name of VA PI (if different)]**

## ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

## STUDY SUMMARY

[Write a concise and focused summary of the key information most likely to assist a subject in understanding why they may or may not want to participate in the study. Feel free to be creative with format and language. Consider including pictures or icons or flowcharts to describe your study. Additional guidance about the concise presentation is available at <https://research.iu.edu/compliance/human-subjects/guidance/informed-consent.html>.]

**[If the consent is concise as written (typically no more than a few pages total), you may delete this section entirely including bolded text immediately below.]**

**Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.**

## WHY IS THIS STUDY BEING DONE?

[Insert explanation for why the research is being done. Use language understandable to the subject (i.e., eighth grade level).]

[If the study involves the use of an investigational drug or device, explain that “investigational” means it is not approved by the Food and Drug Administration (FDA).]

We are asking you if you want to be in this study because [Insert explanation regarding how and/or why the subject was identified].

The study is being conducted by [Insert investigator(s) name(s) and University/Departmental affiliation]. It is funded by [Insert Sponsor name, if any, and include if the Sponsor is also the manufacturer of the drug/device being studied, if applicable].

## HOW MANY PEOPLE WILL TAKE PART?

[**This section is only required for greater than minimal risk research. Otherwise, this section can be deleted.]**

You will be one of [Insert number] participants taking part in this study. [For multi-center studies, include both the local and multi-site number of subjects.]

## WHAT WILL HAPPEN DURING THE STUDY?

[Insert explanation of all procedures/tests that are included in the study using language understandable to the subject (i.e., eighth grade level). This should include, when applicable, randomization, assignment to study groups, study visits, administration of study medications, x-rays or imaging, blood draws, surveys and questionnaires, audio or video recordings, and all other study procedures.

For each procedure, explain:

* Where the procedures are performed and how frequently they are performed
* The expected amount of time each procedure and/or visit will last
* Whether the procedure is experimental or part of usual care for patients
* For measurements, such as blood draws, translate the amount to common measurement terms (e.g., teaspoons, cups)

Include the total duration of subject participation, e.g., You will be in this study for about two years.]

[If clinically relevant results will be generated by the research but will NOT be given to subjects]: You will not receive the results of any of these tests or procedures because they are being done only for research purposes.

[If you will return research results to participants, carefully customize the following language to align with your plan for returning results. See the IU HRPP Guidance on [Returning Research Results](https://research.iu.edu/compliance/human-subjects/guidance/returning-research-results.html) for details about creating a plan and important considerations. The three bullets below correspond to the four categories of results discussed in the guidance. You should only include bullets for the categories that are appropriate for your study. You may not need all three, or you may need to draft new language to fit your plan. Where possible, we strongly recommend incorporating this information within the description of each procedure above.]

If you participate in this study, we may learn things about you from the study procedures that could be important or interesting to you. Depending on the information, you might need to meet with professionals with expertise to help you decide what to do with the information. We do not have money or funds available to cover the costs of any follow-up consultations or actions. We will share the following information with you:

* [If your study will generate information critical to the management of a participant’s health in the immediate/near future]: Any information that might be immediately critical to your health will be shared with you or your health care provider.
* [If your study will generate information that has known implication for health or risk AND is clinically actionable]: [Describe information to be shared, e.g., genes that may suggest you have an increased risk of [disease]; lab tests, x-rays, or other images that could suggest you have a disease that could be treated]. This information may be helpful for your health in the future. [You are encouraged to allow subjects to opt-in/out of receiving this information. If your plan for sharing results includes opt-in/out, include options and initial lines for subjects to indicate whether they want to receive information. See [Guidance](https://research.iu.edu/compliance/human-subjects/guidance/returning-research-results.html) for details.]
* [If your study will generate information that is not clinically actionable OR not known to have any implication for health or risk]: During this study, we will learn things about you that you may find interesting but probably will not help you. Health care providers may not know what the information means or what to do about it. Examples include [describe]. Some people find this kind of information confusing or stressful. You can choose whether to receive this information. [Include options and initial lines for subjects to indicate whether they want to receive information. See [Guidance](https://research.iu.edu/compliance/human-subjects/guidance/returning-research-results.html) for details.]

## WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

[Insert explanation of the risks, side effects, and/or discomforts of each of the procedures using language understandable to the subject (i.e., eighth grade level).

