Status Page

PROTOCOL **12-249**

MGH

Closed to accrual

Closure Effective Date: 12/12/2014

DFCI

Open to Accrual

No new subjects may be enrolled in the site(s) as described above. Any questions regarding this closure should be directed to the study's Principal Investigator

Research Consent Form for Social and Behavioral Research

Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates

OHRS 01.06.12

Protocol Title: The Institutional and Professional Impact of Genomic Sequencing in Cancer Care

DF/HCC Principal Research Investigators / Institution: Stacy W. Gray, MD, AM
Dana-Farber Cancer Institute

A. INTRODUCTION

We are inviting you to take part in a research study that examines the impact of the use of whole-exome sequencing (WES) on physicians and institutional systems at the Dana-Farber Cancer Institute (DFCI). The two primary goals of the research are to understand: 1) the ways in which the use of WES in cancer care impacts clinical oncologists and the care they provide; and 2) the institutional systems and processes that are developed by the DFCI to integrate WES data into clinical care.

This study will enroll two groups of professionals: 1) clinically active oncologists from disease centers participating in the NIH-funded pilot study of WES in the care of cancer patients (DFCI protocol 12-078), 2) members of the Cancer Genomics Evaluation Committee (CGEC) that has been established to guide the incorporation of WES into cancer care. This study is a companion study to protocol 12-078, which focuses on patients who are undergoing WES of tumor and germline DNA.

It is expected that about 52 people will take part in this research study. Approximately 13 thoracic oncologists (TOP), 14 gastrointestinal oncologists (GI), and 25 members of the Cancer Genomics Evaluation Committee (including a few oncologists who are also in the thoracic or gastrointestinal centers) will participate in the study. The sponsor of this protocol is the National Human Genome Research Institute and the National Cancer Institute.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

Disclosure of external financial relationships: Two study investigators, Dr. Levi Garraway (principal investigator) and Dr. Nikhil Wagle (co-investigator) are consultants for and equity holders in a company called Foundation Medicine, Inc. (FMI). FMI sells a DNA sequencing-based cancer diagnostic product. However, no product or service from FMI is being tested in this study, and no patient information or study results will be transferred to FMI. Furthermore, neither FMI nor any other commercial entity is providing funding to support this study.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to:

- Understand how the integration of WES into cancer care impacts oncologists who provide clinical care. We will assess oncologists' views about the limitations and benefits of WES and explore the challenges that they face and the decisions that they make when using WES data in clinical practice.

- Understand the institutional systems and processes that are developed by the DFCI to integrate WES data into clinical care. We will examine the collaborative processes by which CGEC members evaluate WES data and develop policies and/or guidelines for the integration of WES data into clinical care.

We will use the information gained from this study to systematically assess oncologists' views about WES and to identify the advantages and disadvantages of the structures and processes guiding implementation of WES data. Aggregate data from this study will be fed-back to the CGEC committee members and to the study investigators to facilitate reflective decision-making and the development of evidence-based recommendations related to the use of WES data in clinical cancer care.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this study is entirely voluntary. You may choose not to take part. **However, participation in study-related activities (including in-depth interviews, surveys, and group observations) is a condition of oncologists' participation in the whole-exome sequencing project (Protocol 12-078, "The use of sequencing to guide the care of cancer patients"), as well as of CGEC members' involvement with the Cancer Genomics Evaluation**

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

Committee. Oncologists and potential CGEC members have the option to decline involvement with the WES project if they do not wish to participate in the surveys, interviews, and group observations.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

There are a number of study-related activities that you may be asked to participate in during the duration of this study. As noted above, a study subject will be asked to participate in research activities based on the roles and responsibilities that he or she has as they relate to WES integration at DFCI.

Study activities include the following:

- **Surveys**: All clinically active oncologists in the thoracic and GI disease centers will be asked to complete a number of study-related surveys. We will administer:

    - A baseline survey that queries physicians about their use of genetic testing prior to the introduction of WES, how they expect to use WES data in clinical practice, and about demographic information.

    - Post-disclosure surveys that query physicians about their disclosure practices ***for each patient*** whom they enroll on the companion patient study (Protocol 12-078). We will ask about topics including, but not limited to, the type of genetic information that was disclosed, satisfaction with the communication of test results to patients, treatment modifications based on WES test results, and challenges of test-result disclosure.

You have the right not to answer individual survey questions that you feel uncomfortable answering. However, because data from physician surveys are necessary to achieve the scientific aims of this protocol as well as the companion protocol (12-078), oncologists who do not return surveys will be temporarily unable to continue enrolling patients in protocol 12-078.

- **In-depth interviews**:
  Some of the oncologists in the thoracic and GI disease centers (approximately 20 oncologists in total) will be asked to participate in in-depth interviews related to the use of WES in clinical care.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

All CGEC members of the CGEC will be asked to participate in in-depth interviews related to the structures and procedures that are developed to evaluate genomic information.

