Note: This document contains only the requirements for the institution.

It is not a complete template.

Check the submitted consent form, protocol level WCG IRB/Advarra IRB approved consent form template, or the sponsor’s template for the sections that need additional language. If the language is not in those documents, contact the site for the information.

**WARNING** – There are header and footer requirements:

Please see the footer, the footer must be on each page of the consent form.

**Footer – all pages**

The footer must contain the bar code and page numbers in x of y format and be on each page of the consent form.

**Header – First Page:**

University of Toledo consent forms must have the logo of the university as seen above, on the first page of the consent form only. The first page header should also include protocol version & date and the ICF version date if not included in the face page (see next page of this document).

**Header – All Other Pages:**

The following information should also be in the header beginning on page 2:

ICF Version: Date

Protocol Name

Protocol Version #: Date

This institution has retained the face page and an empty page following, please use the following:

Protocol Version & Date:

ICF Version: Date

*If the face page includes the protocol version and date and the ICF version date, it is not necessary to include this in the header of the first page (this information is still required to be included in the header beginning on page 2 through the rest of the document). If the Protocol version & date is missing, add it to where the ICF Version date is listed (either the header or face page) and vice versa if the ICF Version date is missing. Do not add the information to both places.*

Sponsor name, City, State, USA

Sponsor Protocol Name

|  |
| --- |
| **Research subject information and Consent form****and****Authorization for use and discloSure of** **protected health information** |
| **TITLE:**  | Title of study here IN ALL CAPITAL LETTERS |
| **PRINCIPAL INVESTIGATOR:** | PI Name | **TELEPHONE:** | XXX-XXX-XXXX (24 hours) |

**This consent form contains important information to help you decide whether to participate in a research study.**

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

* **Being in a study is voluntary – your choice.**
* **If you join this study, you can still stop at any time.**
* **No one can promise that a study will help you.**
* **Do not join this study unless all of your questions are answered.**

**After reading and discussing the information in this consent form you should know:**

* Why this research study is being done;
* What will happen during the study;
* Any possible benefits to you;
* The possible risks to you;
* Other options you could choose instead of being in this study;
* How your personal health information will be treated during the study and after the study is over;
* Whether being in this study could involve any cost to you; and
* What to do if you have problems or questions about this study.

**Please read this consent form carefully.**

**NO TEXT THIS PAGE**

If your Consent/Authorization form has an odd number of pages, include an additional page labeled "NO TEXT THIS PAGE" as page two of the form before copying the entire form double-sided. Please be sure to assign the "NO TEXT THIS PAGE" a page number.

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Use WCG IRB/Advarra IRB standard headings with the following exceptions:

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

**AND**

**AUTHORIZATION FOR USE AND DISCLOSURE OF**

**PROTECTED HEALTH INFORMATION**

**Title:** IN ALL CAPITAL LETTERS

Do not include spaces after the section headings.

**Key Study Information:**

Include this section after the pre-amble:

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Toledo or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

The purpose of this study is [SITE: Briefly describe the purpose of the study].

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 [SITE: Indicate reasonably foreseeable risks. An example is serious health complications.] More detailed information will be provided later in this document.

[SITE WILL SELECT ONE OF THE OPTIONS BELOW]

This study may offer some benefit to you now or others in the future by [SITE: Briefly summarize]. More information will be provided later in this document.

OR

This study may not offer any benefit to you now but may benefit others in the future by [SITE: Briefly summarize]. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be [SITE: Indicate total time commitment].

Your participation is voluntary. You can decide not to be in this study, or agree to take part now and change your mind later. If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.

Alternatives to joining this study include [SITE: Briefly address alternatives such as standard of care alternatives or other clinical trials]

**Risk Section**

Use submitted consent form or the WCG IRB/Advarra IRB protocol level consent form template - plus

NOTE: The following section is required if there is a known risk or a potential for risk to unborn children.

**RISKS TO UNBORN CHILDREN**

**Special Notes About Pregnancy and Breastfeeding during the Study**

This research represents a significant risk to unborn children. Therefore, if you are a female of childbearing potential and you wish to take part in this research, you will be given a pregnancy test before the start of the research. If this test is positive, you will not be able to take part in this research. If this pregnancy test is negative, you will be given information on birth control procedures that must be used while you are taking part in this research so that you can avoid getting pregnant. A pregnancy test does not prevent you from becoming pregnant.

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant within the next 6 months. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects. Women who can get pregnant will be tested for pregnancy during the study and you will be questioned about your current method of birth control.

