

# Revised Common Rule Changes to the Consent Process and Consent Form

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**Background:** The Federal Policy for the Protection of Human Subjects—the Common Rule—was revised in 2017 to reduce administrative burdens for low-risk research while enhancing protections for human subjects enrolled in greater-than-minimal-risk trials. These enhanced protections involve changes to the consent process.

**Methods:** We review the general requirements applicable to the consent process, as well as the additional elements of consent mandated by the revisions to the Common Rule. The regulations apply to federally funded studies and are optional for non-federally funded studies.

**Results:** Two new general requirements for the consent process, one basic required element for the consent form, and three optional additional elements for the consent form were added in an effort to improve potential subjects' understanding of research studies and to facilitate the exchange of information between the research staff and potential subjects. Important information about the study should be extracted into a concise key information section to help potential subjects make informed decisions regarding participation.

**Conclusion:** The revisions to the Common Rule are intended to enhance human subject protection by providing more information in an understandable form during the consent process. The new consent elements aim to increase transparency and help improve clarity.

**Keywords:** *Consent forms, ethics committees—research, informed consent*

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## INTRODUCTION

Respect for human dignity and individual autonomy is one of the basic principles of research ethics.<sup>1,2</sup> Consequently, voluntary informed consent is required from potential subjects before they can be enrolled in a research study. Obtaining this consent involves ongoing interaction between the research staff and the potential subject. The consent process should ensure that subjects have the information they need to make an informed decision about whether or not to participate. In addition to verbal discussions, the written consent form plays an important role in the consent process and should be used as a guide for the exchange of information between the research staff and the potential subject. The consent form should not only facilitate discussions that expand the subject's understanding of the study, but it also serves as a reference for the potential subject to take home as he/she considers whether to enroll in the study.<sup>3-8</sup>

The Federal Policy for the Protection of Human Subjects, known as the Common Rule, is a set of regulations that guide the ethical conduct of human subjects research. Revisions to the Common Rule were published on January 19, 2017 with

a general compliance date of January 19, 2019, the first significant changes to the rule since it was published in 1991. The revisions to the regulations changed the consent form to improve potential subjects' understanding of a research study and to accommodate changes in the research environment. The regulations apply to federally funded studies and are optional for non-federally funded studies. The goal of the revisions is to promote subjects' autonomy so that they can make informed decisions regarding participation in a research study.

We review the changes to the general requirements for the consent process and the new consent form elements mandated in the revised Common Rule.<sup>8-14</sup>

## TWO NEW GENERAL REQUIREMENTS

When a potential subject is invited to participate in a research study, the following general requirements apply to the consent process:

1. Informed consent of the subject or the subject's legally authorized representative must be obtained prior to involving the subject in research.

2. Investigators must give the potential subject or the legally authorized representative the opportunity to discuss and consider whether or not to participate, and the investigator must minimize coercion or undue influence.
3. Informed consent information must be in language understandable to the subject or the legally authorized representative.
4. Information must be provided that a reasonable person would want to know to make an informed decision about whether to participate, and there must be an opportunity to discuss that information.
5. Informed consent must begin with a concise and focused presentation of the key information that is organized and presented in a way to facilitate understanding of the reasons why one might or might not want to participate.
6. Informed consent cannot include exculpatory language through which the subject or legally authorized representative is made to waive any of the subject's legal rights or that releases the investigator from liability for negligence.<sup>9</sup>

Requirements 4 and 5 are new. The "reasonable person" standard is used to clarify the level of information that potential subjects would want to know before deciding if they'd like to participate. Potential subjects should have the opportunity to engage in ongoing discussions with the research staff to ensure understanding. The other new requirement is to begin the consent form with a brief and focused summary of the information that is most relevant to the decision-making process.<sup>6</sup> The summary should include a statement that the subject's participation is voluntary, an explanation of the purpose of the research, and a description of the procedures, as well as how long the subject will be involved in the study, the risks, the benefits, and the alternatives if the subject decides not to participate.<sup>6,8,9-11,15-20</sup>

The key information summary addresses a problem in the consent process. Research has documented that consent forms have become lengthy and complex, and many subjects therefore have limited understanding of the research for which they are providing consent.<sup>3</sup> A 2009 review of the literature found that fewer than one-third of subjects adequately understood important aspects of their studies, such as study goals, risks/benefits, and randomization.<sup>21</sup> Many consent documents are written at a reading level that is higher than the average recommended eighth-grade level, but almost half of American adults read at or below the eighth-grade level.<sup>3,22</sup>

The reasonable person standard for presenting information and the key information summary can help subjects with the decision-making process by facilitating discussion with the research staff and by presenting significant information in a transparent and easy-to-understand manner.