For drug studies, include risks and side effects of all medications given to subjects for the purpose of the study, as well as the likelihood of the risks and/or side effects (e.g., rare or common or provide a percentage).

Include an explanation of measures that will be employed to minimize the risks. If applicable, include an explanation of any psychological/counseling, social, or medical services that may be required because of participation in the research.

Examples of risk statements with protection procedures:

* You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.
* There is a risk someone outside the study team could get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is below.
* The risks of drawing blood include pain, bruising, and, rarely, infection. Blood will be drawn by experienced staff members. We will also try to collect blood for the study when you are already getting a blood draw for your regular medical care.
* Common side effects associated with taking the study drug are confusion, sleepiness, depression, anxiety, and headaches. Side effects that occur more rarely include hair loss, rash, and pain or tingling in your hands or feet. We will ask you about any side effects at each study visit.]

[If appropriate, insert the following:] There also may be other side effects that we cannot predict. If you become pregnant while you are participating in this study, this may include risks to your unborn baby.

## WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees in accordance with applicable federal regulations. This does not apply to (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.

By signing this form, you are not giving up any legal rights or benefits to which you are otherwise entitled.

## WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

[Insert a statement of potential benefits. Examples include:

We don’t think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

Participating in this study may lessen the symptoms of your disease. However, we don’t know for sure. We are doing this research study to find out if this treatment helps or not.]

## WILL I BE PAID FOR PARTICIPATION?

[Insert one of the following:]

You will not be paid for participating in this study.

**OR**

[Insert a description of the details and any conditions of payment, including if partial payment is applicable.]

[For research involving payment, insert the following:] In order to receive payment, you may be required to provide your Social Security number or tax identification number. You may receive a 1099 tax form the following January and will need to report this payment as income on your federal and state tax returns. You are responsible for paying any state, federal, or Social Security taxes. If you have questions regarding how this impacts your tax return, please contact a tax professional to assist you.

## WILL IT COST ME ANYTHING TO PARTICIPATE?

[List any additional costs to the subject that may result from participation in the study. Note, listing additional costs should be rare.]
**If not applicable, then use this statement:** There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

You will not be required to pay for medical care or services received as a subject in a VA research project except as follows:

Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are **not** part of this study.

## WHAT ARE THE OTHER TREATMENT OPTIONS?

**[This section is only required for treatment/therapeutic research. This section should be deleted if the research is not intended as potential treatment for the subject’s medical condition.]**

There may be other options for treatment of your [insert applicable condition]. [Insert details regarding other possible treatment options such as surgery, drug treatment, management of symptoms, etc.]

## HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study [and databases in which results may be stored].

[If audio or video recordings will be made, insert the following section:] **Audio/Video Recording and Photography**

Your interview will be [audio and/or video recorded or photographed], which will be used for research purposes. At any time you may tell the researcher that you feel uncomfortable or do not wish to continue. The Audio/Video/Photograph files will be stored on a password-protected computer at \_\_\_\_ (give location or entity name and list on the HIPAA Authorization). The Audio/Video/Photograph will be shared with someone outside the VA at\_\_\_\_\_(give location or entity name and list on the HIPAA Authorization). NOTE: No VA audio/video/photographs can be stored on the device itself. All recordings must be uploaded to a secure server from the device. After the upload is complete the device recording must be erased.

The investigator may list additional protections, such as if the subject may be identified by a code.

Research records will be maintained by the investigator in accordance with the VHA Records Control Schedule. [If sensitive VA data will be removed or stored outside of the VA facility or electronic firewall, please mention where it will be stored, how long it will be stored and by whom.]

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor, the Indiana University Institutional Review Board or its designees, the VA Research and Development Committee’s designees, and federal agencies, including but not limited to the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), VA Office of the Inspector General (OIG), [list all additional relevant federal agencies, such as General Accounting Office (GAO), National Cancer Institute (NCI), Food and Drug Administration (FDA), etc. If an FDA-regulated test article is involved, FDA requires a statement that the FDA may choose to inspect research records that include the subject’s individual medical records].