If you become pregnant during the study, you must report it immediately to the study doctor. He will discuss with you what you should do. If you get pregnant, you will be asked to stop taking part in this study and active study drug will be stopped as fast and as safely as possible.

You should obtain and follow good prenatal and postnatal care. You will be responsible for all routine pregnancy-related expenses. You will be asked about the outcome of the pregnancy and the health status of your baby. The sponsor would like to follow you through to the end of your pregnancy and check the status of you and your child. This information may be available to the study doctor, the sponsor, and WCG IRB/Advarra IRB.

[If applicable, add:]Males who are sexually active must take precautions while participating in this research so that that their female partners do not become pregnant. If you are a sexually active male and wish to take part in this research, you will be offered information on birth control procedures that you and your partner must use while taking part in this research so that your female partner does not become pregnant. You also will be advised as to the danger to the fetus should your partner become pregnant.

You must agree to continue using an acceptable method of birth control during the entire study. Some methods of birth control will not work when you are taking certain drugs. Be aware that you can still become pregnant even if you use an acceptable birth control method.

Ask your study doctor any questions that you may have about acceptable methods of birth control and the risk to you, your partner or your unborn child at any time before or, if you decide to enroll, while you are taking part in this research.

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**PAYMENT OR OTHER COMPENSATION TO THE RESEARCH SITE**

This language or a close resemblance of this language will be submitted by the site: The University of Toledo is receiving money or other benefits from the study sponsor for conducting this research study.

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**OTHER IMPORTANT INFORMATION**

You are the only one who should take the study drug. Keep it out of the reach of children and persons who may not be able to read or understand the label.

[If the research involves blood or tissue samples, include:]Tissue donated by you for this research may be used to invent a process or to develop scientific matter (for example, establish a cell line) that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

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**POSSIBLE BENEFITS TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH**

Use submitted text or WCG IRB/Advarra IRB protocol level template language – plus

We cannot and do not guarantee or promise that you will receive any direct medical benefits from this research study.

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**COSTS TO YOU FOR TAKING PART IN THIS STUDY**

Use submitted text or WCG IRB/Advarra IRB protocol level template language – plus

While you are in the study, you still need to get regular medical care. You (and/or your health care insurance) will be billed for the costs of your regular medical care that are not a part of this study.

The study drug, study-related procedures, and study visits [the site should submit language stating whether study expenses are provided at no charge or will be charged to the subject, for example “will be provided at no charge to you or your insurance company.” OR “will be billed to you and your insurance company.”]

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

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**PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH**

Use submitted text or WCG IRB/Advarra IRB protocol level template language – plus include the following statement when applicable.

If you receive payment for taking part in this study, The University of Toledo will collect your name, address, social security number, payment amount, and related information. The information collected will be used for processing the payment to you. The University of Toledo is required to submit this information to the Internal Revenue Service (IRS) when you receive any individual or collective payments greater than $599.

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The site will include the following text if appropriate to the research:

**POST-STUDY COMPLETION PERMISSION TO CONTACT**

Participation in this study includes permission to contact you after the study ends [specify frequency] to update your contact information so we know how to reach you should we decide that it is important to continue following your progress or open a new study to follow-up on people who take part in this study. We may also ask questions about [specify].

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**CONFIDENTIALITY**

The site will include one of the two options below:

*1.* The identifiable information or biospecimens that are collected from your participation in this research will not be used or distributed for future research.

*OR*

*2.* With your permission, the identifiable information or biospecimens that are collected from your participation in this research may be used in future research studies without your consent, but only after your identifying information has been removed from the information. If you do not grant permission for your data to be de-identified and used for future research purposes, you **can** still participate in the research described in this document. Your agreement to this is voluntary and there are no consequences should you decline to allow your data to be used for future research purposes. [SITE: Indicate any additional risks the future research may pose and describe efforts to minimize them].

If you agree to allow us to use and/or share your de-identified information or biospecimens for future research purposes, please place your initials here: \_\_\_\_ (opt-in) ; if not \_\_\_\_ (opt-out)

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HIPAA text must be in the body of the consent form.

