

## Informed consent template for patient participation in rare disease registries linked to biorepositories

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### ABSTRACT

**O**ne of the major challenges in obtaining consent from patients participating in patient registries is ensuring that participants receive all the information and background material necessary to make a fully informed decision and understand what his/her participation and signature mean. One challenge is how to include all of the regulatory elements in a short consent document that is easily understood. In addition to a well-written consent form, much thought and attention need to be given to the consent process itself. The patient registry process will be helped by having a common template for an informed consent document and common consent processes adopted by the rare disease registries will be part of the GRDR.

Based on recommendations from the subject matter experts that participated in a workshop organized by the Office of Rare Disease Research at the National Center for Advancing Translational Sciences, NIH, a template for informed consent for patient participation in patient registries was developed. This template addresses key aspects and regulatory issues related to participating in a patient registry and can be used for any registry and modified according to the specific needs of the individual registry.

### KEYWORDS

informed consent, patient registries, rare diseases, common data elements, biospecimens, biobank

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## INTRODUCTION

On December 13-14, 2010, the Office of Rare Diseases Research (ORDR) conducted an international workshop: "Informed Consent Models/Templates for Rare Disease Registries Linked to Biorepositories" where experts and patient advocacy groups from the USA and other countries discussed the informed consent process for patient participation in patient registries. Based on the discussions and the recommendation from the subject matter experts, a template for informed consent for patient participation in patient registries was developed. This template can be used for any registry and modified according to the specific needs of the individual registry.

As plans are moving ahead to establish the Global Rare Disease Patient Registry Data Repository (GRDR),<sup>1,2</sup> contributing registries are in need of guidance on the informed consent process for patients whose information will be included in a registry. One of the GRDR goals is to aggregate de-identified<sup>3</sup> patient medical information linked to their biospecimens<sup>4</sup>, using a Global Unique Identifier (GUID)<sup>5</sup> that tracks the patient's data for research purposes. The aim of the GRDR is to provide a resource for research that will improve the quality of life of those with rare diseases, develop therapeutic interventions and, ultimately, find cures. Since biospecimens are essential resources for medical research and the understanding of the mechanism and the pathogenesis of different diseases and conditions, the sponsor of individual patient registries are strongly encouraged to create biorepositories, or use existing biorepositories, where patient participants can voluntarily donate their biospecimens to be stored along with their registry medical information.

Contributing registries will need to inform their participants, as part of the informed consent process, that their de-identified information will be shared with the GRDR.

One of the challenges in obtaining consent is ensuring that participants receive all the information and background material necessary to make a fully informed decision and understand what his/her participation and signature mean. One challenge is how to include all of the regulatory elements in a short consent document that is easily understood. In addition to a well-written consent form, much thought and attention need to be given to the consent process itself. The patient registry process will be helped by having a common template for an informed consent document and common consent processes adopted by the rare disease registries..

The workshop<sup>6</sup> discussed the informed consent process for participating in a patient registry that is linked to a biorepository. The workshop participants focused on developing recommendations on the informed consent process. Participants agreed in order to obtain meaningful informed consent, additional information beyond what can be presented in the written consent form may be needed. There was consensus among workshop participants that, in cases where the registry is linked to a biorepository, a separate consent form should be used to address issues specific to specimen donation.

For many rare diseases, adequate information may not exist and may need to be developed and provided to patients and their family members as appropriate as part of an ongoing consent process. Providing additional information beyond what can be presented in a written consent form may be essential in order to obtain meaningful consent from participants. The rare disease community should address these issues and develop templates and recommendations for obtaining the informed consent of patients, facilitating participation in patient registries, and adequately protecting the information provided<sup>7</sup>.

A template for informed consent form for participating in patient registry was developed based on the discussion and recommendations from the workshop. This informed consent template addresses key aspects related to participating in a patient registry.

## **<sup>8</sup>INFORMED CONSENT TEMPLATE FOR PARTICIPATING IN RARE DISEASE REGISTRIES**

### DEFINITIONS

For the purpose of this Consent form, "the patient" refers to the person diagnosed with XXX (*insert disease being studied*). Registry information will be collected on patients who are diagnosed with XXX (*insert participation criteria*). "You" refers to the person providing the information, who may be the patient himself or herself, or a family member or guardian who is legally responsible for the care and health of the patient.

### PURPOSE

A patient registry collects and stores patient medical information, family history and other related information for use in medical research. The purpose of the (*insert title*) registry is to collect and store medical and other information from individuals with the same or related disease (*Each registry may insert additional aims/purposes*). In addition to what is written here, you will be given supplemental information about the XXX Registry.

<sup>1</sup> *Creating a Global Rare Disease (Patient) Registry Linked to a Rare Diseases Biorepository Database: Rare Disease-HUB (RD-HUB)*,<sup>7</sup>/Rubinstein et al. *Contemporary Clinical Trials*. 2010 Sep;31 (5):394-404

<sup>2</sup> *The case for a global rare diseases registry*. Forrest CB, Bartek RJ, Rubinstein Y, Groft SC. *Lancet* 2010 Aug. 2 193: 5-7

<sup>3</sup> *De-identified data refer to coded data or information where all 18 elements that could be used to identify the individual have been removed but the link to the individual has been preserved*. [http://privacyruleandresearch.nih.gov/pr\\_08.asp](http://privacyruleandresearch.nih.gov/pr_08.asp)

<sup>4</sup> *Biospecimens is a collective term for tissues, body fluid or any sample taken from the body*

<sup>5</sup> *Using Global Unique Identifiers to Link Autism Collections*. Johnson SB, Whitney G, McAuliffe M, et-al, *J. Am. Med. Inform. Assoc.* July 17, 2010. 10.1136/jamia.2009.002063

Some registries are also linked to a biobank, which is a place that stores tissue, blood or other samples from patients. If there is a biobank for people with your disease, you may be asked to donate your samples to the biobank. You will be asked to provide separate consent for donating your samples to the biobank.

