19-010791

Cohort Study of Pancreatic Cancer Risk

NCT04247503

Document Date: 03/17/2023

MAYO CLINIC

Name and Clinic Number

Approval Date: March 17, 2023

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Cohort Study of Pancreatic Cancer Risk

IRB#: 19-010791

Principal Investigator: Shounak Majumder, M.D.

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to develop a biobank resource (registry) of individuals currently without pancreatic cancer, but who are at high risk due to family history of pancreatic cancer. You have been asked to take part in this research as a result of your previous participation in the Biospecimen Resource for Pancreas Research Family Registry which identified you as someone who has a known family history of pancreas cancer.
What's Involved	Study participation involves completing an annual questionnaire and blood sample each year for 5 years.

Key Information	The risks of drawing blood include pain, bruising, or rarely, infection at the site of the needle stick. The study will cover any fees for the blood draw and postage however; you will not be paid for taking part in this registry.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. If you have questions at any time, please ask us and a member of our research team will talk with you about taking part in this study before you sign this form.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Shounak Majumder, M.D. Phone: 800-914-7962 **Study Team Contact:** Bridget Rathbun, CCRP Phone: 507-266-3294 Toll Free: 800-914-7962 **Institution Name and Address:** Mayo Clinic 200 1st Street SW Rochester, MN 55905

▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on 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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because of your previous participation in the Biospecimen Resource for Pancreas Research Family Registry which identified you as someone who has a known family history of pancreas cancer.

Why is this research study being done?

The purpose of this research is to develop a biobank resource (registry) of individuals currently without pancreatic cancer, but who are at high risk due to family history of pancreatic cancer.

Information you should know

Who is Funding the Registry?

The National Institutes of Health (NIH) is funding the registry. The NIH will pay the Principal Investigator or the institution to cover costs related to running the registry.

This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.

Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at 507-284-0075.

One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

Your participation in the registry will take approximately five years, but your samples and data will be stored indefinitely.

What will happen to you while you are in this research study?

If you agree to be in this study, you will be asked to participate in the following:

1. During this study, we will ask you to fill out an annual questionnaire about family, health and environmental exposure histories. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer.

    a. The first year of your participation we will ask you to complete an initial baseline questionnaire which will take about one hour to complete. If you have completed this questionnaire within the last calendar year as a result of your participation in the Biospecimen Resource for Pancreas Research Family study you will not be asked to complete this again.

    b. In years two through five you will be asked to complete a Cohort Study of Pancreas Cancer Risk Follow-up Questionnaire to update information from the baseline questionnaire. It will take approximately twenty minutes to complete.

2. You will be asked to donate about 3 and one half tablespoons of blood each year for five years.

3. You will be asked to sign a medical release allowing us to review or request medical records.

No visits to Mayo Clinic are required for your participation.

What are the possible risks or discomforts from being in this research study?

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Are there reasons you might leave this research study early?

You may decide to stop at any time. If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Annual blood draw for five years

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

Approval Date: March 17, 2023

When you die, your sample will be considered a gift to Mayo Clinic. That means that Mayo Clinic can use it for research forever. Since your sample has your genetic information in it, your family may want access to it after you die. They can use that information for many things, such as learning if you had a genetic disease or if you were related to someone.

Read the following statement and mark your choice:

I permit Mayo Clinic to give my family access to my sample after I die:

☐ Yes ☐ No Please initial here: _____ Date: _____

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Our electronic database is password protected and stored on a server that only those directly involved with the registry have access to. Samples are de-identified with a random number.

All paper research materials collected will be maintained in locked cabinets in a secured area. We have been granted a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, 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. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

Approval Date: March 17, 2023

The research team may share your information with:

- DHHS, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

Approval Date: March 17, 2023

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

MAYO CLINIC

Name and Clinic Number

Approval Date: March 17, 2023

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature