

Informed Consent Form

PROTOCOL FULL TITLE: Testing a Low Cost Population- and Theory-Based Outreach Intervention to Engage Ovarian Cancer Survivors and their Close Relatives to Consider Genetic Services

PROTOCOL BRIEF TITLE: Connecting Families to Overcome Ovarian Cancer

NCT NUMBER: NCT04927013

IRB APPROVAL DATE: December 15, 2021



Emory University

Study Title: Connecting Families to Overcome Ovarian Cancer

IRB #: IRB00000224

Principal Investigator:

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National Cancer Institute, award # U01CA240581-02

Study overview

Thank you for your interest in genetic counseling through our “Connecting Families to Overcome Ovarian Cancer Study”. We are offering free genetic counseling for you and your close relatives. The counseling can help you decide if genetic testing would be useful for you and your family. The free genetic counseling is available for a limited time with funding from the National Cancer Institute.

How do I take part?

You will be asked to schedule a free genetic counseling session through yourfamilyconnects.org. After confirming a time, the genetic counseling session will be hosted via Zoom video conferencing. The session will take about 1 to 1.5 hours to complete.

We will ask for your permission to record the session for research purposes. After each session, all recorded files will be uploaded to Emory password protected, research network drives. The recordings will be deleted at the end of the study. Access will be given to essential team members only. Be assured that your responses will be anonymized; your name and other identifying information will not be transcribed or reported.

After the session, you will receive a copy of your family history, a follow-up letter summarizing key aspects of the counseling session and options for genetic testing, and other patient educational materials.

What are the benefits?

Participating in the genetic counseling session, may help you and family members gain a better understanding of how genetics contributes to the risk for ovarian and other cancers. This information can greatly impact treatment, screening, and prevention options, and help to save lives. Note that it will completely be your choice whether you share this information with your healthcare provider.

Are there any risks?

Risks of participating in genetic counseling are considered to be minimal. You may feel some distress thinking about your personal experiences with ovarian cancer or family history. You may experience fear, worry, and other emotions as you discuss your genetic and cancer risks with the genetic counselor. The chance of health/employment discrimination is extremely low given existing protective state and federal laws, and the confidential nature of your participation.



Are there any costs?

There are no costs to you for participating in genetic counseling.

Will I be compensated?

You will not be compensated for your participation, or any discomfort you might experience in connection with your participation in the genetic counseling session.

Certificate of Confidentiality

The investigators have obtained a Certificate of Confidentiality for this study. If Emory received a subpoena for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing the following information about you:

- Information to state public health offices about certain infectious diseases.
- Information to law officials if child abuse has taken place.
- Information Emory gives to prevent immediate harm to you or others.
- Information Emory gives to the study sponsor as part of the research.

What if I don't want to take part?

Taking part in genetic counseling through our study is voluntary. You can choose not to schedule the counseling session or to withdraw from the session at any time. This decision will not affect your current or future medical care or any benefits to which you are otherwise entitled. Your decision about participation will not change any present or future relationships with Emory University or their affiliates. To withdraw from the study, please contact us at: yourfamilyconnects@emory.edu.

Contact Information

If you have questions about this study, your part in it, or if you have questions, or concerns about the research you may contact the following:

Dr. Colleen McBride, Principal Investigator: [REDACTED] or

The study email at: yourfamilyconnects@emory.edu

If you have questions about your rights at research participant, complaints about the research or an issue you rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or toll-free at 877-503-9797 or by email at irb@emory.edu.