#### FOUR NEW CONSENT FORM ELEMENTS

The revised Common Rule adds four new elements to the consent form: a required basic element (increasing the number of basic elements from 8 to 9) and three additional elements that should be included only if applicable (increasing the number of additional elements from 6 to 9). The new required basic element addresses the collection of identifiable private information or identifiable biospecimens, and the three new additional elements address commer-

cial profit, return of clinically relevant research results to the subject, and whole genome sequencing. The Ochsner Clinic Foundation Research Informed Consent template that incorporates these changes is included as an addendum to this article. A summary of the four new consent form elements is provided in the Table.

#### Consent Form Required Basic Elements

All basic elements of consent must be included in the consent form.<sup>9</sup> The revisions to the Common Rule did not change the original eight basic elements of consent:

1. Explanation of the purpose, duration of participation, and procedures
2. Risks
3. Benefits
4. Alternative procedures
5. Information about confidentiality, compensation, and treatments if injury occurs
6. Compensation or medical treatment if injury occurs in studies greater than minimal risk
7. Contact information
8. Statement that participation is voluntary; no penalty or loss of benefit if subject refuses to participate or if they withdraw from the study<sup>9</sup>

The new basic element requirement is to include one of the following statements if the research involves the collection of identifiable private information or identifiable biospecimens:

- The identifiable private information or identifiable biospecimens may be used for future research or distributed to other researchers without additional consent after identifiers have been removed.

OR

- Private information or biospecimens will NOT be used for future research even if identifiers are removed.<sup>9,11</sup>

Deidentification involves removing information about subjects so that information or biospecimens are not likely to be linked back to them (ie, name, address, phone numbers, email address, Social Security number, photos, fingerprints). Historically, subjects have not been informed that their deidentified private information and/or deidentified biologic specimens (eg, blood, tissue samples, urine) may be used or shared with other researchers for additional research without their knowledge.<sup>12</sup> One well-known example is the use of cancer cells removed from Henrietta Lacks without her knowledge to establish a cell line that was reproduced and distributed for a multitude of research studies.<sup>16,23</sup> In 2004, the Havasupai Tribe sued the Arizona Board of Regents and the Arizona State University researchers for using DNA samples that were collected for studies on type 2 diabetes but were later used in other studies to research mental illness and theories of the tribe's geographic origins that contradicted their traditional stories.<sup>23</sup> Clarifying the private information/biospecimen issue will decrease concerns related to unauthorized sharing of data and biospecimens.<sup>8</sup> Subjects have the right to know that their deidentified information or specimens may be used for future research without their additional consent.<sup>15</sup>

**Table. Summary of New Consent Form Additional Elements**

When the research involves	Include in the consent form
the collection of identifiable information or identifiable biospecimens	a statement indicating whether identifiers may be removed and if the deidentified information or biospecimens may or may not be used or shared for future research
use of biospecimens	a statement indicating whether biospecimens may be used for commercial profit and if the subject will share in that profit
clinically relevant results	a statement indicating whether clinical results, including individual research results, will be returned to the subject and if so, under what conditions
whole genome sequencing	a statement indicating that the research will/will not/might involve whole genome sequencing

Studies have shown that subjects are generally willing to consent to the use of their biospecimens in research; however, subjects want to be asked for their consent.<sup>24</sup> Not having the opportunity to give their permission for this use often leads to lack of trust and feeling deceived.<sup>25,26</sup> One study showed that 90% of subjects felt it was important for researchers to ask their permission.<sup>27</sup> Education should be provided to subjects on how their information and/or biospecimens will be stored and the potential contribution to other research studies. This education should include a conversation about individual risks and societal benefits. D'Abramo et al reported that subjects often overestimate the individual benefits, which are nonexistent, and are unaware of risks<sup>28</sup> that can include insurance discrimination, employment issues, psychological harm, and family disruption. In addition, researchers should not guarantee confidentiality.<sup>24</sup> Once education is provided during the consent process, subjects are given the opportunity to make their own decisions regarding participation.<sup>29</sup>

The Ochsner informed consent template language for this new required basic element is as follows:

We may use or share your research information and/or biospecimen for future research studies, but it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We may also share your deidentified information and/or biospecimen with other researchers at Ochsner or at other institutions.