Patient information in this registry will be used for medical research and experimental clinical trials to better understand rare diseases and to develop new treatments. Researchers studying XXX need accurate information to understand how the disease affects people. In addition, researchers may access the XXX registry to locate people who may be eligible to participate in particular studies, such as studies to test new treatments. (*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.

### **WHAT WILL HAPPEN IF YOU JOIN THIS REGISTRY**

If you join this registry, you will be asked to provide medical information on your (or the patient's) disease and diagnosis. The registry aims to share detailed medical and other information with researchers while protecting your privacy. One way the registry protects your privacy is to remove your name, address and other "identifying" information from your medical information before providing it to researchers. This information is "de-identified" because it has had all personal identifiers removed including your name, address, or other information that identifies you or your family. Your registry information will be labeled with a code number and stored on secured computers and servers and protected with encryption and passwords. Only authorized people who work in the registry will have access to the key to the code and will be able to identify you if needed. Although we take measures to protect your privacy and confidentiality, because your disease is rare, there is a small risk you may be identifiable from the information in the registry.

The registry will not share your identifiable information with anyone outside the registry (unless you give your permission to share it). Approved researchers and clinicians will be allowed to see only the de-identified information. Approved researchers and clinicians may use de-identified information to conduct research, including research on diseases unrelated to your (the patient's) disease. They may also search the de-identified information to find patients for their studies. If a patient looks like a good match for a researcher's study, the XXX registry or registry's agent (such as genetic counselor) will contact you; the researcher will not be able to contact you directly. The XXX registry or agent will provide you with information about the study and a way to contact the researcher if you wish to do so.

Your de-identified XXX Registry information will also be shared with other databases such as the Global Rare Disease Patient Registry Data Repository (GRDR). This will allow more researchers to use the information to do research.

The de-identified information collected and compiled by the registry belongs to the XXX community. The XXX registry 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.*)

You will be asked to update your registry information at least once per year. Based on your preference for how you would prefer to be contacted, the registry will contact you each year to remind you to update your data. 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 your health, change in medication, or new symptom. If the registry tries but is unable to contact you, your account may become inactive.

### **YOUR PARTICIPATION IS VOLUNTARY**

Providing information to the registry and/or contributing blood or other samples to a biorepository is voluntary. You do not have to contribute information. If you do participate, you can withdraw from the registry at any time and for any reason.

### **RIGHT OF WITHDRAWAL**

Should you change your mind and wish to withdraw your information from the registry in which you are registered, you will be free to do so without having to provide any explanation. Simply contact the registry and your information will be removed from the database. Information that has already been shared with the GRDR or sent to a researcher for a specific study prior to your request for removal cannot be retrieved or removed.

### **ANTICIPATED BENEFIT**

Participation in the registry is not likely to benefit you (or the patient) personally, medically or financially. However, 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. Having an available registry of information about xxx disease may help speed up research, such research could eventually help researchers to learn whether or how treatments work, or help medical professionals improve how they treat the disease. Participants may receive information about opportunities to participate in research and clinical trials, as well as information about medical advances and other news from the registry.

### **RISKS OF PARTICIPATING**

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

### **PARTICIPATION OF MINORS AND ADULTS UNABLE TO CONSENT**

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 legally provide their own consent (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 form for the patient to join. When a minor participant becomes 18 (and if they are able), consent will be obtained directly from them for continued participation.

### **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 XXX registry at (insert email). To report concerns about 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 Institutional Review Board (IRB) for this study at: (insert email here).

#### **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 patients to participate in research, there is no guarantee that an individual patient will be eligible for a particular trial or contacted about a clinical trial. Even if you are contacted about possible eligibility based on your information in the Registry, you may or may not meet the study requirements.

Please also be aware that if the registry informs you about a trial, this does not imply that the registry endorses it. Each study you enroll in will require that you sign an informed consent form for that study. Please make sure to discuss any study you are considering carefully with the research staff before signing its 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 clinical trial. Your information may 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 about whether or not to participate in this registry will not affect your health-care, your medical treatment or insurance benefits.

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.

**Checking the boxes below and your signature means:**

a) you have been given background or supplemental material and the opportunity to ask any questions; b) you understand the content of the informed consent; c) you have had the time to consider fully whether you want to join the registry, and d) you agree to participate in the registry.

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 identity 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 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 assigned to a specific study cannot be removed.

**Yes**

9. If any information is obtained through the patient’s participation in this registry that has implications for the patient’s health, would you like the repository to tell you so that you can get that information?

**Yes**     **No**

10. I would like to be contacted of any future clinical trials or other studies that I may be able to participate in.

**Yes**     **No**

11. I understand the content of this form and all my questions were answered. I had enough time to decide that I want to participate in this registry. I was given a copy of this consent form and background information about the registry.

**Yes**     **No**

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

Name of patient or legal representative:	
Signature of the of patient/legal representative confirming that he/she understood the content of the consent form:	
Name of the person (not relative of the patient) who explained the content of the consent form:	
Date:	

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