Appendix A:
Informed Consent Form

The University of New Mexico Health Sciences Center
Consent to Participate in Research

Personalized Genomic Testing for Skin Cancer: Maximizing Utility and Reach
SOMBRA
Phase II Consent

November 10, 2016

Purpose and General Information

You are being asked to participate in a research study that is being carried out by Dr. Marianne Berwick and Dr. Jennifer Hay, who are the Principal Investigators, and their associates. The goal of this research is to find out how New Mexicans respond to an offer of genetic testing for skin cancer. You are being asked to participate because you have been a patient at UNM for at least six months, you have a primary care provider, you are fluent in English or Spanish and you are age 18 or older. Approximately 650 people will take part in this study at the University of New Mexico. This study is sponsored by the National Cancer Institute.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen:

Initial Data Collection. You will complete a survey today in clinic. This survey includes questions regarding your thoughts and feelings about skin cancer, and behaviors you might do to help prevent skin cancer. You will be given a $15 Target card for your participation today.

You will be randomly assigned (like the flip of a coin) to one of two groups that will receive an offer for skin cancer genetic testing.

If you are assigned to one offer (Group 2), you will be referred to an Internet Website so you can learn about genetic testing for skin cancer, and then decide whether you want to have genetic testing for skin cancer. You can choose to complete 3 learning modules on line. After each learning module, you will be asked to complete a very brief survey. You will receive a $5 Target card (with a maximum of $15) for your effort in completing each brief survey. You will then have the opportunity to make a decision to have skin cancer genetic testing or not.

If you choose to have genetic testing for skin cancer, you will be mailed a kit at no cost to you. You will be given instructions to “spit” into a small tube, seal the tube and mail it in the postage paid envelope supplied by us to the Molecular Epidemiology Laboratory at the University of New Mexico. We will send you your genetic testing results, free of charge, in a letter or in an email, whichever you prefer. On average, people who have 1 or more risk types of the gene we will test, *MC1R,* have a 3 in 100 chance of getting skin cancer (that is, melanoma or basal cell carcinoma).

About two weeks after you receive your genetic testing results, we will contact you by telephone to find out your thoughts and feelings about your results. We will answer any questions you have about your results. We can refer you to a genetic counselor if you wish. You will receive a $5 Target gift card for completing this telephone call.

Whether or not you decide to participate in genetic testing, after about three months we will contact you by telephone to find out about your thoughts and feelings about skin cancer, and how you can help prevent skin cancer. You will receive a $15 Target card for completing this telephone call with us.

If you are assigned to the other offer, Group 1, of the study you will be contacted by telephone after 3 months to respond to some questions about your thoughts and feelings about skin cancer, and how you can help prevent skin cancer. You will receive a $15 Target card for completing this telephone call with us. After that, you will be offered the opportunity to complete the educational modules and have skin cancer genetic testing if you wish.

Participation in this study will take a maximum of 1.5 hours over a period of three months.

What are the possible risks or discomforts of being in this study?
Every effort will be made to protect the information you give us. However, there is a small risk of loss of privacy and/or confidentiality that would not have a significant effect on your health or insurance coverage. There is also the risk that you might feel distressed by the results of the genetic test if you choose to have it. We will provide answers to all your questions about your risk. There are risks of loss of privacy, insurance and employment with some types of genetic tests. There are some protections afforded by the Genetic Information Nondiscrimination Act (GINA). For a detailed list of protections, please read the GINA information sheet we provide you.

We keep all records in coded format, in locked file cabinets, in a locked room. Only people associated with this project, such as Dr. Berwick at University of New Mexico and other necessary trained staff at Memorial Sloan Kettering, University of New Mexico, the Food and Drug Administration, or other sponsors, such as the National Cancer Institute, would be able to see individual data. Your research and hospital records are confidential. Your name or any other personal identifying information will not be used in reports or publication resulting from this study. All information is presented in group form, and no one would be able to tell if any person is in these groups.

We will also offer you care if you become distressed, as necessary, but paid for by your insurer. If you feel any distress, call Dr. Jessica Bigney at 505-272-9431, and she will help you. She may refer you to a genetic counselor who can help you further.

How will my information be kept confidential?
Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

If you choose to send in a sample for genetic testing, the sample will be destroyed after the testing is complete. We will also keep a copy of your results until August1st, 2017, and then destroy the records. We will keep your records this long in case you want to follow up with us for any reason.

The Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that prohibits discrimination in health coverage and employment based on genetic information.
This Federal law generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that is obtained from research.
• Health insurance companies or health plan administrators engaged in research may not use the information obtained to discriminate against you.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information from research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.
Limitations (The following are not all inclusive, but the main limitations of GINA):

• The law does not exclude life insurance companies from using genetic information to make decisions.
• The law does not protect an individual if they already have a disease. It only protects an individual that has a genetic predisposition to a disease.

For more detailed information regarding the provisions of GINA see:
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf
Just as in any research project, your participation in genetic research is voluntary. You can choose whether or not to participate or quit at any time.

Information from your participation in this study may be reviewed by NCI, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

What are the benefits to being in this study?

There may or may not be direct benefit to you from being in this study. However, your participation may help find out more about your risk of developing skin cancer, and ways you can prevent skin cancer.

What other choices do I have if I don't participate?

Taking part in this study is voluntary so you can choose not to participate.

Will I be paid for taking part in this study?

As we indicated previously, there will be incentives in the form of gift cards at several stages of the research.

What will happen if I am injured or become sick because I took part in this study?
If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost.

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell Dr. Berwick or the Project Assistant immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the (505) 272-1129 for more information.

How will I know if you learn something new that may change my mind about participating?
You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your participation in the program or access to care.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation. The National Cancer Institute may stop the study at any time.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you. Sometimes research information is shared with collaborators or other institutions. Your records may also be reviewed by representatives of NCI or the Food and Drug Administration to check for quality, safety or effectiveness, or the Human Research Review Committee (HRRC) for the purposes of oversight and subject safety and compliance with human research regulations.

This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: your name, address, telephone number, and ethnicity.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Marianne Berwick, Ph.D.
MSC 10-5550
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Marianne Berwick, Ph.D., or her associates will be glad to answer them at 505-272-4369, from 8 AM to 4 PM daily. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNMHSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

What are my rights as a research participant?
If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____	_____ / _____
Name of Adult Participant (print)	Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____	_____ / _____
Name of Research Team Member	Signature of Research Team Member Date