THE CLEARITY FOUNDATION

Improving Treatment Options for Ovarian Cancer Patients

Molecular Profiling Checklist

1. Submit the online Patient Background Form http://www.clearityfoundation.org/form/Default-staged.aspx

   Complete the background questions and submit your information securely to Clearity. Please consult your physician's office if you have questions about details of your medical history.

2. Send the following to Clearity via email (patientsupport@clearityfoundation.org) or fax (858.657.0265)

   a. Clearity Consent Form (need last page only)

      Gives Clearity permission to have your tissue samples tested and to have your results and clinical information incorporated into the Clearity Foundation Database

   b. Clearity Repository Consent Form (optional, need last page only)

      Gives Clearity permission to have your tumor molecular profiling data and associated clinical information incorporated into the Repository and used for research purposes

   c. Clearity Authorization for Release/Disclosure of Medical Information Form

      Allows Clearity to request and obtain your tumor sample and medical records

   d. Foundation Medicine Authorization for Release/Disclosure of Medical Information Form

      Complete this form if you are considering clinical trials (e.g., PARP inhibitors); NextGen sequencing analysis will be included in your tumor profile. Note: international patients should contact us for more information.

   e. Insurance Card(s)

      Send a front and back copy of your card(s)

3. Medical Records

   Send us copies of the following:

   a. Most recent pathology report (corresponding to sample you would like us to profile)

   b. Pathology report(s) from original diagnosis as well as staging surgery

   c. Oncology flowsheets (records indicating drug(s), doses, and dates given) OR pharmacy records for the chemo regimen received prior to collection date of sample to be profiled AND subsequent treatments, if any

   d. Summary of chemotherapy treatments with dates since diagnosis (e.g., from recent oncology office visit/progress note)

   e. CA-125 data **summary** from at least the past year (from diagnosis, if possible)

   f. CT/PET/MRI reports from each recurrence and from the past year

4. Submit the online Financial Assistance Form (optional)

   http://www.clearityfoundation.org/financialform/financialform.aspx

Informed Consent for Tumor Molecular Profiling Assistance Program

Introduction

This consent form gives you information about the types of molecular profiling tests offered through The Clearity 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 should feel free to 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 researchers are learning a lot about how cancer drugs work or do not work in stopping the growth of certain tumors. Some of the learning 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 work with specific chemicals called proteins, also called "targeted therapy".

The goal of the molecular profiling tests described in this form is to provide information about the genetic and/or chemical make-up of your tumor that may help your doctor make decisions about the best treatment options for your ovarian cancer. Treatment options may include using cancer drugs already available to cancer patients because they have been approved by the FDA or finding a clinical trial that is studying new treatments that have not yet been approved by the FDA, for your type of cancer.

The test results and interpretations are not intended or implied to be a substitute for medical advice.

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 unlikely for the sole purpose of these profiling tests.

Your tumor samples will be sent to special laboratories to do the tests to find out if your cancer cells have molecular markers, certain genetic and chemical make-up, that may be present in some of your cancer cells. The markers include chemical materials, such as proteins and RNA, which may cause cancer cells to grow out of control. The markers may also include changes in your DNA, called mutations.

Storage of Your Information in the Clearity Database

The Clearity Foundation will provide you with a report that summarizes the results from your tumor testing. In order to generate that report, we must enter the chemical and genetic information about your tumor samples into The Clearity Foundation Database so that your profiling results can be compared to those from other ovarian cancer patients. We will also enter clinical information that you provide to us or obtain from your medical records (e.g., surgeries, chemotherapy treatments) to help with discussions that you may have with Clearity staff. Your personal information (name, address, medical record number, social security number, etc.) and clinical information will be kept confidential in a privacy-protected, securely encrypted place.

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

Possible Risks

It is intended that 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 procedure, if necessary, and will ask you to sign another consent form, if applicable.

The Clearity Foundation takes all reasonable steps to protect confidentiality, but confidentiality cannot be guaranteed.

Possible Benefits

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

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 our grant application. If you are awarded a grant through The Clearity Foundation, you will only have to pay for the amounts specified in the grant agreement. We encourage all patients concerned about cost of the tests 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:

- For a medical or study-related question, contact your doctor
- For questions about the process for the testing, contact The Clearity Foundation at the following email address: patientsupport@clearityfoundation.org

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 and to have my results and clinical information incorporated into the Clearity Foundation Database.

