**INFORMED CONSENT TEMPLATE (Version – SEP-2014) – Medical**

Note to the Investigator:

Prior to writing the informed consent, please review:

1. Institutional Review Board (IRB) Procedure 201 “How to Write an Informed Consent for a Protocol Submitted to the UC IRB-M.”
2. The PRISM Readability Toolkit, Third Edition ©2006 Group Health Research Institute Download a free PDF of the PRISM Toolkit at <http://www.grouphealthresearch.org/capabilities/readability/readability_home.html>

**Quick Reference Guide for Improving Readability**

**Guiding principles of plain language include:**

* Use language your audience can easily understand.
* Write in a conversational style, as if you were speaking.
* Organize and filter content with your readers’ needs in mind.
* Use reader-friendly formatting so that your document *looks* easy to read.

**The following specific strategies will help you adhere to these principles:**

**Check the reading level.** Choose a readability formula, but be aware that they all have limitations—getting a “good score” is not a guarantee that your document is easy to read.

**Choose common, everyday words.** Replace multi-syllable (or short but complex) words with simpler vocabulary. Avoid research and medical jargon whenever possible. If you must use a complicated term, define it in plain language and provide an example, an analogy, or a visual aid. Don’t use math symbols (such as >, <, +) – spell these items. Spell out micro, nano, kilo, milli for scientific notations of µg, ng, kg, mg.

**Use active voice.** The subject of your sentence should act, instead of being acted upon. “We will ask you questions about your health” is active, while “You will be asked questions about your health” is passive

**Write in the first-person.** Use pronouns, such as “I,” “we,” and “you.” This encourages the use of active voice and will be clearer and more engaging to the reader.

**Keep sentences short and to the point.** Break up sentences joined with conjunctions or semicolons. It’s okay to begin a complete sentence with “And” or “But.” Try to vary sentence length. Sentences should average 15 words or less.

**Limit paragraphs to one main idea.** Start with a clear and concise topic sentence. Remove or relocate details that do not relate to the central topic. A paragraph of 1 or 2 sentences is okay.

**Use clear and descriptive headings.** Meaningful headings that describe the content of different sections will give your readers “road signs” and help them navigate your document more easily.

Use large font, bold, or other emphasis to ensure the headings stand out.

**Consider the needs of your audience.** Include only the information that your audience really needs to know.

Use large font and/or age-appropriate or culturally-sensitive language to meet the needs of special populations like the elderly, children, minorities, or people with chronic health conditions, etc.

**Organize and format your document so that key information is clear and easy to find.** Lead with the most important information, and sequence the information in a logical fashion that the audience can easily follow.

Use bold, larger font, bullets, or graphics to emphasize critical information. *Do not* use justified margins or put entire sentences in all caps or italics.

Put long lists of items into bulleted lists whenever practical. Use numerical lists whenever if the items need to be understood or completed in order

**Use adequate white space and margins.** Break up dense copy by using ample white space between paragraphs and headings. Consider using all white space that may be leftover by adding space between paragraphs or increasing the font size of headers or text.
 **Read your document aloud.** This is one of the best ways to find errors and test for overall flow and clarity when you proofread. It can also help you troubleshoot—when you get stuck, try just speaking your thoughts.

**Ask others to read and edit the document.** Someone unfamiliar to the project is more likely to notice text that is unclear. The person who will use the document most—such as the person who will administer informed consent—should always have a chance to review it.

**Use fresh eyes when you edit or proofread.** Whenever possible, set the material aside for a day or two and proofread it again after taking a break. This step, along with reading your document out loud, is a good way to find errors that may have been overlooked before.

**Double-check names and contact information.** Call all phone numbers and check all links and email addresses. Confirm that all names have been spelled correctly and that all titles are correct.

