***GENETICS INFORMED CONSENT TEMPLATE (Version SEP-2014)***

**The Genetics Informed Consent Statement is to be used in the following cases:**

1. When the investigator is conducting genetic research on blood or tissue acquired from known subjects (one consent form).
2. When the investigator is conducting genetic research as a sub-study within another study *and* the participation in the genetic research is optional (two consent forms for those who participate, one for those who do not).
3. When the investigator is conducting genetic research as a sub-study within another study, but the participation in the genetic research is *not optional*, incorporate the additional elements in the genetics consent form into the primary informed consent statement (one consent form).

**To the Investigator:** Instructions for you are included in brackets and italics and should not be included in your final consent document. Most of the following statements and wording are for guidance. When possible, you are encouraged to present the information to the subject in more clear and simple terms so that the subject has all the information that he/she needs to make an informed decision. The most important utility of the consent form is to provide the subject with as much information as possible, at a reading level understandable to someone who has not graduated from high school, so that they can make an informed decision. (For example, this template is written at the 10.6 grade level.)

Do not alter the order of these sections. The Institutional Review Board may require supplemental sections and information to be added to the consent document during the review process. Use no less than 12 point and preferably in Arial or Times New Roman font. Number the pages \_\_ of \_\_ at the bottom. Do not bold in the consent form for emphasis. Only the Section Headers should be bolded. Please format carefully so that headers are on the same page as some of the content for that section.

# UNIVERSITY OF CINCINNATI

# CONSENT TO PARTICIPATE IN A GENETICS RESEARCH STUDY

STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

UC IRB STUDY #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SPONSOR NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

(e.g. Investigator-Initiated, Name of

Sponsor, NIH)

INVESTIGATOR INFORMATION:

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

Principal Investigator Name

Telephone Number

24hr Emergency Contact

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

**INTRODUCTION:**

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.

Your participation in this research study is entirely voluntary. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without unfairness to you or your medical care. The study doctor(s) do not promise that you will receive any benefits from this study.

This informed consent document is a brief written summary of what your study doctor is telling you. Be sure to ask questions while you read this if there is anything that is not clear.

**WHY IS THIS RESEARCH BEING DONE?**

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

**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 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*<<HOURS, DAYS, WEEKS, MONTHS, 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.

*<<List circumstances, such as in the subject’s medical best interest, funding is stopped, subject’s condition worsens, new information becomes available>>*

**WHO IS CONDUCTING THE RESEARCH STUDY?**

This study is funded by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*<<NIH, GOG, SWOG, ACTG, NSABP, Pharmaceutical firm, name of UC Department if departmental funds, etc. 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 site>>*

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

*<<if applicable>>*

*<<If the IRB determines that a financial conflict of interest or a perceived conflict of interest exists, you will be given a statement to insert in this section of the ICS.>>*

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

About \_\_\_\_\_\_\_\_\_\_ people will take part in this study at

*<<insert name of local site(s)>>*

A total of \_\_\_\_\_\_\_\_\_ will take part across the country.

*<<if applicable>>*

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

If you take part in this study, you will have the following tests and procedures:

<<If there is a chart or calendar showing when procedures, 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.

*Provide a lay description of the genetic research. All genetic research procedures must be disclosed and described. Technical details need not be included, but if disease specific genes are being investigated, the subject should be so informed. An auditor comparing the protocol and the consent should find that they are consistent. If a subject is to undergo a procedure(s) that is not part of the genetic research and If it will further help the subject’s comprehension by giving a frame of reference, list the non-research procedure(s) also, and indicate the relationship to the research (e.g., a biopsy for ----). Indicate the relationship between the genetic research and another research protocol, if appropriate.*

*If blood is to be drawn, describe how often and how much each time, with a total amount 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.”*

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

Examples of risks related to genetics research include

*<<Include all that apply, in addition to any risk specific to this study>>*

* Discovery of information about yourself or your family that you do not want to know

<<*insert appropriate example if known, such as discovery of non-paternity, possible incest or a genetic disorder that has not yet manifested itself>>*

* Risk to your self-esteem if you are found to have a genetic mutation.
* Disclosure of information about yourself to other family members.
* Unauthorized disclosure of your health or genetic carrier status that may affect your employability, insurability, immigration, paternity suits, or social reputation.
* Stereotyping or stigmatizing as belonging to a particular community or cultural group.
* Any inherent risks involved in the actual collection of the genetic material.

