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 University of Pittsburgh
 Institutional Review Board
 IRB: #010873

CONSENT TO PARTICIPATE IN A RESEARCH DATA REGISTRY

Title of Proposal: Center for Clinical Pharmacology Research Data Registry

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Source of Support: Center for Clinical Pharmacology, University of Pittsburgh

TO PERSONS BEING ASKED TO PARTICIPATE IN THIS RESEARCH DATABASE:

The following information is provided to you about this research project and your participation in it. Please read this form carefully. Any questions you may have about this database registry will be answered. Please feel free to ask any questions you may have about this database registry and/or about the information below.

DESCRIPTION AND PURPOSE:

Why is the Center for Clinical Pharmacology Research Data Registry being done and who is in charge of it?
The Center for Clinical Pharmacology at the University of Pittsburgh Medical Center has long standing experience in research in the area of drug metabolism (how the body and the liver break down medications) in both healthy volunteers and patients. This is done in part by analyzing information contained in some cells of the body such as blood cells and liver cells (genotyping). The members of the Center include physicians, clinical and research nurses, pharmacists, data specialists, data coordinators and other scientists. Frequently, this research team conducts research studies in both healthy volunteers and patients. Therefore, the Center has decided to create a *Research Data Registry* (a list of names and other pertinent information) that will help recruit participants in research studies that the Center is conducting. Dr. Robert A. Branch will be the Director of *Center for Clinical Pharmacology Research Data Registry*. Only investigators listed on the front sheet of this consent form will have access to this *Research Data Registry*.

What is the purpose of the Center for Clinical Pharmacology Research Data Registry?

The purpose of the *Center for Clinical Pharmacology Research Data Registry* is to identify individuals who are willing to be contacted to participate in research studies that are being conducted in clinical pharmacology.

Who is being asked to take part in the Center for Clinical Pharmacology Research Data Registry?

Past, current and future participants in research studies of the Center for Clinical Pharmacology will be invited to take part in the Center for Clinical Pharmacology Research Data Registry.

What is involved with my participation in the Center for Clinical Pharmacology Research Data Registry?

If you agree to be included in the *Center for Clinical Pharmacology Research Data Registry*, you are allowing us to gather basic personal information which includes: name, gender, address, phone number, date of birth, social security number, ethnicity, race, medical history and the names of the research studies of the Center in which you participated, or are currently participating. Your genotype information (information contained in some cells of the body such as blood cells and liver cells) will also be included. This information will be stored in a secure computer database.

If you agree to be included in the *Center for Clinical Pharmacology Research Data Registry*, it does not mean that you are obligated to be in any future research studies but it gives the Center the ability to screen for possible candidates for upcoming studies.

RISKS AND BENEFITS

What are the possible risks of participating in the Center for Clinical Pharmacology Research Data Registry?

There are no physical risks associated with agreeing to participate in the *Center for Clinical Pharmacology Research Data Registry*. There is a possibility of a breach of confidentiality of your basic personal information, which is addressed below.

What are the possible benefits to participating in the Center for Clinical Pharmacology Research Data Registry?

You will not directly benefit from being in this *Center for Clinical Pharmacology Research Data Registry*.

COST AND PAYMENT

Will my insurance provider or I be charged for the costs of any part of the Center for Clinical Pharmacology Research Data Registry?

Neither you, nor your insurance provider will be charged for the costs of participating in the *Center for Clinical Pharmacology Research Data Registry*.

Will I receive a compensation or a payment if I take part in the Center for Clinical Pharmacology Research Data Registry?

You will neither receive any compensation nor any payment if you take part in the *Center for Clinical Pharmacology Research Data Registry*.

CONFIDENTIALITY

Will this research study involve the use or disclosure of my identifiable medical record information?

This research study will not result in identifiable information being placed in your medical records held at the University of Pittsburgh Medical Center.

How will you protect my privacy?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet in the Center for Clinical Pharmacology for 5 years after completion of the study. In addition, your research records will be stored in a computerized filing cabinet that is secured and password protected with access only by the research administrators, faculty, and staff. Your research records at times can be directly linked with your identity, but this link will only be viewed by the principal investigator and research coordinator. Your identity on your research records will be indicated by a code number rather than by your name. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Who will have access to my identifiable medical information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, other investigators may request to have access to the *Center for Clinical Pharmacology Research Data Registry* to identify subjects for their research studies. If approved by Dr. Branch, a member of the Center for Clinical Pharmacology research team will search the database to identify potential subjects. If you are eligible, a member of the Center will then contact you and inform you about your potential eligibility in the other investigator's study. If you are interested, you will be given the name and telephone number of the other investigator or a team member. Should you change your mind, you are not obligated to call the other investigator's team. The following individuals will or may have access to your identifiable medical information related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical record information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release your identifiable research information in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

How long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your study participation in this research study for a minimum of 5 years or as long (indefinite) as it may take to complete this research study.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) You do not have to take part in this research study and, should you change your mind, you can withdraw from the study at any time. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

RIGHT TO WITHDRAW FROM PARTICIPATION

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of the decision to the principal investigator of this research study at the address listed on the first page of this consent form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC Health

System hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Who do I call if I have a question?

If at any point you wish to discuss any aspect of the database registry with the investigators, you can contact them at:

R. A. Branch, M.D., F.R.C.P.	100 Technology Drive	412-648-1880
Y. Cannon, R.N., CCRC	100 Technology Drive	412-648-9103
L. DeRiso, MSN, CRNP	100 Technology Drive	412-648-1939
A. Cecchetti, M.S.	100 Technology Drive	412-648-1880
Mordechai Rabinovitz, M.D.	3471 Fifth Avenue	412-647-1170
Obaid Shakil, M.D.	3471 Fifth Avenue	412-647-1170
Nathalie Zgheib, MD	100 Technology Drive	412-648-1880
Amy Steele, R.N.	3471 Fifth Avenue	412-802-3160

VOLUNTARY CONSENT: I certify that I have read the consent, or it has been read to me. Any question that I have pertaining to the research have been, and will continue to be answered by the investigators listed at the beginning of this consent form at the phone numbers given. I also understand that I may always request that my questions be answered by a physician involved in this research study.
Any questions I have concerning my rights as a research subject will be answered by the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (412-578-8570). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this project.

I give my permission to be re-contacted to obtain my consent if there is a desire to use information or genetic material collected in this research, with personal identifiers, in other research projects.

Yes _____ No _____

Subject's Signature

Date and Time

Subject's Printed Name

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date