*Excerpted from the PRISM Readability Toolkit, Third Edition ©2006 Group Health Research Institute Download a free PDF of the PRISM Toolkit at* [*http://www.grouphealthresearch.org/capabilities/readability/readability\_home.html*](http://www.grouphealthresearch.org/capabilities/readability/readability_home.html)

General instructions:

* Use a 12 point and preferably in Arial or Times New Roman font.
* Please format carefully so that headers are on the same page as some of the content for that section.
* You must include all of the 8 essential elements required by federal regulations (noted with an \*; please remove the \* before creating the final document). Do not alter the order of these sections.
* Include any optional studies after the main study signature page.
* All comments should be deleted in final document. All comments in the document may be deleted at the same time using the delete function in the comments section under the review tab

**UNIVERSITY OF CINCINNATI - Medical**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:**

|  |  |
| --- | --- |
| **UC IRB Study #:**  | **Sponsor Name:** (e.g., Investigator-Initiated, Name of Sponsor, NIH) |

**Investigator Information:**

|  |  |
| --- | --- |
|  |  |

Principal Investigator Name Telephone Number 24 hr Emergency Contact

Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_

**INTRODUCTION:**

A biomedical or health-related research study is performed to answer specific questions about a disease.

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study. The informed consent document is a written summary of this information. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

Your participation in this research study is entirely voluntary.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The researcher and sponsor of this study do not promise that you will receive any benefits from this study.

*<< If you are enrolling cognitively impaired subjects through surrogate consent, please add the following:*

*If you are acting as a representative to give consent for another person to participate in this study, “you” throughout this consent form refers to that individual.*

*The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest.  If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.>>*

 **WHY IS THIS RESEARCH BEING DONE?**

*<< Include in this section the FDA status of each drug, device, or biologic to be used. Make sure to state what disease, etc. the drug is approved for AND if not approved for indication in this study – clearly state this.>>*

The purpose of this research study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*<<Use these suggested phrases if applicable:*

*Phase 1 study: Test the safety of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (DRUG/INTERVENTION) and see what effects (good and bad) it has on you and your \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (type of disease/condition).*

*or*

*Find the highest dose of a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (DRUG) that can be given without causing severe side effects.*

*Phase 2 studies: Find out what effects (good and bad) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (DRUG/INTERVENTION) has on you and your \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (type of disease/condition).*

*Phase 3 studies: Compare the effects (good and bad) of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (DRUG/ INTERVENTION) with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (COMMONLY-USED DRUG/INTERVENTION) on you and your \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (type of disease/condition) to see which is better. >>*

**WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?**

You are being asked to take part in this research study because you are {age criteria} and you have been diagnosed with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*<<Include information in lay terms about the condition being studied. Include eligibility requirements if it helps the subject understand the research.*

*If the subjects are normal, healthy volunteers, explain why they have been asked to participate>>*

**HOW LONG WILL YOU BE IN THE RESEARCH STUDY?**

You will be in the research study for approximately \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*<< MONTHS/WEEKS, UNTIL A CERTAIN EVENT. Where appropriate, state that the study will involve long-term follow-up.>>*

The researcher may decide to take you off this research study at any time.

*<< When applicable, subjects should be informed of circumstances under which their participation may be terminated by the investigator without the subject's consent. List circumstances, such as in the subject’s medical best interest, funding is stopped, drug supply is insufficient, subject’s condition worsens, new information becomes available. A statement that the investigator may withdraw subjects if they do not "follow study procedures" is not appropriate. Subjects are not in a position to know all the study procedures. Subjects may be informed, however, that they may be withdrawn if they do not follow the instructions given to them by the investigator.>>*

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

<< *When withdrawal from a research study may have deleterious effects on the subject's health or welfare, the informed consent should explain any withdrawal procedures that are necessary for the subject's safety and specifically state why they are important to the subject's welfare. An unexplained statement that the subject will be asked to submit to tests prior to withdrawal, does not adequately inform the subjects why the tests are necessary for the subject's welfare.>>*

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

**WHO IS CONDUCTING THE RESEARCH STUDY?**

***<<****If the IRB determines that a financial conflict of interest exists with this a study must be managed by disclosure, you will be given a statement to insert in this section of the ICS.>>*

