



Research Participant Registry Consent and Authorization Document

BACKGROUND

The University of Utah Center on Aging includes approximately 100 faculty members from ten of its schools and colleges. An important part of the Center's mission is to promote interdisciplinary research to help people lead longer and more fulfilling lives. To accomplish this mission, Center faculty who are conducting patient-oriented aging research wish to contact individuals of all ages who may be interested in participating in aging-related research and determine if they qualify to enter their research studies.

The Research Participant Registry (RPR) is part of the University of Utah Center on Aging, directed by Mark A. Supiano, M.D. The primary goal of the RPR is to link people interested in participating in aging research studies to studies being conducted by Center on Aging faculty members. To meet this goal, we ask interested persons to complete an initial questionnaire that serves to enroll them in the program and a follow-up questionnaire every 18 months that allows us to keep their information current. These surveys take about 30 minutes to complete and contain questions on medical conditions and medications as well as other health-related and demographic questions.

You are being asked to enroll in the RPR. Before you decide, it is important for you to understand why the registry exists and what your participation will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

STUDY PROCEDURES

To enroll in the RPR you will be asked to do the following:

- 1. Complete an entry questionnaire and follow-up surveys approximately every 12 to 18 months.**

If you come across any question on these surveys that you do not want to answer, for any reason, you may skip the question. In the questionnaire, you will tell us what kinds

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	«IRB»
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	«Expiration» «ExpirationDate»

of research studies you are willing to consider and how often you want to be contacted about other research projects. You may change the kinds of research you are willing to consider or the frequency with which you are asked to consider research by contacting us. You may also enter the registry directly through our web site, www.aging.utah.edu, which will link you to an on-line version of the registry's entry questionnaire.

2. Allow us to contact you to update your registry information.

3. Release portions of your Medical Records.

Some people who join the RPR may also be listed in the Utah Population Data Base (UPDB) and have received medical care through the University of Utah or Intermountain Health Care. The RPR will access these medical records from the UPDB – Resource for Genomic and Epidemiological Research (RGE) that will help determine whether you should be excluded from a specific study.

4. Consent to be contacted about future research studies.

We use the questionnaire responses and additional information about you to match you to research projects that are recruiting volunteers. Matching is based on meeting criteria for a study and your expressed willingness to be contacted for that type of research. If you are matched to a project based on the information you provide in the questionnaire, your name will be provided to the researcher. The researcher will then review your information in the RPR. If it seems that you are eligible based on the review of this information, the researcher will contact you to explain the specific study. You will then decide if you want to participate in this new study, based on a full explanation of what is involved in that research project. You will complete a separate IRB-approved consent document for any future research studies you participate in.

RISKS

There is a risk that a breach of security may occur such that confidential information about you and your medical conditions would inadvertently be released. Every effort is made to protect your information, and to the best of our ability we will limit access to the information in the RPR to only authorized individuals.

BENEFITS

There are no direct benefits to you from your taking part in this registry. This registry process of linking people in the community to aging-related research projects at the University of Utah enables researchers to conduct their investigations more efficiently. Your participation in the RPR will allow investigators to advance our knowledge about important aging-related medical concerns.

	«Institution»
	«IRB»
«Image:Stamp»	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»

ALTERNATIVE PROCEDURES

You may choose not to participate in this registry. Joining the RPR is entirely voluntary and will not alter your health care in any way.

CONFIDENTIALITY

All personal information provided to the RPR will be kept in secured computers or locked file cabinets. To maintain confidentiality, your information will be assigned a code number in which only RPR faculty and staff will have access to. Personal identifying information will not be released unless you give specific permission. Information will not be released to insurance companies or employers. Your name or identifying information will not be released or published in reports.

PERSON TO CONTACT

You should contact the RPR coordinator at (801) 581-3670, Monday through Friday from 9 a.m. to 5 p.m. with any questions, complaints, or concerns about Registry-related matters.

If you think you may have been harmed from being in this study, please call Dr. Mark Supiano at (801) 587-9103, Monday through Friday from 9 a.m. to 5 p.m.

INSTITUTIONAL REVIEW BOARD

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

RESEARCH PARTICIPANT ADVOCATE

You may also contact the Research Participant Advocate by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving any reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of

	«Institution»
	«IRB»
«Image:Stamp»	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»

benefits to which you are otherwise entitled. If you choose not to participate, this will not alter your standard medical care in any way.

REGISTRY RIGHTS

By signing this consent form you agree to give the RPR rights to the access and control of information that you provide. The RPR may retain, preserve, or dispose of the information and may use it in future aging-related research studies for an unlimited period of time. You do not waive your legal rights by signing this consent form.

COSTS AND COMPENSATION TO PARTICIPANTS

You will receive no compensation nor will you be charged for your participation in the RPR.

NUMBER OF PARTICIPANTS

We will invite several thousand individuals currently listed in the Utah Population Database to participate in the RPR. We will also invite participants from other referral sources and outside medical centers from the surrounding area. We expect ultimately to have approximately several thousand individuals listed in the RPR.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name, address, telephone number, telephone listing
- Personal medical history
- Family medical history
- Other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites.
- Demographic information such as gender, race and religion (optional)
- Contact information for a friend or relative so we can contact you in the future and follow you over time

	«Institution»
	«IRB»
«Image:Stamp»	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»

Others who will have access to your information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the Center on Aging and the Center for Clinical and Translational Studies who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters). The information we share may include information that directly identifies you.

You may revoke this authorization. **This must be done in writing.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to: Dr. Mark Supiano, Division of Geriatrics, University of Utah School of Medicine AB 193; 30 N 1900 E; Salt Lake City Utah; 84132. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

	«Institution»
	«IRB»
«Image:Stamp»	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»

NATIONAL INSTITUTES OF HEALTH Reporting Race and Ethnicity Data

Date of Birth	Sex/Gender <input type="radio"/> Male <input type="radio"/> Female
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Ethnicity

1. Do you consider yourself to be Hispanic or Latino? (See definition below.)
Select one.

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

- Hispanic or Latino**
- Not Hispanic or Latino**

Race

2. What race do you consider yourself to be? Select one or more of the following.

- American Indian or Alaska Native.** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

- Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

- Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American."

- Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

- White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

- Check here if you do not wish to provide some or all of the above information.

	«Institution»
	«IRB»
«Image:Stamp»	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»