

Informed consent template for participating in rare disease registries (sharing de-identified data with GRDR)¹

For the purpose of this Consent “the patient” will refer to the person diagnosed with XXX. “You” will refer to the person entering the information. This may be the affected individual or a family member or guardian of the affected individual (the person legally responsible for the care and maintenance of the affected individual).

A patient registry is a place where medical information, family history and other related information from patients is collected and stored for medical research. The purpose of the xxx registry is to collect and store medical information and other information from individuals with the same disease (*Each registry may insert additional aims/purposes*). Sometimes the registry may also be linked to a biobank which is a place that stores tissue, blood or other samples from the patients. If there is a biobank for people with your disease, you may be asked to donate your samples to the biobank. If you decide to donate your samples, you will need to provide separate consent for the biobank.

Information from patients will be used for medical research and experimental clinical trials to better understand rare diseases and to develop new treatments. The registry also addresses other critical needs. Scientists studying XXX need accurate information to understand how the disease affects people. In addition, scientists who want to start studies, such as to test new treatments will need access to the XXX registry to locate people who may be eligible to participate in studies. (Each registry may insert additional reasons to explain why the registry is important.) The XXX registry is sponsored by YYY and there is no cost to you to participate.

If you join the registry, you will be asked to provide medical information on your disease and diagnosis. The goal of the registry is to share detailed medical and other information with scientists and other researchers, while still protecting your privacy. This is done by hiding the name, address and other “identifying” information from the researchers. We call this information “de-identified” because it has been removed of all personal identifiers. Your personal information such as, your name, address, or other information that identifies you or your family will be labeled with a code number and stored in a secure place and protected with a password. Only authorized people who work in the registry will know the code and be able to identify you if needed.

Your identifiable information will not be shared with anyone outside the registry (unless you give your permission to share it). Approved scientists, researchers, and clinicians, will be allowed to see only the de-identified information and may search the de-identified data for patients for their studies. If a patient looks like a good match for a study and a researcher wants, to contact you, he can do it only through the XXX registry. The XXX registry or registry’s agent (such as genetic counselor) will then contact you but the researcher will not contact you directly.

¹ This template can be modified, as needed, and be used by any patient registry.

Your de-identified information (information that has been removed of all identifiers) will be shared with other databases such as the Global Rare Disease Patient Registry and Data Repository (GRDR).

The de-identified data collected and compiled by the registry belongs to the XXX community. The XXX is the guardian of the information contained within the registry. (***Provide applicable supplemental information about ownership, duration, legacy plan, oversight policies, regulations, and IRB approval, as needed.***)

If there is a biobank for people with your disease, you may be asked to donate your samples to the biobank. If you decide to donate your samples, you will need to provide separate consent for the biobank. Providing your information to the registry, contributing blood or other samples, and participating in this registry is voluntary. Participation may not benefit you personally medically or financially. However, your participation may help members of your family and others with the same xxx disease or other diseases by increasing the understanding of your disease/condition and other diseases. Collected data may help speed up research by collecting information scientists can use. Researchers may learn whether how treatments work. Medical professionals may be able to improve how they treat the disease. Participants may receive information about opportunities to participate in research, clinical trials, medical advances and other news from the registry.

Should you change your mind and wish to withdraw your data from the registry, you will be free to do so without having to provide any explanation. Simply contact the registry and all of your data will be removed from the database. Data assigned to a specific study prior to your request for removal cannot be retrieved from researchers that have already accessed it.

There is minimal risk in taking part in the registry. The registry includes questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information you do not want to. Another unlikely risk is potential breaches in the computer system. In the event there is a breach in the registry's computer system all participants will be notified.

Registry information will be collected on patients who are diagnosed with XXX (***insert participation criteria***). Patients over the age 18 who understand the consent form (and thus do not have a legal guardian) are eligible to join the registry on their own. Otherwise, the legal guardian or parent of the patient must sign the consent for the patient to join. When the patient becomes 18 (and if they are able), consent will be obtained directly from them for continued participation.