This study is sponsored by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*<< name of company, agency or departmental providing funding for study. Spell out the names of cooperative groups that you usually identify only by abbreviations.>>*

The study is directed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the researcher at \_\_\_\_\_\_\_\_

*<<insert name of research sites>>*

Medical supervision for the study is provided by Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*<<if applicable>>*

**HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?**

*<< If the IRB determines that the numbers of subjects in a study is material to the subjects' decision to participate, the informed consent document should state the approximate number of subjects involved in the study.>>*

About \_\_\_\_\_\_\_\_\_ people will take part in this study at *[insert name of local site(s)]*. A total of \_\_\_\_\_\_\_\_ people will take part across the country. *(if applicable)*

**WHAT IS INVOLVED IN THE RESEARCH STUDY?**

*<<If there is a chart or calendar showing when procedures, medications, etc., occur, it will help the study subject understand what happens when. It would also be helpful to the subject if the length of each study visit were stated in case the subject needs to make personal accommodations for travel, work, school, children, etc.*

*[For randomized studies:]*

*You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

[Or for blinded or double-blinded studies:]*

*Neither you nor the researcher conducting this study will know or choose what group you will be in. You will have a(n) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (EQUAL/ONE IN THREE/ETC.) chance of being placed in any group. However, in the event of an emergency, the researcher will be able to find out which treatment you are receiving.*

*[For non-randomized and randomized studies:]*

*You will have the following tests and procedures:*

*{Provide a sequential description of each research procedure to be applied to participants and how often it will be performed. \* All experimental research procedures must be disclosed and described. An auditor comparing the protocol and the consent should find that they are consistent. If a participant is to undergo a procedure(s) not part of the research and if it will further help the subject’s comprehension by giving a frame of reference, list the non-research procedure(s) also; (e.g., a subject will undergo routine surgery for therapeutic reasons and an endoscopy will be performed for research purposes.)}. \*\*Include all invasive procedures.\*\**

* *State whether their blood will be used for genetic research or not.*
* *If blood is to be withdrawn, describe how often blood will be drawn and how much each time, with a total mount for the study using household terms as teaspoons/tablespoons/ pints.*

*If applicable, indicate all locations where various procedures will be performed. >>*

*Include the name of the facilities being utilized (e.g., UC Medical Center, West Chester Hospital, Holmes Hospital, Medical Arts Building, etc.). Suggested language for including multiple UCHealth hospital and university locations: “Research will take place at University of Cincinnati and the facilities of the affiliated health systems UC Health, LLC and University of Cincinnati Physicians Company, LLC.”*

*<< If the study is being conducted at a UC Health facility and involves imaging, include one of the following statements as applicable to your research study. If the study will not be interpreted and will go into the medical record you* ***MUST*** *include Option 1. If your study falls out of option one, you may use another statement provided which may also be revised to accurately reflect your study:*

*Your “scan type(s)” will be* ***placed*** *into your medical record, but it will* ***not be used for diagnostic*** *or clinical purposes, or to guide your medical care at this time. The scan will be used only for the research, and a* ***Radiologist will NOT provide an interpretation*** *in the same way as for scans used for medical care.*

*OR*

*Your “scan type(s)”* ***will be******interpreted*** *by a radiologist,* ***placed*** *into your medical record, and* ***used for diagnostic purposes****, clinical purposes, and/or to guide your medical care.*

*OR*

*Your “scan type(s)” will* ***NOT be placed*** *into your medical record, and* ***will not be used for diagnostic*** *or clinical purposes, or to guide your medical care at this time. The scan will be used only for the research, and a* ***Radiologist will NOT provide an interpretation*** *in the same way as for scans used for medical care. (additionally, you should describe what will happen with the scan)>>*

**WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?**

*<<*In simple language and in a simple bullet format (whenever possible), explain the possible risks and discomforts:

Start with the side effects for the experimental drugs, devices or procedures. List, for example:

* most common
* less common
* rare]

When available include the incidence of the risks in how many out of 100 people

Follow with risks and side effects for all drugs, devices or procedures used in the study.