_____	_____	_____	***Patient***
Name of Patient	Date	Signature	
_____	_____	_____	***Witness***
Name of Witness	Date	Signature	

Improving Treatment Options for Ovarian Cancer Patients

Informed Consent for The Clearity Foundation Repository for Ovarian Cancer Patient Clinical and Tumor Profiling Data

TITLE:	The Clearity Foundation Repository for Ovarian Cancer Patient Clinical and Tumor Profiling Data
PROTOCOL NO.:	WIRB® Protocol #20150611
SPONSOR:	The Clearity Foundation
INVESTIGATOR:	Deborah A. Zajchowski, PhD 4365 Executive Drive Suite 1500 San Diego, California 92121 United States
STUDY-RELATED PHONE NUMBER(S)	Deborah A. Zajchowski, PhD 858-657-0282

Introduction

This consent form describes the purpose of the Data Repository Study, an on-going study that is being conducted to create a data repository, or information storehouse, (the "Repository") that contains ovarian cancer patient clinical information and tumor molecular profiling data to be used for research purposes. It also describes which data or information will be stored, the duration, location of the storage, and how the data will be used by Clearity Foundation researchers and shared with other researchers. Lastly, it talks about the potential risks to you, particularly with regard to how your privacy and confidentiality will be protected if you decide to participate in the study.

How will the Data Repository be used?

Medical researchers are learning a lot about how cancer drugs work or may not work in stopping the growth of certain tumors. Some of the learning 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 patients' tumor cells together with clinical information about how the patients' diseases have behaved may help to identify novel or new ways to treat ovarian cancer, and potentially other cancers, and may also help identify the specific groups of patients who could benefit from those therapies.

You have already agreed in a written form you signed called "a consent", to have your clinical data and molecular profiling results included in the Clearity Foundation database as part of your Tumor Profile Analysis. By signing this current consent form, you are agreeing to permit the use of your data for research purposes. The researchers who use the Repository will not have access to any information that can identify who you are. Your data will be combined with the molecular and clinical information from many other patients, so that trends may be identified that may lead to the discovery of better ways to diagnose, prevent, and treat ovarian cancer patients.

Which data will be in the Repository?

The Repository will safely and securely store data about the molecular characterization or makeup of your tumor, including whether certain chemicals such as proteins and abnormal genetic material are present in your tumor cells (called mutations), together with clinical information about your general health and your ovarian cancer (e.g., your age, your diagnosis, your biopsy results, your treatment details, and your clinical history). This information is de-identified in the Repository, which means that your personal information (name, address, medical record number, social security number, etc.) will not be included in the Repository. Your information in the Repository will have a code associated with it that can be used to link you to your data. The linking code will be safely and securely stored in a separate location and will only be accessible to authorized Clearity personnel.

Where will the Repository data be stored and for how long?

This Consent lets us include your data in the Repository in a de-identified format, which means that we will not use your name or include any information that can identify you. This should ensure that when researchers look at the Repository, it will not be possible for them to know that any of the data came from you, and it will not be possible for them to find out. The Repository includes information from the Clearity Foundation Database where your personal information is stored, but the Repository data is stored in a separate location and the information in it does not have any personally identifying information, so it meets the legal standards for de-identifying your medical information. All personal information that could identify you, such as your name, address, medical record number, which is in the Clearity Foundation Database will never be transferred to the Repository. The date of your diagnosis will not be in the Repository and the dates of your tests and treatments will be presented as the number of days after your diagnosis instead of a date. The linking code that connects your data in the Repository with your data in the Clearity Foundation Database will be safely and securely stored separate from the Repository. We expect that your data will be stored indefinitely or for as long as the Repository is a useful research tool. By signing this consent, you are giving permission for the data to be used and shared until 12/31/2075.

How will my information be shared with other researchers?

No personal information that could identify you will ever be shared. Only the information in the Repository, which is de-identified, will be shared with researchers. Researchers can only receive data from the Repository if they 1) give us a research proposal which must be reviewed and approved by the Clearity Foundation, and 2) sign a user agreement, where the researcher agrees not to share information from the Repository with anyone. The Repository files are protected by a password, too.

De-identified pieces of information from your molecular profiling data and from your medical records may be put in scientific publications, like journals, along with information from other research participants. Since there will be no personal information available to those conducting research, it will not be possible to tell which information came from you or any individual in the database.

Will you benefit from taking part in the Data Repository Study?

Taking part in the Data Repository Study is not meant to help you directly; there will likely be no direct medical benefit from your participation. What is learned through research studies that use the data in the Repository may improve the treatment results and quality of life of future cancer patients. Having your data included in the Repository may improve the chances that new treatments for patients like you will be identified. This research will take time to do and there are no guarantees that any new treatments will be identified. In addition, we expect that the first results from this research will have to be verified, so we do not know if or when we will get information that could be useful to you. However, it is possible that research studies and findings from the Repository could help you in the future.

Confidentiality of Information in the Repository and Possible Risks

There is a possibility that someone unauthorized could gain access to your information stored in the Repository. The information is de-identified and does not include personal information, but it could include the results of your tumor profile and relevant medical information, like treatments and outcome. However, the code that links the Repository information back to your personal information will be safely and securely stored outside of the Repository and is only accessible to the Clearity manager in charge of the Repository.