You will be asked to update your registry information at least once per year. The registry will send you a reminder each year. The registry may also ask you to fax or upload your genetic test results, and any other relevant reports or testing results. Your registry account can be updated whenever there is a change in the patient's health, change in medication, or new symptom. If the registry cannot contact you, your account may become inactive.

Other common questions:

Who do I contact with questions?

If you have any questions about the registration process or about participation in the registry, please contact the registry at (*insert email*). To report concerns that result from your participation in the registry, you may contact the registry at (*insert email address*). To inquire about your rights as a participant in the registry, you may also contact the IRB for this study at: (*insert email here*). For additional information regarding the terms and conditions of this web site or the privacy policy please go to Terms and Conditions and Privacy Policy sections of this website.

I want to be involved in a clinical trial. If I register, is this guaranteed?

Although one of the main goals of the registry is to make it easier for affected individuals to participate in research, there is no guarantee that those participants will be eligible for a trial. Please note that even if the coordinators of a clinical trial believe that you might be eligible for the trial, based on the data about you stored in The Registry, it is still possible that later on it will turn out that you do not meet the trial requirement criteria after all. Please also be aware that if we inform you about the existence of a trial, this does not imply that we endorse it. In order to participate in any trial, you will need to discuss with the research staff about the trial and fill out a separate informed consent form.

I don't want to be involved in a clinical trial. Should I still register?

Absolutely, we hope that you will still be willing to register, even if you don't want to take part in a trial. Your information may still be useful to researchers who are trying to learn more about patients with XXX.

What are my options if I do not want to be in the Registry?

You do not have to join this registry. Participation is voluntary. You do not need to participate in this Registry to remain a member of the XXX community. Your decision to participate in this registry or not will not affect your healthcare.

By signing this form you do not give away any legal rights or benefits to which you are otherwise entitled. If you do join, you can change your mind and withdraw from the registry at any time and request to remove any of your information that has not assigned yet to any specific study. You will not be able to remove any information that already has been assigned to a specific study. If you decide not to sign this form, there will not be any effect on your regular health care, your medical treatment or insurance benefits.

Your signature below means: 1) you have been given the background/supplemental material and the opportunity to ask any questions; 2) you understand the content of the informed consent; 3) you have had the time to consider fully whether you want to join the registry, and 4) you agree to participate.

1. I understand that my participation in the registry is voluntary and that I can change my mind and withdraw at any time. Yes
2. I understand that all attempts will be made to protect my privacy and my family's privacy. I understand that my personal information will be protected and saved in the registry using a code. However, there is a very small risk that my personal information could be revealed. Yes
3. I understand that by agreeing to participate, I will be contacted by the registry to update or correct my health information regularly. Yes

I would like to be contacted by: Choose one or more.

Email Mail Phone Voice Mail In Person

4. I am willing to provide my de-identified medical information to be used for clinical trials and other medical studies related to my disease. Yes No
5. I understand that my de-identified information can be used for any approved research study including diseases that are not associated with my disease. Yes
6. I understand that my de-identified information will be shared with other databases such as the Global Rare Disease Patient Registry and Data Repository (GRDR). Yes
7. I understand that I may not personally benefit from participating in the registry or from the use of my de-identified medical information in any research study. Yes
8. I understand that I can withdraw from the registry at any time and remove my information. I also understand that any information given previously and already have been assigned to a specific study, cannot be removed. Yes
9. If it is permitted, I would like to know of any findings or results that may affect my health. Yes No
10. I would like to be contacted of any future clinical trials or other studies that I can participate. Yes No
11. I understand the content of this form, I was given the background information, I had enough time to ask questions, all my questions were answered and I had enough time to decide that I want to participate in this registry and I will be given a copy of this consent. Yes No

If you have any questions about the registry or need help, please contact:

Name, phone & email address

Name of patient or legal representative

Signature of the of patient/legal representative confirming that he/she understood the content of the consent form

Date -----

Name of the person (not relative of the patient) who explained the content of the consent form

Date -----