Other examples of personal information/biospecimen text are as follows:

- Any personal information that could identify you will be removed from your sample. Your sample may be used for future research studies without the investigator asking for your additional permission.<sup>30</sup>
- Any personal information that could identify you will be removed from your sample. Your sample will not be used for any future research studies.<sup>30</sup>
- Your name and other information that could identify you will never be released into a scientific database.<sup>31</sup>

The purpose of adding this new basic element requirement is to inform subjects of what might happen in the interest of full disclosure. This new basic element does not require that

subjects be given a choice to opt out of having their deidentified data or biospecimens used for future research. If subjects do not wish to allow their deidentified data or biospecimens to be used or distributed, their only choice may be to not participate in the research.<sup>16</sup>

### Consent Form Additional Elements

The additional elements of consent are statements that must be included in the consent form if the information is relevant to the research. The revisions to the Common Rule did not change the original six additional elements of consent:

1. Statement about potential risks to the subject or to the embryo or fetus if the subject is or becomes pregnant
2. Circumstances under which subject's participation may be terminated
3. Any additional costs
4. Consequences of a subject's decision to withdraw from the research and procedures for termination of participation
5. Statement that significant new findings that may relate to the subject's willingness to continue participation will be provided
6. Approximate number of subjects involved<sup>9</sup>

The revision to the Common Rule mandates three additional elements that must be included in the consent form if they are relevant to the research:

7. A statement indicating whether biospecimens may be used for commercial profit and whether or not the subject will share in that profit
8. A statement indicating whether the results will be given to the subject and if so, under what conditions
9. A statement indicating that the research will, will not, or might include whole genome sequencing<sup>9</sup>

*Commercial Profit.* Many subjects are not aware that their tissue has any commercial value.<sup>32</sup> Subjects must be informed of the possibility that research using their biospecimens could lead to the development of commercial products, and whether the subjects will share in any commercial profits must be made clear.<sup>24</sup> Courts have held that individuals do not hold property rights to their donated tissue and cells. One example is *Moore v Regents of the University of California*. Moore was being treated for a rare form of cancer and signed a surgical consent form for removal of his

spleen. Prior to the surgery, his physician was aware that the cells from Moore's spleen could have commercial value. A cell line was developed from Moore's tissue that helped produce drugs which may be beneficial in the treatment of leukemia and possibly for acquired immunodeficiency syndrome. The cells were valued at approximately \$3 billion.<sup>33</sup> Moore sued for damages based on the failure of his physician to inform him of the commercial gains made from his cells but lost when the case was referred to the California Supreme Court.<sup>33</sup> The requirement that investigators disclose the potential for commercial profit and whether subjects will share in that profit is intended to enhance the subjects' understanding because such knowledge may affect their willingness to participate in a study.<sup>11,12</sup>

The Ochsner informed consent template provides an example of how the new additional element regarding commercial profit can be written:

Data or biospecimens collected from you for this research may be used to develop new tests, drugs, or devices. Your samples may be used for commercial profit and there is no plan to share these profits with you.

Another example of the commercial profit language is "Your sample may be used to develop new drugs or other products for commercial purposes. If these products make money, there are no plans to share the money with you."<sup>30</sup>

*Return of Results.* Consent forms must now include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.<sup>11</sup> Disclosure of results in research has been the subject of much debate.<sup>34,35</sup> Some authors argue that, based on the principle of respect for persons, disclosure should be routine in research, while others argue that respect for persons is not violated when results are not returned.<sup>36,37</sup> Some authors think results should be made available only to subjects who desire the results and that subjects should have the option of receiving all their research results or just those with clinical significance.<sup>38</sup> Others believe only clinically relevant research results should be returned because the information can have a positive impact on the subject's health.<sup>39</sup> Beskow and Burke recommend returning results when the probability of a serious condition that has an effective intervention is high.<sup>34</sup> An example includes a mutation known to result in high risk for colon cancer; having this information would allow subjects to pursue aggressive screening.<sup>25</sup> Others believe that results should not be returned because returning results can cause psychological risks (anxiety about the discovery of future disease or uncertain information); stress for family members; social risks of stigmatization or discrimination; and issues with confidentiality, insurability, and employment.<sup>24,38,40-43</sup>

In contrast, research has documented that 96% of subjects have a strong preference for receiving results.<sup>44</sup> Subjects express a feeling of ownership of the findings. Some subjects believe returning results is a moral obligation of the investigator. Other subjects feel that learning results is a benefit of their participation. Some subjects consider results as an acknowledgment of their contribution to research, a sign of respect. However, although subjects want to know the results of the studies they have participated in, results are rarely returned.<sup>43-47</sup>

Research differs from treatment. The goal of research is to produce generalizable knowledge for future patients, whereas in the clinical setting, the goal is to provide the best possible treatment for the patient. Some argue that returning individual results may promote therapeutic misconception.<sup>43</sup> Therapeutic misconception occurs when subjects believe that the purpose of the research is to advance their own interests by providing them with medical benefits rather than to advance human knowledge.<sup>3,33,36,43,48,49</sup>

As these examples demonstrate, the question of disclosing research results is controversial. Attention is needed during the consent process to clarify whether results will be returned to subjects and under what conditions.<sup>25,41,49</sup> The consent form should specifically state whether or not results will be returned.<sup>36</sup> Subjects should not enroll in a study thinking they will get information about their health or the results of the study if they will not.