The in-depth interviews will take place either in person or by telephone and will last approximately 30-40 minutes. All interviews will be audiotaped. The tapes will be transcribed for later review by members of the research team.

In-depth interviews related to the use of WES in clinical care:

We will administer interviews at two time-points: a baseline interview (at, or around, the time the oncologist enrolls in this study) and a follow-up interview (approximately one year after the oncologist enrolls in this study). Areas for discussion include, but are not limited to:

- Baseline interview related to the use of WES in clinical care:
  - Expectations related to the use of WES in clinical care
  - Anticipate benefits and challenges of WES integration
  - Intentions to disclose WES results to patients

- Follow-up interview related to the use of WES in clinical care:
  - Benefits and challenges that were encountered through the use of WES in clinical practice
  - Factors that were most helpful in overcoming sequencing-related challenges
  - Reflections on cases in which predictive, prognostic, cancer susceptibility, and incidental genomic test findings were disclosed (or decisions were made not to disclose)
  - Ideas about the structures or procedures that would be needed to improve the integration of sequencing in cancer care.

In-depth interviews related to the structures and procedures that are developed to evaluate genomic information:

We will interview each member of CGEC approximately two times over the 4 year study period.

Areas for discussion include, but not limited to:

- Types of decisions faced by the committee

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

- The reasoning underlying their recommendations and the principles applied in making their decisions
- Values emphasized or de-emphasized in the deliberations
- Procedures employed to reconcile differences in opinion
- Members' perceptions about the deliberation process and resulting recommendations.

- Group observations:
  Dr. Sarah McGraw, an expert in ethnographic methods, will observe regularly scheduled CGEC meetings for an average of 6 meetings a year. She will write field notes on each meeting, noting: members present at the meeting; member interactions; topics covered during the meeting and those tabled for later meetings; agreements and disagreements arising during deliberations; and rationales given for opinions expressed. Meetings will be tape-recorded and transcribed for later review by the research team.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study during the duration of your participation in protocol 12-078 as a clinical oncologist and/or CGEC member. The duration of your participation will be up to 4 years, depending on your time of enrollment.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

We anticipate no physical risks or discomforts as a result of your participation in this interview study. There is a risk of loss of privacy, although we have developed rigorous procedures to ensure confidentiality. Please see Section G for additional details.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you. You may derive educational benefit from these activities. You may gain information that helps you to improve your activities as clinician and/or CGEC member. The information gained from the surveys, interviews, and ethnographic observations of the CGEC deliberations will also help us to refine DFCI systems for clinical integration of genomic data into oncology care.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in activities related to this study or to the activities outlined in Protocol 12-078.

You can stop being in the research study at any time. However, if you withdraw from this research study, you will not be able to enroll additional patients in protocol 12-078 (if you are a clinical oncologist), or (if you are a member of CGEC) will no longer be able to participate in the committee.

I. WHAT ARE THE COSTS?

Taking part in this study will not lead to added costs to you.

J. WILL I GET PAID TO BEING IN THIS STUDY

You will not receive compensation for participating in this study.

K. WHAT ABOUT CONFIDENTIALITY?

Your identity will be kept strictly confidential. Everything you say is private and will not be shared with anyone other than the research team. All survey, interview, and group observation information that is fed-back to the TOP or GI oncology groups or the CGEC will be done stripped of identifying information.

Paper copies of notes taken during the interviews and other study materials will be stored in a locked file cabinet, to which only the study staff will have access.

All electronic data, including audio recordings, will be stored in secure password-protected files on the investigators' computer networks, to which only study staff will have access.

You will not be identified in any publication that results from this interview.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

L. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

- Stacy Gray, MD, AM: 617-632-6049, email at: stacyw_gray@dfci.harvard.edu, or page at 617-632-3000 #41145
- Steven Joffe, MD, MPH: 617 632-5295, email at: steven_joffe@dfci.harvard.edu, or page at 617 632-3352

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

M. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana Farber/Harvard Cancer Center (DF/HCC) and its affiliated research Investigators, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

- The only identifying information we will collect is your name, business address, business telephone number, fax number, and email address. We will not collect any health-related information from you.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	

P. DOCUMENTATION OF CONSENT

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time. I understand that all interviews will be audiotaped and that information from the surveys, interviews, and group observations may be fed-back, in a de-identified way, to oncologists who are participating in this study and who provide sequencing care to patients and/or to the Cancer Genomics Evaluation Committee.

Signature of Subject _____ Date _____

Adult Participants

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant.

DFCI Protocol Number: 12-249	Date DFCI IRB Approved this Consent Form: 07/22/2014
Date Posted for Use: 08/05/2014	Date DFCI IRB Approval Expires: 07/21/2015
OHRS Version Date: 08/27/2013	