

Getting Started Checklist

- Submit the online Patient Background Form**
Fully complete the background questions and submit your information securely to Clarity online. Please consult your physician's office if you have questions about details of your medical history. If you are unable to complete the form online, please contact us for other options.
- ___ Date of First Diagnosis
 - ___ Stage: I (a,b,c), II(a,b,c), III (a,b,c), or IV
 - ___ Histological subtype: Serous, Mucinous, Clear cell, Endometrioid, Other _____
 - ___ All Ovarian Cancer Surgery dates
 - ___ All Chemotherapy: Drug name(s), Cycles, Start and End date
 - ___ Recurrence(s): Date(s), Description, Detection Method (CA125, CT, PET)

**Please send the following paperwork by
fax (858.657.0265) or email (mary.buhler@clarityfoundation.org)**

1. **The Clarity Consent Form** (last page only needed)
This form states your permission for the Clarity Foundation to run tests on your tumor samples and retain copies of your data for research purposes.
2. **The Clarity Authorization For Release Form** (1 page)
This form allows Clarity to request and obtain your tumor sample and pathology report from your doctors.
3. **Insurance Card(s)**
If you are insured; please include a front and back copy of your insurance card(s).
4. **Pathology Report**
If available, a copy of your **most recent** pathology report (corresponding with the tumor biopsy you would like us to profile). If you do not have a copy on hand Clarity will be happy to obtain one on your behalf.

**Please note: Submitting all of the above requested forms and copies
will help Clarity ensure you receive your testing results in a timely manner.**

5. **Clarity Foundation Grant Form (OPTIONAL)**
Grant information can be found online in our "Lab Costs and Grant Support" section.

Informed Consent for Molecular Profiling Tests

Introduction

This consent form gives you information about the types of molecular profiling tests offered through The Clarity Foundation. These tests are voluntary. Some tests involve testing your tumor cells to see if they make certain chemical materials called proteins and RNA. Some tests may involve using your genetic material (also called DNA) and you may wish to seek genetic counseling before signing this form. Read this form carefully before making your decision about testing. You may discuss your decision with your family and friends and with your healthcare team. If you decide to have the testing, you will be asked to sign this consent form.

Purpose

Medical research is learning a lot about how cancer drugs work or do not work in stopping the growth of certain tumors. Some of this success comes from understanding more about the “molecular profile”, also called the genetic and chemical make-up, of tumor cells. Information about the molecular profile of tumor cells may help doctors select cancer drugs that interact with specific proteins, also called “targeted therapy”.

The goal of the molecular profiling tests described in this form is to find out if the genetic and/or chemical make-up of your tumor can help your doctor make decisions about the best treatment options for your ovarian cancer. Treatment options may include using cancer drugs already approved by the FDA or finding the best clinical trial that is studying new treatments for your type of cancer.

Test Procedures and Results

The tests will use tumor samples already taken during your surgery as part of your regular cancer care. Your doctor will tell you if you need to have another biopsy but this is very unlikely for the sole purpose of these profiling tests.

Your tumor samples will be sent to a special laboratory to find out if your cancer cells have certain molecular markers that are known to be present in some cancer cells. The markers include chemical materials, such as proteins and RNA, that may cause cancer cells to grow out of control. The markers may also include changes in your DNA, also called mutations. If there is any left-over tumor sample, it will be returned to your doctor after the tests are done.

The Clarity Foundation and the laboratory where the tests are done keep your results confidential and fully obey the Health Insurance Portability and Accountability Act (HIPAA). Your results will only be released to your healthcare provider, his or her designee, or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required by federal and state laws.

Possible Risks

The molecular profiling tests use tumor or biopsy samples already taken as part of your regular cancer care. Your doctor will explain the risks of any additional biopsy procedures and will ask you to sign another consent form, if applicable.

The Clarity Foundation takes all reasonable steps to ensure confidentiality, but strict confidentiality cannot be guaranteed.

Possible Benefits

There is no guaranteed benefit from having the testing done. Knowing the molecular profile of your tumor samples may help you and your doctor make more informed choices about your cancer treatment.

Financial Responsibility

The costs of the tests are sometimes covered by insurance. If you would like help paying for the portion of the tests not covered by your insurance or if your insurance does not cover the costs and you would like help with the costs, please fill out a grant application. In the case you are awarded a grant through The Clarity Foundation you will only be responsible for the amounts specified in the grant agreement. We encourage all patients concerned about financial responsibility to apply for a grant on our website's grant page.