The Ochsner informed consent template provides examples of how the new additional element regarding returning of results can be written:

We may learn things about your health as part of this research that may affect your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. You can discuss this information with your doctor.

OR

We may learn things about your health as part of the research; however, we will not share this information with you because ...

Other examples of the returning results language follow:

- Results of research testing on your sample will be returned to you.<sup>30</sup>
- Results of research testing on your sample may be given to you or your doctor. This will be done only if the results may be necessary for your care.<sup>30</sup>
- You should not expect to get individual results from research done using your sample.<sup>31</sup>
- We will offer to tell you a finding like this only if it is about a disease that is likely to cause early death if not treated.<sup>31</sup>

*Whole Genome Sequencing.* Subjects must be informed if the research will, will not, or might include whole genome sequencing. Whole genome sequencing is increasingly being used in research to identify genetic variations and is expected to continue to expand. Whole genome sequencing provides information that could predict subjects' future medical conditions and has the potential to impact an individual's family members.<sup>50,51</sup> Ethical and practical concerns related to whole genome sequencing include storage, analysis, and return of results. Because every person's DNA is unique, the realization that fully guaranteeing privacy may be impossible is becoming increasingly evident.<sup>52-54</sup>

Communicating the concept of whole genome sequencing to subjects can be challenging, and whether subjects gain sufficient understanding of all the implications of whole genome sequencing is unclear. In one study, more than 40% of subjects reported that they did not know they were enrolled in a genetic research study, 53% did not know if

they had already given DNA to their doctors, and 62% did not know if their DNA would be stored as part of a genetic research study.<sup>55</sup> The informed consent process should help subjects understand the implications of whole genome sequencing, the possible results, and the limitations of testing to help them make decisions about participation.<sup>12,23</sup>

The potential uses and outcomes of whole genome sequencing may currently be too extensive to know, explain, or understand.<sup>22</sup> Albert Einstein may have summed it up best when he said: "If you can't explain it simply, you don't understand it well enough."<sup>56</sup> The need for more effective ways to communicate information about whole genome sequencing during the informed consent process to subjects is growing. Genetic counselors are often involved.<sup>7,57</sup> Providing verbal explanations along with written materials has been suggested to improve subjects' ability to comprehend the information.<sup>21,52</sup>

The Ochsner informed consent template provides an example of how the new additional element regarding whole genome sequencing can be written to facilitate an ongoing discussion between the research staff and a potential subject:

This research will/will not/might involve whole genome sequencing. Please ask the principal investigator or study team if you have any questions about how your genetic information will be used.

Another example of the whole genome sequencing language is "Research testing on your sample will include whole genome sequencing. This means we will map your entire genetic code. If you have questions about this ask the study staff."<sup>30</sup>

## CONCLUSION

The revisions to the Common Rule are intended to enhance human subjects protection by providing more information during the informed consent process than was provided under the prior regulations. The intent of the revisions is to make consent forms clear and focused on providing information up front so that potential subjects can make informed decisions. The new consent elements aim to increase transparency and help improve clarity. These changes call for providing information that is relevant to a subject's decision-making process and that promotes autonomy. Consent forms should facilitate discussions to ensure understanding. Education of institutional review board members, investigators, and research organizations/institutions is needed to implement these changes. Making sure subjects have clear information that is easy to read and understand and that highlights the information most important to them when making decisions is an ongoing opportunity and challenge.