When appropriate, explain the monitoring, safeguards, and/or precautions that will be available to minimize these events, as well as what will be done should any of these events occur.

**Include the following statement if research involves investigational drugs, biologics, devices, or when the research involves procedures whose risks are not well known:**

“There may be unknown or unforeseen risks associated with study participation.”

[***Tables of Possible Side Effects for Commonly-Used Oncology Drugs***](http://ctep.cancer.gov/protocolDevelopment/sideeffects/drugs.htm)

[*http://ctep.cancer.gov/protocolDevelopment/sideeffects/drugs.htm*](http://ctep.cancer.gov/protocolDevelopment/sideeffects/drugs.htm)

[***Tables of Possible Side Effects for Commonly-Used Oncology Regimens***](http://ctep.cancer.gov/protocolDevelopment/sideeffects/regimes/regimes.htm)

[*http://ctep.cancer.gov/protocolDevelopment/sideeffects/regimes/regimes.htm*](http://ctep.cancer.gov/protocolDevelopment/sideeffects/regimes/regimes.htm)

***Instructions for building Tables of Possible Side Effects (Ctrl-click):***

[***Instructions for building Tables of Possible Side Effects for commercial agents***](http://ctep.cancer.gov/protocolDevelopment/docs/Instructions-Tables-Commercial.doc) *(MS Word)*

[***MICROMEDEX Scientific Terms - IC Term Spreadsheet 01-2013***](http://ctep.cancer.gov/protocolDevelopment/docs/MICROMEDEX-IC_Terms_Sheet.xls) *(MS Excel)*

[***Instructions for building Tables of Possible Side Effects for investigational agents***](http://ctep.cancer.gov/protocolDevelopment/docs/Instructions-Tables-Investigational.doc) *(MS Word)*

[***NCI Scientific Term CTCAE - IC Term Spreadsheet 06-2013***](http://ctep.cancer.gov/protocolDevelopment/docs/CTCAE-IC_Terms_Sheet.xls) *(MS Excel) >>*

**WHAT ARE THE RISKS OF STOPPING YOUR CURRENT TREATMENT?**

***<<***Only include if a participant will stop treatment to enter study

*List any symptoms that could occur with cessation of the participant’s current treatment and/or relapses. Include this statement in this section} “You should not stop or alter dosages of medication on your own.”>>*

**WHAT ARE THE REPRODUCTION RISKS?**

*<<* When appropriate, please add information on reproductive risks

*All known risks should be explained.*

*If known, add a statement regarding the specific information on birth defects or drugs known to be present in breast milk OR you may use a statement such as:*

*Because the drug(s) in this research study can affect an unborn baby, you should not become pregnant or father a baby (cause a pregnancy) while in this research study. You should not nurse your baby while on this research study. You will notify the researcher immediately if you become pregnant or suspect you have caused a pregnancy. You should discuss birth control options with your researcher.*

*If applicable:*

*If you/ or your partner become pregnant, the treatment used in this research study might involve unknown risks to the embryo or fetus.*

*AND/OR*

*The study doctor will wish to follow the outcome of any pregnancy and condition of any new born and report this to the study sponsor.*

*Add to or modify as appropriate to your study.>>*

**ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?**

*<< Suggested language if there are not specific risks to be gained from participation in the study:*

*“If you agree to take part in this research study, there may/will not be a direct medical benefit to you. We hope the information learned from this research study will benefit other patients with {insert name of disease/condition] in the future. Potential benefits to you may include*

*list benefits, such as more frequent than usual medical exams.”*

*Be very careful that this section does not contain statements that could be perceived as coercive; i.e., exaggerating benefits or minimizing risks.>>*

**WHAT OTHER CHOICES FOR CARE ARE THERE?**

<< *List alternatives including approved drugs, devices, interventions, etc.. Do not include drugs, devices, etc which are investigational or which could be used “off-label” to treat someone.*