*<<If the research involves GENE THERAPY, the risks regarding the unknown should be addressed; e.g., potential for long-term toxicity, inadvertent alteration of the subjects germ line and the introduction of new infectious agents into the subject>>*

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

If you agree to take part in this research study, there may not be a direct medical benefit to you. The information learned from this research study may benefit other patients with \_\_\_\_\_\_ in the future.

*<<insert name*  *of disease/condition>>*

Potential benefits to you may include

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

* Receipt of information which could determine your life or health choices; e.g., marriage, reproduction, medical treatment, disease prevention)

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

Instead of being in this research study, you have these options:

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

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

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

<<If applicable, the following statement must be used when VA patients are a source of subjects>>

Department of Veterans Affairs Medical Center (VA) patients may be financially responsible for care at the Department of Veterans Affairs Medical Center. Financial responsibility is individually determined based upon legislative criteria.

**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>>*

***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 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.

*<<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 well being. If the subject is asked to return, explain here the reason for the return visit>>*

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.

## 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 investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators 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, the investigators continue to have ethical and legal obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person.

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

Every effort will be made to maintain the confidentiality of your study records. Agents of the University of Cincinnati and any sponsoring company, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ will be allowed to inspect sections of your medical and research records related to this study. <<*List relevant agencies like the National Cancer Institute, study sponsor, etc. >>*

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.

*<<Describe what information will be revealed, to whom and under what circumstances. Indicate the method for disclosure (written, telephone, in person).*

*Identify who will be disclosing the results. Describe how confidentiality will be maintained and list any limitations>>*

*<<If clinically relevant information may be discovered from this study, include this section>>*

Please indicate who is, or who is not, to receive the genetic information obtained during this study by circling the underlined word(s) that apply for each question:

1. You **DO**

**DO NOT**

want to be informed of the study results.

2. You **DO**

**DO NOT**

want your family physician informed of the study results.

3. You **DO**

**DO NOT**

want the family members listed below informed of the study.

results

**DO NOT LIST FAMILY MEMBERS UNDER AGE 18.**

**Name**

**Address**

**Phone No.**

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

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

If new information is discovered after this study is complete, may the researcher contact you?

\_\_\_ YES

\_\_\_\_ NO

**WHAT IS GENETIC MATERIAL?**

The term Agenetic material refers to your *(list blood and/or other tissue)* that will be collected in this study for genetic analysis. When the study is finished, or if you withdraw from the study, or if you are asked to withdraw, you have the following choices for the disposition of your genetic material. Please circle a choice for each item:

1. When this study is completed or terminated, your genetic material (circle one)

**A.** Must be destroyed

**B**. May be kept if all links to your identity are removed

**C**. May be kept with links to your identity

1. If your genetic material is kept it may be used for future studies (circle one)

**A**. Only by (*investigator’s name*)

**B**. By this investigator (*investigator’s name*) or other investigators

1. If your genetic material is kept, it may be used (circle one)

**A**. Only for studies related to (*conditions/diseases in this study*)

**B**. For studies of any condition or disease

If you decide to withdraw from this study prior to its completion, you may require that your genetic material be destroyed.

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

If you have questions about this research study or to report a research-related injury, you can contact the researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(NAME (S))* at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(TELEPHONE NUMBER).*

If you have general questions about giving consent or your rights as a research participant in this research study, you can call the University of Cincinnati Medical Institutional Review Board at 513-558-5259*.*

To discuss questions, concerns, complaints and/or suggestions with an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

**SIGNATURES**

<<*Please format so that all signatures are on the same page. If this signature page is separate from the consent form due to formatting, insert the following information from the first page>>*

# UNIVERSITY OF CINCINNATI

# CONSENT TO PARTICIPATE IN A GENETICS RESEARCH STUDY

STUDY TITLE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

UC IRB STUDY #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SPONSOR NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(e.g. Investigator-Initiated, Name of

Sponsor, NIH)

INVESTIGATOR INFORMATION:

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

Principal Investigator Name

Telephone Number

24hr Emergency Contact

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

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. I will not lose any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this 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.

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

Participant (or Parent, if signing for a minor)

Date

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

Next of Kin (state relationship to participant)

or Subject’s Representative

Date

*<<Only required if subject not competent to consent>>*

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

Witness to the Consent Process

Date

*<<To be signed if the subject is unable to read the consent document and it has been read to the subject instead>>*

**PERSON OBTAINING CONSENT:**

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

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

Signature and Title of Person Obtaining Consent Date

 and Identification of Role in the Study