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*This article meets the Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties Maintenance of Certification competencies for Patient Care, Medical Knowledge, Interpersonal and Communication Skills, and Systems-Based Practice.*

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*This template has been developed to assist you with creating an informed consent document that meets regulatory requirements with Ochsner approved language.*

***Instructions:*** *Bold italicized text throughout this template is instructional and must be replaced or deleted as applicable.*

## OCHSNER CLINIC FOUNDATION RESEARCH INFORMED CONSENT

***INSERT THE NAME OF YOUR STUDY HERE – as it appears on the protocol***

**Principal Investigator:** *PI name here*

**Contact Information:** *Include mailing address and phone #*

**Alternate Study Contact:** *Name here and 2<sup>nd</sup> phone #*

**Sponsor's Protocol #:** *As entered in eIRB*

**Sponsor Name:** *If internally funded, enter Ochsner*

You have been invited to participate in a research study. The doctors and staff at Ochsner study the nature of disease and attempt to improve methods of diagnosis and treatment. This is called clinical research. Understanding this study's risks and benefits will allow you to make an informed judgment about whether to be part of it. This process is called informed consent.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

***(If needed:)*** In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

### KEY INFORMATION

***This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice. This section must be brief and in layperson language. The IRB staff will return for revision if these instructions are not followed.***

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this document.

#### **Why is this research being done and why am I being invited to take part?**

You are being invited to take part in a research study because

***Fill in study specific details. Fill in the circumstance or condition that makes subjects eligible for the research.***

#### **What should I know about being in a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss whether to participate with family, friends, and/or your doctor.
- You can ask any questions before making a decision.

#### **How long will I take part in this research?**

***Outline the expected time commitment to complete the study including the length of time and approximate number of study visits, eg, "It will take you about 14 months to complete the study. During this time, you will be asked to make 14 study visits."***

#### **What will I be asked to do in this study?**

***Provide a limited number of bullet points with a high-level summary of the procedures that will be done, eg,***

- ***You will be given an investigational drug.***
- ***You will be asked to come to the study clinic for 3 study visits.***
- ***You will give a total of 3 blood samples and fill out questionnaires.***

More detailed information about the study procedures can be found under the PROCEDURE section of this form.

#### **Is there any way this study could be bad for me?**

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study some of these risks may include

***Indicate reasonably foreseeable risks. This cannot be a list of all potential risks.***

This is not a complete list of all potential risks. More detailed information about risks can be found under the RISKS section of this form.

**Will being in this study help me in any way?**

*Select one of the options below that describes the potential benefits for participants. Briefly summarize potential benefits*

This study may offer some benefit to you now or others in the future by *explain benefits*.  
This study may not offer any benefit to you now but may benefit others in the future by *explain benefits*.

**What happens if I do not want to be in this research study?**

You can decide not to be in this study. Alternatives to joining this study include  
*Briefly address alternatives such as standard of care alternatives or other clinical trials.*

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

Please review the rest of this document for more details and important things you should know if you decide to join. Before you agree to be in the study, please ask the study team to answer all your questions.

**DETAILED INFORMATION**

**PURPOSE**

*This section should describe to the potential subject the purpose of the study in LAYPERSON terms and why they have been asked to participate. If a drug or device is being used, a description of that drug/device and whether it is FDA approved for the indication under study (if applicable) should be added.*

The purpose of this study is *(add explanation)*. You have been asked to participate in this study because *(add explanation)*.

**LENGTH OF STUDY AND NUMBER OF PARTICIPANTS**

*This refers to an individual subject's participation, not the length of time a study is enrolling.*

Your participation in this research study will be for *indicate number of month/years as appropriate*. At Ochsner, about *indicate number* subjects will be enrolled.

In total, there will be about *indicate number* subjects enrolling for participation in this study.

**PROCEDURE**

If you agree to be in this study, we will ask you to do the following things:

*Describe the procedures chronologically using lay language, short sentences, and short paragraphs.*

*Include time tables or study schema (if available and appropriate).*

*Specify the assignment to study groups, frequency of procedures, etc.*

*Clearly identify all procedures that are experimental or standard of care procedures done for the research, such as "For the research you will receive a right heart catheterization." If the RHC would be done regardless you could state "You will receive a right heart catheterization, which is standard procedure for your condition."*

*For research involving randomization, specify the randomization procedure. For two groups, use "flipping a coin." If the research includes two or more groups, use "like drawing numbers from a hat."*

*For research involving the use of placebo, clearly define the term placebo. Use language like "A placebo is an inactive substance that looks like the study drug, but contains no medication."*

*If appropriate, state that the study will involve long-term follow-up.*

**RISKS**

*Describe any reasonable risks, discomforts, inconveniences and how these will be managed.*

*List risks in order of relative probability (eg, "likely," "less likely" or "unlikely," and "rare but serious").*

*In addition to physiological risks/discomforts, describe psychological, emotional, financial, and social risks that might result.*

**General / Unforeseeable**

There may be side effects and discomforts that are not yet known. You should tell your study doctor about any side effects you experience even if you think they are not related.

*The following must be included in all greater than minimal risk studies. Do not alter this language without approval from Research Legal office. Attach approval e-mail in eIRB.*

Louisiana law requires us to set forth the known risks of a medical treatment, including the risks, if any, of death, brain damage, quadriplegia (paralysis in all arms and legs), paraplegia (paralysis of both legs), the loss or loss of function of any organ or limb, and disfiguring scars, which might be associated with a necessary procedure. Any clinical study carries with it risks of which we may be unaware at this time, including those listed in this paragraph.

**Reproductive Risks**

*Where applicable, indicate whether a particular treatment or procedure may involve currently unforeseeable risks to the subject or the embryo or fetus, if the subject is or may be pregnant. The usual language expected if women of childbearing potential are involved is*

The treatment or procedure may involve unforeseeable risks to the subject, or embryo or fetus, if the subject becomes pregnant. Because the possibility of injury or harmful effects to an embryo or fetus exists you must not be pregnant or conceive a child while in this clinical trial. Acceptable methods of contraception include intrauterine device, spermicide and barrier (eg, condom, diaphragm) method, oral contraceptives (birth control pills) and total abstinence. Please discuss the best choice for you and your partner with your study doctor.

If you or your partner becomes pregnant while participating in this study, you MUST contact your study doctor immediately.

**Radiation Risks**

*If there are no ionizing radiation/radioactive materials or the radiation that will be received during the study is standard of care, then delete this section.*

*Any procedure with ionizing radiation or exposure to a radioactive agent that is required by the research and is not standard of care should be indicated in the eIRB application and will require radiation safety review. Ionizing radiation includes CT scan, X-ray, fluoroscopy, etc (NOT MRI or U/S).*

This research study involves exposure to radiation from \_\_\_\_\_ (*list the procedures*). This radiation exposure is not necessary for your medical care and is for research purposes only.

You are exposed to radiation every day. This radiation comes from the sun and the earth. It is called background radiation. The total amount of radiation that you will receive in this study is \_\_\_\_\_ mSv and is equivalent to a \_\_\_\_\_ (*specify days or years*) of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

*Radiation safety will complete the mSv and equivalent based on the list YOU provide.*

**POTENTIAL BENEFITS**

*State the direct benefits, or the possibility of direct benefits, that are likely for research subjects.*

*If there are no direct benefits, state*

You may not receive direct personal or health benefit from taking part in this study. However, the information gained from your participation in this study may be used to help others in the future.

**COSTS**

*This is the agreed upon language for our consent template. If this section is changed in any way you must upload approval from OSP in eIRB or the language will be reverted back to template language at IRB approval.*

Although the Sponsor may pay for certain study-related items and services, any other tests, procedures, or medications that may be necessary for the treatment of your medical condition will be billed to your insurance in the normal way. You may be responsible for co-payments or deductibles. These costs are not covered by this research study. If you have any questions about treatment for which you may be responsible for paying, please discuss this with your physician or study staff.

**PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES**

*If payment for participation or reimbursement of expenses will not be provided, include the following statement:*

You will not be paid or offered any other compensation for participating in this study.

*This part on biospecimens is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice. For research involving biospecimens, a statement must be added regarding (even if identifiers are removed) whether the biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit. Delete this statement if you are not collecting biospecimens.*

Data or biospecimens collected from you for this research may be used to develop new tests, drugs, or devices. Your samples may be used for commercial profit and there is no plan to share these profits with you.

*The following must be included if participants are receiving payment for participation or reimbursement of expenses:*

*A statement should be included indicating whether or not a subject is to be paid for participation or for reimbursement of expenses. Example: "You will receive \$XX per study visit. This will be paid to you after the completion of each visit. If you complete the entire study, you will be paid a total of \$XXX. If you withdraw from the study early, you will be paid for the number of study visits you complete." Non-dollar amount incentives such as gift certificates, etc. should be included in this section.*

You will be issued a Greenphire ClinCard, which is a debit card that your study funds are loaded onto at the completion of a study visit. These funds can be used at your discretion. If your card is lost or stolen, you can contact the Ochsner study team for a replacement card. Greenphire will collect information about you, including name, address, social security number, and date of birth. Your information will be kept completely confidential and will be stored in a secured fashion. *Greenphire collects your social security number and other information to permit the preparation of IRS-1099 form(s) for participants receiving \$600 or more in any one calendar year, in accordance with Treasury Regulations, Sub-chapter A, Sec. 1.6041-1.*

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

*This is a required statement for Ochsner ICFs. Delete only if this is an unfunded study.*

Ochsner Clinic Foundation is being funded by [*the Sponsor, or other wording, as appropriate*] to conduct this research.