*For normal, healthy subjects the only alternative may not be to participate. For all other subjects the alternative may be the usual standard medical care. DO NOT STATE “There is no alternative”.*

There may be other drugs that could be prescribed for your {insert the condition}. Ask your physician. >>

**What is the Clinical Trials Registry?**

<<*Insert this section if your trial* *meets the FDAAA 801 definition of an "applicable clinical trial" <http://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>*

*Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" "Applicable Clinical Trials" include the following:*

* ***Trials of drugs and biologics.*** *Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation*
* ***Trials of devices.*** *1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2)* [*pediatric postmarket surveillance*](http://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#PediatricPostmarket) *required by FDA*

*"Applicable clinical trials" generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:*

* *The trial has one or more sites in the United States*
* *The trial is conducted under an FDA investigational new drug application or investigational device exemption*

*The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research*>>

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 results. You can search this Web site at any time.

 **WHAT IS A CERTIFICATE OF CONFIDENTIALITY?**

<<*This section and the following language is to be used only when a Certificate of Confidentiality has been requested from the NIH >>*

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

**AVAILABILITY OF INFORMATION**

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

**WHAT ARE YOUR COSTS TO BE IN THIS STUDY?**

*<< If the subjects may incur an additional expense because they are participating in the research, the costs should be explained.*

*Clearly indicate what the costs are that subjects are expected to pay and what costs are covered under research and general insurance. >>*

**WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**

*<<{Include the amount of payment, if any, and the schedule of payment (which must be prorated over the visits). Subjects are to be reimbursed even if they do not complete the entire study based upon their participation up to the point of termination/withdrawal from the study. Subjects must be informed how (e.g., check, cash, gift certificate, etc) and when (e.g., on-site at each visit, by mail at each visit, etc.)*

*(The IRB recommends the following statement be included if subjects receive payment. PIs and Study Coordinators should check with their business units for direction.)*

***Suggested Informed Consent Document language on the Greenphire system***

*You will be paid \_\_\_\_\_\_ for your time and travel costs related to taking part in this study.*

*Compensation will be made to you using a prepaid debit card. The money will be loaded onto your card within one business day of your participation. Details of the debit card system are explained on an additional information sheet.*

*If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.>>*

**WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?**

*<< This wording must be used when this section is required. If the study is a minimal risk study, this section is not required.>>*

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. \_\_\_\_\_\_\_\_\_\_\_\_\_ Name of Sponsor OR the University of Cincinnati will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses.

*<< If the sponsor has a more generous policy, use the sponsor’s statement (suggested language below) In the section about compensation in case of injury, ensure that the compensation in case of injury language in the consent is consistent with the clinical trials agreement with the funding organization when a funding sponsor is paying for study related injuries.>>*

If you think that you have been hurt by taking part in this research, call \_\_\_\_\_\_\_\_\_\_\_\_\_ (name of PI) at \_\_\_\_\_\_\_\_\_\_\_\_\_ (phone number), as soon as possible.  If needed, emergency medical care will be provided. If the injury is a direct result of a study-related procedure or because you are taking \_\_\_\_\_\_\_\_\_\_\_\_\_ (name of study drug), the cost of the emergency medical care will be paid by the sponsor, only if it is not paid your health insurance, a government program, or other third party. The Sponsor has no plans to pay for medical care for any other injury whether or not it might be related to taking part in this research.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

<<*Subjects cannot be asked to return for a study visit after they withdraw unless a return visit is necessary for the subject’s health or wellbeing. If the subject is asked to return, explain here the reason for the return visit.>>*

**HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?**

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the United States Food and Drug Administration (FDA) if the study involves articles regulated by this agency, the University of Cincinnati, and the sponsoring company, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, *[List relevant agencies like the National Cancer Institute, VA Medical Center, etc.] \*\* The monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies)* will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.<< *This information must be included for research that does not require a HIPAA authorization.>>*

