

INFORMATION SHEET FOR PARTICIPATION IN A RESEARCH STUDY**YALE UNIVERSITY****Study Title: Legacy Registry & Community Engagement Program****Principal Investigator (the person who is responsible for this research):**

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Research Registry Summary:

- We are asking you to join a research registry because you have been involved with previous or ongoing research at Yale related to metabolic health.
- The purpose of this research registry is to organize and connect your research data with your updated clinical information. The Legacy Registry will include people who participated in studies as children and adolescents since the year 1990 and will eventually serve as a way for researchers to identify and contact people who may want to be a part of future research.
- Registry activities will include:
 - *The Registry research team will review and organize all of the information so that it can be a centralized source of data for studying health outcomes*
- Inclusion in the Registry does not require you to do anything.
- Inclusion in the Registry does not carry any physical risks. There is the possible risk of loss of confidentiality.
- The Registry may have no benefit to you. Including your information in this Registry will be contributing to a large dataset that may shape the direction of ongoing and future research in the field of metabolic health and weight related conditions.
- Taking part in this Registry is your choice. You can choose to take part, or you can choose not to take part in this Registry. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University or any of the research team or clinical providers.
- If you are interested in learning more about the Registry, please continue reading, or have someone read to you, the rest of this document. Please contact us and ask the Registry staff questions about anything you do not understand. Once you understand the Registry, you will be given the opportunity to opt out by pressing a button at the bottom of this message, or by contacting the Registry staff directly through various means of communication.

Are there any costs to participation? Will I be paid for participation?

You will not have to pay for taking part in this Registry. You will not be paid for contributing your data in the Registry.

How will you keep my data safe and private?

All of your information will continue to be strictly confidential. Only the researchers involved in this Registry and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share information about you with other researchers for future studies only after approval by the Yale IRB and Legacy research team. We will not ask you for any additional permissions.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. All data will be managed and maintained at the Yale School of Medicine.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

What if I want to refuse or end participation before the Registry is over?

There is no end date for the Legacy Registry. Taking part in this Registry is your choice. You can choose to take part, or you can choose not to take part in this Registry. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University, the research team or your clinical providers. You do not give up any of your legal rights by giving allowing your data to be included in the Registry.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Dr. Clare Flannery, at 203-737-5619.

If you have questions about your rights as a research participant, or you would like to speak with someone other than the Principal Investigator or study team to discuss problems, concerns, or questions, or to obtain information or offer suggestions, you can call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- The entire research record and any medical records held by Yale New Haven Hospital System and Yale Medicine created from: **1990** to: **ongoing**
- Records about phone calls made as part of this registry
- Information obtained during this research may or may not include:
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Diaries and questionnaires
 - Records about any study drug you received
 - Records about the study device
 - The diagnosis and treatment of a mental health condition
 - Use of illegal drugs or the study of illegal behavior
 - HIV / AIDS test results
 - Hepatitis infection
 - Sexually transmitted diseases
 - Other reportable infectious diseases

How will you use and share my information?

We will use your information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Governmental agencies to whom certain diseases (reportable diseases) must be reported

- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- The Principal Investigator
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- The National Institutes of Health, the study funder
- Others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I agree to the use of my information?

By giving permission for the use of your health information, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Clare Flannery, MD** Yale School of Medicine, 333 Cedar Street, PO Box 208063, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this Registry but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected and given to others may not be reversed. After your withdrawal, there will be no further use or distribution of your data.

To decline enrollment in the Legacy Registry, or to ask questions about the Legacy Registry, please contact the Principal Investigator at:

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If you want to learn more about future research opportunities, please visit yalestudies.org, email helpusdiscover@yale.edu, or call 1-877-978-8343 for more information.