**ALTERNATIVE METHODS/TREATMENTS**

*Describe any alternatives that should be considered before deciding whether or not to be in the study. If there are no alternatives, state that an alternative is to not take part in the study. Avoid suggesting that participation in the research is the only way to obtain medical care.*

You do not have to join this study. If you do not join, your care at Ochsner will not be affected.

**STUDY-RELATED QUESTIONS AND COMPENSATION FOR INJURY**

If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury, contact the study doctor or their alternate contact listed on the front page of this consent form.

*This is the internally agreed upon language for sponsored studies. If this section is altered, you must upload approval from Research Legal in eIRB or the language will be reverted back to template language at IRB approval.*

If you believe you are injured as a direct result of your participation in this study, you should seek appropriate medical attention and immediately contact your study doctor on the first page. Medical treatment and/or hospitalization, if necessary for such injuries, is available. This medical treatment and/or hospitalization is not free of charge. You, your insurance company, or the Sponsor may be billed for the care you receive for the injury. We will try to get these costs paid for you, but you may be responsible for some or all of them. You may be responsible for all co-payments and deductibles required under your insurance. If injuries occur that are the result of a medication, device, procedure or test required for this study that is not part of your usual medical care, the Sponsor will reimburse the standard charges for the treatment of these injuries.

By signing this consent form you have not given up any legal rights.

*Below is the acceptable language for investigator initiated and federally funded studies ONLY. Delete the paragraph below BEFORE sending to your sponsor. If no sponsor delete the paragraph above. Do NOT leave both injury paragraphs in the final draft.*

If you believe you are injured as a direct result of your participation in this study, you should seek appropriate medical attention and immediately contact your study doctor at the number on the first page. Medical treatment and/or hospitalization, if necessary for such injuries, is available. This medical treatment and/or hospitalization is not free of charge. You or your insurance company would be billed for the care you receive for the injury. You would be responsible for all co-payments and deductibles required under your insurance.

By signing this consent form you have not given up any legal rights.

### **QUESTIONS ABOUT YOUR RIGHTS**

If you have questions about your rights as a research subject, you may contact:

Ochsner Clinic Foundation Institutional Review Board  
1514 Jefferson Highway  
New Orleans, LA 70121  
Telephone: 1-504-842-3535  
Email: IRB@ochsner.org

The Institutional Review Board (IRB) is a group of people who perform independent review of research for human subject protection. You may contact the IRB to discuss any problems, concerns or questions you have about research. The IRB can assist you in obtaining information about research and encourages input from research subjects.

### **VOLUNTARY PARTICIPATION**

Participation in this study is voluntary. You may decide not to participate in this study or you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some end of study procedures.

Your participation in this study will be entered in your electronic medical record here at Ochsner. You should tell your study doctor about all of your past and present health conditions and allergies of which you are aware, and all drugs and medications which you are presently using.

### **EMPLOYEES IN RESEARCH**

If you are an employee of Ochsner Clinic Foundation (OCF), you are not required to participate in this research study and any decision to participate is completely voluntary. Participation in this research study is not required to maintain employment and your decision to participate or not participate will not affect your employment status in any way. Should you decide to enroll in this study, you may withdraw your participation at any time, and this decision will not affect your employment or performance evaluations.

By signing this informed consent, you acknowledge that you do not believe that you are being unduly influenced by your employer to participate in this study. You also acknowledge that no statements, threats, or implied threats have been made that your job or performance evaluations will be affected in any way whether or not you participate in this study.

### **NEW FINDINGS**

During the study you will be told about any important new information that may change your mind about staying in the study.

### **STUDY WITHDRAWAL**

Your participation in this study may be stopped at any time by the study doctor or the Sponsor without your consent because

- you do not meet study criteria
- the study doctor thinks it necessary for your health or safety
- you have not followed study instructions
- the Sponsor has stopped the study
- administrative reasons require your withdrawal

### **DNA SEQUENCING**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice.*

This research *will / will not / might* involve whole genome sequencing. Please ask the principal investigator or study team if you have any questions about how your genetic information will be used.

**RETURN OF RESEARCH RESULTS**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice. If clinically relevant results will or will not be returned, insert one of the following options. Delete this section if not relevant to the research.*

*If clinically relevant results will be returned, insert the following:*

We may learn things about your health as part of this research that may affect your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. You can discuss this information with your doctor.

*If clinically relevant results will not be returned, insert the following:*

We may learn things about your health as part of the research, however we will not share this information with you because *(describe rationale)*.

