The Cleveland Clinic, IRB 8458
Molecular Mechanisms Involved in Cancer Predisposition

DOCUMENTATION COMPLETION INSTRUCTIONS (External IRB Approved Sites-ONLY)

Every subject is **REQUIRED** to have the following pieces of documentation completed:

- Informed Consent Form
- Informed Consent Documentation Process Form
- Medical Release Form
- Contact Information Form

Please **make a copy** of these documents for your records and **SEND THE COPIES TO THE CLEVELAND CLINIC.** Please note: **ALL PAGES OF THE CONSENT FORM** must be sent along with the participant's sample.

An IRB-approved form is a legal document. **DO NOT MAKE ANY CHANGES TO THE DOCUMENT**. This includes: Underlining, Highlighting, Arrows, Slashes, or Any random or miscellaneous markings. Please do not use white out anywhere on the consent.

The participant **MUST BE ABLE TO READ ENGLISH** in order to sign the English version of the forms. Participants who speak English, but cannot read English must sign a consent written in their native language. Spanish translated research forms are available upon request.

INITIALS ARE NOT ACCEPTABLE where a **SIGNATURE** is required.

You must be an **IRB-APPROVED MEMBER OF THE TEAM** in order to sign the following documents. Please contact Beth Crouser at 216-445-5850 or crouseb2@ccf.org in order to obtain this IRB approval.

Documentation that is not filled in completely and accurately will cause a delay in processing the sample and the sample may be destroyed. If at any time you need help with anything to do with this study, please call our research line at (216) 445-7869.

INFORMED CONSENT FORM

Make sure you give the participant a valid informed consent form. Check the version date and expiration date to ensure you have the correct document. Please have the participant read through the consent in its entirety, and then verbally review study design, risks, benefits, alternative, and follow-up. Answer any questions they may have and ensure they have an understanding of what is being asked of them by asking them open-ended questions such as:

- "Just so that I'm sure you understand what is expected of you here, would you please explain to me what you think we're going to ask you to do?"
- "Describe in your own words the purpose of the study."
- "What additional information would you like to know?"
- " What are the possible risks?"

1. If the participant has a question that you cannot answer, please call our research line at (216) 445-7869.
2. Steps for completing the informed consent document are as follows:

Adult Individual/Deceased Relative Consent	**Parents/Legal Guardian of Minors and Minor Participants**
Complete Page 8:	**Complete Page 9:**
Participant must print name	Parent/Legal Guardian must print name
Participant signs and dates the "Signature of participant" line (in their own writing)	Parent/Legal Guardian signs and dates the parent/guardian signature line (in their own writing)
Participant must choose if they WOULD or WOULD NOT like to receive research results reported to their healthcare provider	Parent/Legal Guardian must choose if they WOULD or WOULD NOT like to receive research results reported to their healthcare provider
	Participants between the ages of 7 to 17 years old, must have child assent, and must print, sign, and date the consent document under the child assent statement. If participant is unable to give assent due to cognitive functioning, person obtaining consent should note this in comment section of "Presentation of Consent."
Person obtaining consent must print, sign, and date at the "Signature of person obtaining consent" section of the consent form	Person obtaining consent must print, sign, and date at the "Signature of person obtaining consent" section of the consent form
Page 9 (minor participant page) should be left completely blank - do not make any additional markings (slash marks, writing, etc.)	**Page 8 (adult participant page) should be left completely blank - do not make any additional markings (slash marks, writing, etc.)**

INFORMED CONSENT DOCUMENTATION PROCESS

Please complete documentation of the informed consent process according to your institutional policy and complete this form as follows:

1. Needs to be completed by the Person Obtaining Consent. All fields need to be completed:
    a. Subject's Name and CCF#
    b. Date and time that consent was obtained
    c. Fill in comments (when applicable)
    d. SIGN, PRINT their name, and DATE when the Informed Consent Form is received, if applicable. (May be later than the Subject's Signature date, if the informed consent was mailed)

MEDICAL RELEASE FORM

1. Subject must fill in the following information:
    a. Last Name, First Name, & Middle Initial (If Applicable)
    b. Date of Birth

    c. The institution(s) where their medical records are stored
    d. Date range from which applicable medical records exist (for example 1999-2005, or 2004-present)
2. Subject must sign, print their name, and date the "Signature of Patient/Patient's personal Representative" section
    a. If completing for deceased relative, subject must print and sign name and give relationship and date the "Next of Kin/Printed Name/Relationship" section, and include notation that subject is deceased.

CONTACT INFORMATION PAGE

1. Subject must fill in all their contact information, including:
    a. Name
    b. Date of birth
    c. Address
    d. City, State/Providence, Zip Code
    e. Telephone number
    f. If subject is a minor, Parent/Legal Guardian must complete and also give their name and contact information
2. Give the Subject time to read the Family Member Contact
    a. If the Subject chooses NOT TO name a family member, he/she must initial that option
    b. If the Subject chooses TO name a family member, he/she must complete the name, address, city, state, zip code, telephone number, and relationship
3. Subject must SIGN, PRINT their name, and DATE