Contact Information

If you have any questions or concerns about testing, you may contact any of the following people:

If you have a medical or study-related question, contact your doctor

If you have questions about the process for the testing, contact The Clarity Foundation at the following email address: info@clarityfoundation.org

OPTIONAL: Permission to place information about my tumor samples in The Clarity Foundation public database.

If you agree, The Clarity Foundation would like to enter the chemical and genetic information about your tumor samples in The Clarity Foundation public database for doctors and researchers to learn more about ovarian cancer and possibly other diseases. Your personal information (name, address, medical record number, social security number, etc) will NOT be placed in the public database. However, The

Clarity Foundation will keep your personal information and may follow you over your life for information on your cancer and response to treatments. The scientific results about your tissue samples and the clinical information about your case that you wish to share, including the updates that you provide to The Clarity Foundation will be placed into the database. This type of information may include your type of ovarian cancer, the types of chemotherapy you have received and the length of your response to each chemotherapy agent. You do not have to give The Clarity Foundation permission to enter the scientific information about your tissue samples. If you say “No” you can still have the testing procedures done. However, if you say “Yes” now, but later change your mind, The Clarity Foundation will not be able to remove the scientific information from the public database but we will not contact you anymore once you withdraw your consent (change your mind).

Mark your choice by placing your initials in the “Yes” or “No” box below. If you have any questions you can talk to your doctor or the staff at the Clarity Foundation.

The information about the chemical and genetic makeup of my tissue samples may be placed in the public database to be used by researchers and doctors to learn more about cancer and other diseases. I understand my personal information will not be placed in the public database.

NO _____

YES _____

INITIAL HERE

Consent

You may take as much time as you like before making a decision to have the testing, and you may wish to discuss the testing with your family, friends or family doctor.

Please sign and date below and have a witness sign and date as well.

I have read and been given a copy of _____ pages of this form. I understand the information provided and my questions have been answered. I agree to have my tissue samples tested.

Name of Patient	Date	Signature

SIGN HERE

Witness	Date	Signature

WITNESS

AUTHORIZATION FOR RELEASE AND/OR DISCLOSURE OF MEDICAL INFORMATIONPlease **REQUEST** Medical Information **FROM:**_____
*Name of Health Care Provider*_____
*Name of Medical Office/Hospital*_____
*Street Address*_____
*City, State and Zip Code*Please **SEND** Medical Information **To:**_____
*Name of Person or Entity to Receive Information*_____
*Title (Physician, Therapist, Attorney)*_____
*Street Address*_____
City, State and Zip Code

I HEREBY AUTHORIZE _____ TO RELEASE AND/OR DISCLOSE THE MEDICAL INFORMATION AS INDICATED BELOW TO THE HEALTH CARE PROVIDER, ENTITY, OR PERSON I HAVE INDICATED ABOVE.

RELEASE AND/OR DISCLOSE RECORDS AND INFORMATION REGARDING:_____
*Name of Patient (List other Names used)*_____
*Medical Record Number*_____
*Date of Birth*_____
*Address*_____
*City*_____
*State*_____
*Zip Code*_____
*Telephone Number***DURATION:**

This authorization shall become effective immediately and shall remain in effect until _____ (enter date) or for two years from the date of the signature if no date entered.

REVOCAION:

This authorization may be revoked in writing by the undersigned at any time prior to the release of information from the disclosing party. Written revocation will not affect any action taken in reliance on this authorization before the written revocation was received.

REDISCLASURE:

I understand that the requester may not lawfully further use or disclose the health information unless another authorization is obtained from me or unless disclosure is specifically required or permitted by law.

SPECIFY RECORDS

Check the box and initial which type of information is to be released and/or disclosed:

TO BE RELEASED General Medical Information (from _____ to _____)**AND/OR DISCLOSED:** Information Regarding Treatment (from _____ to _____) Pathology Reports Laboratory Results Tumor Block Frozen Tumor Sample Other (specify) _____

I REQUEST THAT THE HEALTH INFORMATION RELEASED AND/OR DISCLOSED PURSUANT TO THIS AUTHORIZATION BE USED FOR MOLECULAR DIAGNOSTIC PROCEDURES INCLUDING IMMUNOHISTOCHEMISTRY, GENE AMPLIFICATION AND MUTATIONAL ANALYSES, AND MICROARRAY.

A COPY OF THIS AUTHORIZATION IS VALID AS AN ORIGINAL.**I HAVE THE RIGHT TO RECEIVE A COPY OF THIS AUTHORIZATION. THE COPY IS FOR ME TO KEEP.**_____
*Date:*_____
*Signature of Patient or Patient's Representative:*_____
Indicate Relationship (if Signed by Other than Patient)