**Authorization to Use and Disclose Health Information**

*<< This section replaces the stand-alone HIPAA authorization document. This section is required for all research being performed at a Covered Entity allowing Protected Health Information (PHI) to be shared for purposes specified in the Authorization.>>*

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

**Who Will Use and Disclose My Health Information?** The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

**What Health Information will be Used and Disclosed?** The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

**Who Will Receive My Health Information?** Your study information or medical records (as described above) or both may be shared with the following people or groups:
The study sponsor or its representatives, including companies it hires to provide study-related services

* Researchers who are conducting this study at other study centers
* UC Institutional Review Board and any other committees responsible for overseeing the research
* Staff of the UC Human Research Protection Program
* \_\_\_\_\_\_\_\_\_\_ employees providing service or care to you *<< Please include any covered entities involved in this research UC Health, Mayfield Clinic, LCOH,…*>>
* Federal and State agencies, such as the U.S. Food and Drug Administration
* (FDA), Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

**Will My Information be Protected by the Privacy Rule After it is Disclosed to Others?**

­­­­­­­­­­­­­­­­­­­*<< Please include any covered entities involved in this research UC Health, Mayfield Clinic, LCOH,…*>>\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

**What Happens if I Leave the Study Early?** If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

**Will My Authorization Ever Expire?** This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

**May I Take Back My Authorization?** You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

**May I Look At My Study Information?** You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(NAME [S])* at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(TELEPHONE NUMBER)*.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

* Think the research has hurt you.
* Have general questions about giving consent or your rights as a research participant in this research study.
* Have questions, concerns, complaints and/or suggestions about the research.
* Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

*Please format so that all signatures are on the same page. The signature page should be a separate page from the rest of the consent form.*

*<<* ***Change the following, when appropriate:***

* *Replace “Participant” with “Parent, signing for a minor”, when minors will be enrolled. Add an additional line when both parental signatures are required.*
* *Add a signature line for “Legally Authorized Representative” for non-emergency research which will enroll participants who cannot consent for him/herself.*
* *Add a signature line for “Next of Kin / Legally Authorized Representative” for research which has been approved by the IRB to enroll participants who cannot consent for him/herself through surrogate consent*
* *\*\*Add a signature line for “ impartial witness” \*\**

*ICH requirement 4.8.9 “If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present for the entire informed consent discussion. After the written informed consent and any other written information to be provided to subjects is read and explained to the subject or the subject’s legally acceptable representative, and after the subject or subject’s legally acceptable representative has orally consented to the subject’s participation in the trial, and, if capable of doing so, has signed and personally dated the informed consent from, the witness should sign and personally date the consent form. Note: The FDA allows the subject/ participant to “make their mark,” if appropriate under applicable state law. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative.”>>*

**UNIVERSITY OF CINCINNATI - Medical**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:**

|  |  |
| --- | --- |
| **UC IRB Study #:**  | **Sponsor Name:** (e.g., Investigator-Initiated, Name of Sponsor, NIH) |

**Investigator Information:**

|  |  |
| --- | --- |
|  |  |

Principal Investigator Name Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

*<<* *Add the following language as necessary for studies that involve HIV testing, AIDS or AIDS related conditions, treatment of psychiatric condition(s), and/or treatment of alcoholism or drug abuse*

*I authorize the release of information concerning treatment relating to…*

* *HIV testing*
* *AIDS or AIDS related condition,*
* *psychiatric condition(s)*
* *alcoholism*
* *drug abuse*

*…to the parties listed in the authorization section of this consent for the purposes described above.>>*

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

Participant

Date

PERSON OBTAINING CONSENT

I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant’s satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

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

Signature and Title of Person Obtaining

Consent and Identification of Role in the Study

Date

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

\_\_\_\_I **want** the researcher to inform my primary care physician/specialist of my participation in this study.

\_\_\_ I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.

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

\_\_\_The researcher is my primary care physician/specialist.

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

Participant

Date