

ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY

Off-Site Individual Consent Form

You are being asked to join a research registry to be used to recruit people for participation in research studies.

The title of the database is: **The Human Clinical Phenotyping Core Database**

Principal Investigator (Research Study Doctor): Sophie Molholm, Ph.D.

Office Address: Albert Einstein College of Medicine, Van Etten, 1C-3C, 1225 Morris Park Avenue, Bronx, NY, 10461 Telephone #: (718) 862-1823 Protocol #: 2011-320

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS RESEARCH REGISTRY?

- You are being asked to fill out an enrollment form to be entered into a research registry. This registry is used to compile participants for future research studies. Your information will be stored in this registry, but will only be able to be accessed by HCP personnel. If you qualify for a future research study, you will be contacted by HCP personnel and asked if you wish to participate in that study. Even if you are in the registry, you have the right to refuse participation in any study.

DO I HAVE TO TAKE PART IN THIS RESEARCH REGISTRY?

- You do not have to agree to fill out the enrollment form, and you will still have access to any services that are available.

WHAT IS THE PURPOSE OF THIS RESEARCH REGISTRY?

- The research registry is where basic information (such as age, gender, diagnosis, medical conditions) about people is stored. The HCP is a service that investigators use to recruit for their research studies. The registry allows the HCP to have existing information about people to better aid investigators in their recruitment. By filling out the enrollment form, you agree to be contacted by the HCP if you may qualify for a future research study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH REGISTRY?

- By filling out the enrollment form, you agree to be contacted by the HCP when you may qualify for a research study. Active participation is not required by you once you enter the registry. It just means that your information will be on file and you may be contacted in the future to see if you wish to participate in a specific study.
- As part of this study we may review your medical records and put the information we collect into our research records. You will have the option to consent to this at the end of this consent form. We will not add any information collected during this research study into your medical record.

WHO MAY SEE MY RECORDS?

- By filling out the enrollment form, your information will be added to a portion of the research registry that is only accessible to HCP personnel. No one outside of the HCP will be able to see any of your information.

CERTIFICATE OF CONFIDENTIALITY

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information

WHO CAN ANSWER MY QUESTIONS ABOUT THE REGISTRY?

Name: Alaina Berruti, B.S. Office Phone: (718) 862-1862

Office Address: Albert Einstein College of Medicine, Van Etten, 1C, 1225 Morris Park Avenue, Bronx, NY, 10461

If any questions arise related to this research registry you can call the researcher above. If you have questions regarding your child's rights as a research subject, you may also call the Manager of The Albert Einstein College of Medicine Committee on Clinical Investigations at (718) 430-2253, Monday through Friday between 9 AM and 5 PM.

FOR FUTURE CONTACT, PLEASE INITIAL YOUR CHOICE BELOW:

_____ I consent to have my child's details entered into the registry and to be contacted for participation in future research studies. (Your wish does not constitute a guarantee that you will be contacted.)

_____ I do NOT consent to have my child's details entered into the registry.

FOR REVIEW OF MEDICAL RECORDS, PLEASE INITIAL YOUR CHOICE:

_____ I consent to the researchers reviewing my medical record for this study.

_____ I DO NOT consent to the researchers reviewing my medical record for this study.

Informed Consent Signature Page

The following is a list of items we discussed about this research registry. If you have any questions about any of these items, please call (718) 862-1860 before agreeing to participate.

- What the registry is about.
- Who to contact if I have questions.
- I can discontinue participating in the registry at any time without penalty.
- I have been given the name of the researcher and others to contact.
- I have the right to ask any questions.

Individual Consent:

I voluntarily give permission for my details to be entered in the research registry.

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|----------------------------|-------------------------|------|
| Printed Name of Individual | Signature of Individual | Date |
| Signature of Individual | Date | |