**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

**What information may be used and given to others?**

Participation in research involves using and sharing your health information to conduct the research. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. By agreeing to take part in this research study and signing this document, you give to, The University of Toledo, the study doctor, and all personnel associated with this research your permission to use or disclose (release) your health information that we obtain in connection with this study. This may include information that might identify you. The study doctor may also obtain information about your health including:

* Past and present medical records
* Research records
* Records about phone calls made as part of this research
* Records about your study visits
* Information obtained during this research about

Physical exams

Laboratory and other test results

Diaries and questionnaires

The diagnosis and treatment of a mental health condition

Pregnancy, if you become pregnant during this study

* Records about any study drug you received

**Who may use and give out information about you?**

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

**Who might get this information?**

Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. For this study, “sponsor” also includes:

**list here the sponsor, CRO, and any other agent of the sponsor**

Information about you and your health, which might identify you, may also be given to:

* The U.S. Food and Drug Administration (FDA)
* Department of Health and Human Services (DHHS) agencies
* Governmental agencies in other countries
* The University of Toledo
* The University of Toledo Institutional Review Board
* The University of Toledo Research and Sponsored Programs
* WCG IRB/Advarra IRB

**Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others to carry out the research study. We will also use this information ourselves for the purpose of conducting the research study as described in this consent form. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

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

The information may be reviewed by WCG IRB/Advarra IRB. WCG IRB/Advarra IRB is a group of people who perform independent review of research as required by regulations.

The information may also be reviewed by the University of Toledo Biomedical Institutional Review Board and Research and Sponsored Programs of the University of Toledo for compliance audits.

We may also disclose your protected health information when required by law, such as in response to judicial orders.

**What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**

You generally have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information related to this research study until after the research is completed.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to [insert name of PI] at the University of Toledo, [insert full address]. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others as necessary to maintain the integrity of the research study.

Unless you revoke (cancel) your authorization, this authorization to use and disclose your health information has no expiration date.

**Is my health information protected after it has been given to others?**

There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected by privacy regulations. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information.

**How can I obtain a copy of The University of Toledo’s Privacy Practices?**

A more complete statement of University of Toledo’s Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo’s Privacy Officer at 419-383-6933.

**Federal research database information:**

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.

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**IN THE EVENT OF RESEARCH RELATED INJURY**

The following language precedes sponsor’s language, do not modify or include additional text, except where instructed:

If you suffer a research-related injury, medical treatment is available but you can choose where to go for treatment.

The Sponsor has made conditional plans to reimburse The University of Toledo for medical costs for certain research-related injuries. The study doctor can provide further information about reimbursement from the Sponsor. The Sponsor does not offer other compensation.

The University of Toledo and The University of Toledo Medical Center do not offer reimbursement for medical expenses or other compensation for research-related injuries. In the event that any medical expenses are not reimbursed by the Sponsor, they will be billed to you or your insurance.

By signing this form you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact:

Provide the name and 24-hour phone number the responsible contact person(s) here. Please be sure to separate this statement from the rest of the sentence so that it can be easily identified.

Include sponsor’s language here – check the submitted consent form for negotiated text.

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**OTHER QUESTIONS**

Use submitted text or WCG IRB/Advarra IRB protocol level template language – plus – after WCG IRB’s/Advarra IRB’s information.

OR

Chairperson, Institutional Review Board, The University of Toledo

419-383-6796

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**ADDITIONAL ELEMENTS**

# The site will include this section when there is information that needs to be included in this document, but does not apply to the other sections.

SITE: If applicable to the study, include a statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

SITE: If applicable to the study, include a statement about whether clinically relevant research results, including individual research results will be disclosed to subjects, and if so, under what conditions.

SITE: If applicable to the study, provide a statement about whether the research study will or might include whole genome sequencing.

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Include this section only if submitted by the site:

**PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OF PARTICIPATION IN THIS STUDY**

Please initial below whether you want us to notify your primary care physician or specialist of your participation in this study.

\_\_\_\_\_\_\_\_ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

\_\_\_\_\_\_\_\_ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

\_\_\_\_\_\_\_\_ I do not have a primary care physician/specialist.

\_\_\_\_\_\_\_\_ The study doctor is my primary care physician/specialist.

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**This section cannot appear to be a “stand-alone” section.**

**CONSENT FOR RESEARCH PARTICIPATION AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

**By signing this consent form, I agree that all of the following statements are true:**

* I have read all of the above information (or it has been read to me), and all my questions have been answered to my satisfaction.
* The purpose of the research, the study procedures, and the possible risks or discomfort have been explained to me.
* Alternatives to my participation in this research study have been discussed.
* I voluntarily agree to participate in this study, as indicated by my signature below.
* 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.
* I understand that by signing this consent form, I am not giving up any of the legal rights to which I otherwise have as a subject in a research study.

Subject Name (Please Print)

 a.m. p.m.

Signature of Subject Date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Conducting Position

Informed Consent Discussion (Please Print)

 a.m. p.m.

Signature of Person Conducting Date Time

Informed Consent Discussion