**FUTURE RESEARCH**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice.*

We may use or share your research information and/or biospecimen for future research studies, but it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We may also share your deidentified information and/or biospecimen with other researchers at Ochsner or at other institutions.

**CONFIDENTIALITY**

Your identity and your personal records will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Confidentiality will be maintained during and after your participation in this study.

*Delete reference to ct.gov if the study does not qualify for registration on ct.gov and you have indicated the same on your eIRB application. If you are unsure about this, go to: [https://prsinfo.clinicaltrials.gov/ACT\\_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The results of this research may also be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

**HIPAA AUTHORIZATION TO RELEASE INFORMATION FOR RESEARCH**

*This is the internally agreed upon language for our consent template. If this section is altered, you must upload approval from Research Compliance in eIRB or the language will be reverted back to template language at IRB approval. For minor changes, please contact the IRB office x23535.*

Under federal law (the "Privacy Rule"), your Protected Health Information (PHI) that is created or obtained during this clinical research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." **Therefore, you may not take part in this study unless you agree to this authorization.**

Before you agree to take part in the study, we want to tell you

- how study information may identify you
- who may use or share your protected health information
- why your protected health information will be used or shared
- your rights concerning use and/or sharing of your protected health information

**How may study information identify me?**

Study information may identify you in the following ways:

- Name, address, telephone number
- Other details about you including your past medical records

Medical information that identifies you and relates to your participation will be created and may be used and/or shared, including information obtained from

- study visits and phone calls
- physical examinations, blood and urine tests, x-rays, and other procedures or tests
- your response to any study treatments you receive
- any other information that you may release to us, including information about your health history

**Who may use or share my protected health information?**

The Investigator (study doctor) and research staff may give protected health information to others during and after the study, including

- the study Sponsor, including any people or companies working for or with the Sponsor or owned by the Sponsor
- doctors and healthcare professionals taking part in the study
- government agencies in the United States and in other countries
- Ochsner Clinic Foundation
- Third-party vendors as authorized by Ochsner Clinic Foundation

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**Why will this study information be used and/or shared?**

- To carry out the research study
- To analyze and evaluate the results of the study
- To conduct internal research compliance reviews
- To comply with governmental reporting requirements
- To obtain marketing approval for new products

**What are my rights regarding my health information?**

- You have the right to review and copy your health information. However, as a participant in this research study, you would not be allowed to look at or copy your information until after the research is completed.
- You may withdraw or revoke (cancel) your permission to use and disclose your health information at any time. However, unless you revoke your permission by sending written notice to the study doctor, this authorization (permission) will not expire (end) until it is no longer required by the Sponsor.

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable. **If you withdraw your permission, you will not be able to continue being in this study.**

**Are there possible limitations on the protection of my health information?**

- If your health information is given to the parties listed above and/or to others who are not required to comply with federal privacy laws, your information may no longer be protected, and there is a risk that your information will be released to others without your permission.
- Your personal information may be disclosed if required by law.
- Your records for this study may be sent by facsimile transmission (FAX) or over the Internet. It is possible that your records could be sent to the wrong person.

**How long is my information kept?**

Ochsner Clinic Foundation policy requires that all files related to a research study are stored for ten (10) years after the research study has been closed at the Ochsner site.

**Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.**

**If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.**

**CONSENT**

*This may be altered but phrases such as, "I understand..." will be deleted and replaced with template language.*

I have been informed about this study's purpose, procedures, possible benefits and risks, and the use and disclosure of my healthcare information from this research. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

**CONSENT SIGNATURE**

Subject Signature	Printed Name	Date
-------------------	--------------	------

Signature of Legally Authorized Representative (when applicable)	Printed Name	Date
--	--------------	------

*DELETE IF NOT USING LAR*

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Person Obtaining Consent - Signature	Printed Name	Date
--------------------------------------	--------------	------

*Insert Assent Signature Box for ages 13-17 here, if applicable.*

----- Use the following only if applicable -----

*This section is a required part of the Ochsner ICF. If you delete this section, please provide the rationale in consent section of your application.*

**IMPARTIAL WITNESS STATEMENT (IF APPLICABLE)**

If this consent and authorization document is read to the subject because the subject is unable to read the document, an impartial witness (a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject) must be present for the consent and sign the following statement:

I attest that the information in this consent and authorization was explained to, and understood by the subject. I also attest that the subject agreed to participate in this research study.

\_\_\_\_\_  
Printed Name of Impartial Witness

\_\_\_\_\_  
Signature of Impartial Witness

\_\_\_\_\_  
Date

Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.

Ochsner Health System complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-928-6247.  
CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-928-6247.