Your personally identified medical records will never be in the Repository. But in spite of the state-of-the-art security measures and safeguards we use, we cannot guarantee that your identity will never be linked to your data in the Repository, if the security for the Repository, the Clearity Foundation Database, and the secure access to the linking codes at the Clearity Foundation are breached. There may be other risks that we do not know about right now, because technology is advancing and there may be new ways of linking information back to you that we cannot foresee.

The Department of Health and Human Services (DHHS) and Western Institutional Review Board (WIRB) may have access to the consent form you signed and to your health information stored at the Clearity Foundation as part of their role in reviewing research studies and protecting the rights of research subjects.

Does taking part in the Data Repository Study cost you anything?

In order for you to participate in the study, you have to agree to have your tumor profiled as part of the Clearity Foundation's Tumor Molecular Profiling Assistance Program. There are no costs or charges to you for taking part in the study.

Will you receive anything for taking part in the study?

You will not be paid for participating in the study and for donating your data. The research may lead to new medical knowledge, tests, treatments or products. There are no plans to provide financial payment to you or your relatives if this happens.

What is my alternative?

Your alternative is not to take part in this study.

Do I have to take part in the study?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the investigator or the sponsor without your consent for any reason.

Do I have to sign this consent form?

You do not have to sign this form. But if you do not sign this form, you cannot be a part of this study, which means your tumor profiling results and clinical information will not be put into the Repository. You do not have to sign this consent form to participate in the Clearity Tumor Profiling Assistance Program.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate in this study and sign this consent form, you will be free at any time to withdraw your authorization that lets us put your tumor profiling and health information into the Repository. After you withdraw your consent, your information will be removed from the

Repository. However, the withdrawal will not affect any actions previously taken that relied on your consent before your withdrawal was received. If you wish to revoke your authorization for the research use of your health information in this study, you must write to the: Scientific Director (currently Deborah Zajchowski, PhD) Clearity Foundation 4365 Executive Drive, Suite 1500, San Diego, CA 92121.

Who can I call for questions about the study?

If you have any questions concerning your participation in this study or if you have questions, concerns or complaints about the research, or feel you have experienced a research-related problem, contact:

Scientific Director (currently Deborah Zajchowski, PhD) at 858-657-0282.

If you have questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please sign and date below.

I have read and been given a copy of this form. I understand the information provided and my questions have been answered. I agree to have the data relative to the molecular profiling of my tumor and associated clinical information incorporated into the Repository and used for research purposes. I agree that this data will be stored until 12/31/2075 or until the date that the data in the Repository is no longer useful for research purposes.

Name of Patient	Date	Signature

Authorization for Release and/or Disclosure of Medical Information

A. Release and/or disclose records and information regarding:

Name of Patient (list other names used)		**Date of Birth**	
Street Address		**City, State**	
Telephone Number		**Zip Code**	

B. Please REQUEST medical information FROM:

	Health Care Provider	Hospital where Sample to be Profiled was Collected
Name		
Facility Name		
Street Address		
City, State, Zip		

C. Please SEND medical information as set forth in attached request form(s).

The medical information to be released and/or disclosed may include general medical information, information about my treatment, my pathology reports, my laboratory results, my tumor blocks/slides, my frozen tumor samples, and my blood or serum as further specified in attached request form.

I HEREBY AUTHORIZE ENTITIES LISTED IN SECTION B TO RELEASE AND/OR DISCLOSE THE MEDICAL INFORMATION INDICATED AS SET FORTH IN ATTACHED REQUEST FORM(S).

** CONTINUED ON NEXT PAGE **

Authorization for Release and/or Disclosure of Medical Information (continued)

Duration: **This authorization shall become effective immediately and shall remain in effect until revoked as set forth below.**

Revocation: **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.**

Redisclosure: **I understand that the requestor 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.**

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

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.

Signature of Patient or Patient's Representative: _____

Indicate Relationship (if signed by other than patient): _____

Date: _____

THE CLEARITY FOUNDATION

AUTHORIZATION FOR RELEASE AND/OR DISCLOSURE OF MEDICAL INFORMATION

Please **REQUEST** Medical Information **FROM:**

Foundation Medicine, Inc.

150 Second Street, 1st Floor
Street Address

Cambridge, MA 02141
City, State and Zip Code

Please **SEND** Medical Information **To:**

Clearity Foundation
Name of Person or Entity to Receive Information

Dr. Laura Shawver & Dr. Deborah Zajchowski
Title

4365 Executive Drive Suite 1500
Street Address

San Diego, CA 92121
City, State and Zip Code

I HEREBY AUTHORIZE Foundation Medicine, Inc. **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 revoked as set forth below.**

REVOCATION: **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.**

REDISCLOSURE: **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 TO BE RELEASED AND/OR DISCLOSED: **Check the box and initial which type of information is to be released and/or disclosed:**

- ☐ **General Medical Information**
- ☐ **Information Regarding Treatment**
- ☒ **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)*