[If the study is an NIH funded or FDA regulated clinical trial, insert the following:] A description of this clinical trial will be available on [ClinicalTrials.gov](http://clinicaltrials.gov/), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

[If the study is NIH funded, you automatically receive a Certificate of Confidentiality, and must include this section. If the study is not NIH funded, but the study has obtained or intends to obtain a Certificate, insert the following, as appropriate:] This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations. [If FDA-regulated, insert:] The Certificate also does not stop sharing of information required by the Food and Drug Administration (FDA).

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

## WILL MY INFORMATION [AND SPECIMENS] BE USED FOR RESEARCH IN THE FUTURE?

[If the research involves the collection or use of identifiable private information or biospecimens, insert the following:]

Information [and specimens] collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

[If the research involves the storage and maintenance of identifiable private information or biospecimens for future use:][Insert a description of the proposed use, collection and storage procedures, procedures for oversight of security and maintenance, who will have access, procedures to protect confidentiality, procedures for withdrawal, etc. For more information, see [Guidance on Biospecimens](https://research.iu.edu/compliance/human-subjects/guidance/areas/biospecimens.html).]

[If specimens may be used for commercial profit, insert the following:] Specimens collected from you for this research may be used to develop products which could be sold in the future. The investigator does not plan to share any profits or losses from the sale of those products with you.

## WHAT WILL YOU DO WITH MY GENETIC INFORMATION?

**[Required only for studies collecting or using biospecimens. Otherwise, this section should be deleted.]**

We may [or will not] use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. [If “may” is selected: Insert a description including what information will be gained, how the information will be used and stored, any risks of whole genome sequencing, whether the information will be provided back to the subject, and, if so, whether it may be clinically relevant.]

[If genetics studies will be performed, insert the following:] The specimens collected in this study will be used for genetic studies which may include taking your DNA from the specimens. Every person’s DNA is unique; therefore, it may be possible some day that someone could find out who you are just from knowing your DNA sequence. [If results of genetic testing will be shared with subjects, describe any applicable genetic risks including paternity misattribution and the effects of the knowledge that one is the carrier of a disease gene that might affect their life course. If applicable, also include the risks of stigmatization of a subject or group, generational conflict within a family, harm to relatives, or future use of biospecimens in projects objectionable to the subject. List the precautions that will be taken to minimize the potential harm of receiving bad news and to preserve the confidentiality of the results.]

[If the study involves genetic testing or the tracking of a particular disease or disorder in an individual’s family, insert the following:] The genetic information in this research study is protected by the Genetic Information Nondiscrimination Act (GINA), a federal law that makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to request the genetic information we get from this research and to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

## WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

**[Required only when an investigator has a financial interest deemed related to the research by the Conflict of Interest or IRB office. Otherwise, this section should be deleted. Note, the VA also requires a Conflict of Interest disclosure on the VA form 450 Alt through the RLR VAMC Research Administrative Office.]**

[Insert description of individual and nature of interest, e.g., Dr. XXX provides consulting services for the sponsor of this study] We are giving you this information so you can decide if this affects your willingness to participate in this study. If you would like more information, please ask the researchers or study staff.

## WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

In case there are medical problems or questions, Dr. \_\_\_\_\_\_\_ can be called at \_\_\_\_\_\_\_\_\_\_\_\_ during the day and Dr. \_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_ after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at (317) 988-2602. For questions about your rights as a research subject or complaints about a research study, contact the Indiana University Human Research Protection Program at 800-696-2949 or at irb@iu.edu. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the VA Research Personnel Office at 317-988-3032.

## WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Roudebush VAMC.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, [explain the procedure for withdrawal from the study]. [If withdrawal from the study prior to completion could pose risk to the subject, insert a description of what those risks might be and how orderly termination will occur.]

[If appropriate, insert the following:] The researchers may stop your participation in the study even if you do not want to stop if [Insert a description of when and why study participation may be terminated and how orderly termination will occur]. [If appropriate:] Also, this study could be stopped by [Insert Sponsor/investigator, as appropriate] if [Insert a reason for possible premature termination of the entire study].

[If appropriate, insert the following:] You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

## PARTICIPANT’S CONSENT

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

**Participant’s Printed Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant’s Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Person Obtaining Consent:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_

[If the study involves individuals who cannot consent for themselves, include the following:]

**Participant’s Printed Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Legally Authorized Representative (LAR):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of LAR:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_