Multi-site Research Consent Form

Title of Research Study: Genetic Counseling Processes Result in Outcomes (GC-PRO) Intervention study

This is a multi-site research study, meaning that the study is taking place at several locations. This consent includes two parts to explain the study. Part 1 describes the key information you need to know before deciding to participate in this study. Part 2 includes additional information about how the study will be carried out at this location.

Investigator Team Contact Information:
This study is being led by Dr. Heather Zierhut at the University of Minnesota and Dr. Deborah Cragun at the University of South Florida. To learn who is leading the study at this location and their contact information, see Part 2 of this consent form.

For questions about research appointments, the research study, research results, or other concerns, call the study team listed in Part 2 of this consent form.

Supported By: This research is supported by the National Human Genome Research Institute (NHGRI).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are 18 years of age or older and you have been referred to genetic counseling.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of the GC-PRO study is to try to make genetic counseling better for people of all backgrounds. We are asking participants to complete two surveys and to allow audio recording of their genetic counseling visit. The purpose of the study is to understand whether trying different ways of doing genetic counseling will lead to better experiences for patients. You will not directly benefit from this study, but you may help the research team understand how to improve genetic counseling for other people in the future.

The research team is also working with partners from the Somali, Latino/Hispanic, Black/African American, and Hmong communities to make sure the research is being done in a way that will benefit underserved communities.

How long will the research last?

You will be in this research study for the duration of your genetic counseling visit and the time it takes to complete two short 5-10 minute surveys.

What will I need to do to participate?

You will be asked to complete a 5 minute survey before your scheduled genetic counseling visit. The genetic counseling visit will be audio recorded. After the visit, you will be asked to complete another 5-10 minute survey about your experience with genetic counseling.

More detailed information about the study procedures can be found under *"What happens if I say yes, I want to be in this research?"*

Is there any way that being in this study could be bad for me?

People who have genetic counseling can sometimes feel discomfort, vulnerability, or embarrassment with medical information. You may experience these uncomfortable feelings as part of your normal healthcare visit. If you are uncomfortable, you can stop the audio recording of your visit at any time for any reason.

The audio recordings of the genetic counseling visits will contain individual voices (which may be identifiable). We will remove all information that could identify you (such as your name) from the audio recording and your survey answers. All efforts will be taken to make sure your privacy and confidentiality is protected. However, it is possible for an unintentional breach of confidentiality for participants.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from you being in this research study. However, your survey answers may help the researchers understand how to improve the quality of genetic counseling. Some people like to contribute to research because it may help others who have genetic counseling in the future.

More detailed information about the benefits of this study can be found under "Will being in this study help me in any way? (Detailed Benefits)"

What happens if I do not want to be in this research?

This study is optional. If you do not want to be in this research, you will have your genetic counseling appointment as planned. Your decision to participate or not participate will not impact the healthcare you receive.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the key information listed above.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

1. Taking a short survey (5 minutes) before your genetic counseling appointment.
2. Allowing your genetic counseling appointment to be audio recorded.
3. Taking a short survey (5-10 minutes) after your genetic counseling appointment.

What happens if I say "*Yes, I want to be in this research*"?

Before your genetic counseling appointment, you will complete a survey either online or on paper. After completing the first survey, you will attend your scheduled genetic counseling appointment.

Once you are ready to begin your appointment, the genetic counselor will make sure that you still wish to participate before the audio recording is started. You can choose to stop the recording at any time if you become uncomfortable or decide not to be in the study anymore. If you stop the recording and decide not to be in the study, you will not be asked to complete the second survey and will not receive any compensation for being in the study.

Your genetic counselor will receive additional training at some point during this study. We believe this training could improve the care you receive. You will not be told whether your genetic counselor has had the training or not. Regardless of whether your genetic counselor has had the training, an earlier study found that genetic counselors already give patients quality care.

When your visit is completed, you will be asked to complete a second short survey either online or on paper. Once you complete both surveys and the audio recording of your visit, you will be given a $30 electronic gift card to Amazon or Target (see section "Will I be compensated for my participation?" below).

Specific details about where the procedures will take place locally are listed in Part 2 of this consent form.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the study, information about you that has already been collected may not be able to be removed from the study database. If the study is still ongoing, your data can be removed at your request. If the study has been completed, we will not be able to remove your information because it will no longer be linked to your name.

Will it cost me anything to participate in this research study?

There are no costs to you for any of the research activities.

You or your insurance company will have to pay for all costs for genetic counseling care related to participation in this study, including copayments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)).

If you agree to participate in this research study, a signed copy of this consent document and the HIPAA authorization form *may* be filed in your electronic medical record (EMR) and your study participation *may* be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. We may publish the results of this research or share the resulting data. However, we will keep your name and other identifying information confidential.

For additional information about what information might be shared with authorities, see "What may be shared with authorities?"

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when

required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will I receive research test results?

This study does not have any test-related results. Therefore, there are no individual test results to share with you. A summary of the results from this study will be available on the GC-PRO study website: https://cbs.umn.edu/genetic-counseling-program/gc-pro-study

What will be done with my data when this study is over?

We will use and may share data for future research. Data may be shared with researchers/institutions outside of University of Minnesota and University of South Florida, where the study is being conducted. This could include for-profit companies. We will not ask for your consent before using or sharing them. Audio recordings (which contain potentially identifiable voices) will not be shared outside of the original research institutions. We will remove identifiers from your other data, which means that nobody who works on future research outside of the original study team will know who you are. You will not receive any results or financial benefit from future research done on your data.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, you will receive a $30 electronic gift card (Amazon or

Target) for your time and effort via email after completion of the post-visit survey.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

For how you will be compensated at this location, ***"How will I be compensated at this location?"*** in Part 2 of this consent.

Use of Identifiable Health Information

We are committed to respecting your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us your personal information that includes health information you provide in the research surveys or genetic counseling visit, and information that can identify you. For example, personal information may include your name, email address, or phone number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, or audio recordings) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

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PART 2: LOCAL STUDY INFORMATION FOR THE UNIVERSITY OF MINNESOTA

Who can I contact if I have questions?

Local Investigator Name: Dr. Heather Zierhut Investigator Departmental Affiliation: Department of Genetics, Cell Biology, and Development Phone Number: 612-626-6743 Email Address: zier0034@umn.edu	Local Study Staff: Elena Fisher Phone Number: 612-626-6743 Email Address: fishe912@umn.edu

How many people will be studied?
We expect about 789 people here will be in this research study out of 994 people in the entire study nationally.

Where will study activities take place locally?
This study will take place at various M Health Fairview genetic counseling clinics.

What may be shared with authorities?
There are no reporting requirements for any information obtained in this study.

What happens if I am injured while participating in this research?
No potential for physical injury is associated with this study.

Will anyone besides the study team be at my consent meeting?
Members of your clinical team, such as the genetic counseling assistant, may be present at the consent meeting.

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

How will I be compensated locally?
You will be given an emailed, electronic gift card to Amazon or Target once you complete the study.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Heather Zierhut