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Research Subject Information and Consent Document

TITLE:	Open Humans: Public Data Sharing
PROTOCOL NO.:	None WIRB® Protocol #20141970
SPONSOR:	PersonalGenomes.org
INVESTIGATOR:	Madeleine P. Ball, PhD 423 Brookline Avenue #323 Boston, Massachusetts 02215-5410 United States
STUDY-RELATED PHONE NUMBER(S):	Madeleine Ball (617) 383-4332

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A. Introduction and Purpose of the Study

Introduction

You are being asked to participate in a research study. The purpose of this consent form is to help you decide whether or not you want to be in this research study. If you agree to be in the study, we will email you an electronic copy of this consent form for your records. Please do not join this study until you have had a chance to ask questions and have received satisfactory answers.

What is the purpose of this study?
This study will invite you to publicly share data you have received from research studies and other activities. Public data is broadly believed to benefit society and help advance science. Usually, researchers decide when to publicly share research data. It is also possible for their participants to play a role in public sharing decisions. This "participant-mediated" data sharing may be very important, but isn't studied very much. So, we want to study this and seek answers to questions, such as: What happens to participants who share? What data do people choose to share, how useful is it, and who uses it?

Studying this type of public data sharing is important because there are many types of data that are not publicly shared by researchers, in many cases, this is because the research data is believed to be "identifiable." This means someone might be able to discover a participant's identity using very little information, even if their name is not in the data. Even if some participants aren't concerned about their privacy, others will want their privacy to be protected. As a result, researchers often do not publicly share any data in order to respect the privacy of all participants.

We believe some participants may want to publicly share their own data, despite the risk to personal privacy. By doing this, they create public data resources that would not otherwise exist. This new model could enable many new types of public data sharing, but the consequences are not well understood. This study aims to understand the consequences of this model, to help others decide whether they should pursue similar approaches.

Who is running this study?

The Open Humans: Public Data Sharing Study is a research project of PersonalGenomes.org, a 501(c)(3) non-profit organization. It is being conducted by Madeleine Ball, PhD (Principal Investigator).

Am I required to participate in this study?

No. Your participation in this study is voluntary. You can refuse to join or later decide to quit without penalty or loss of benefits. However, participation in this study is required to enable public data sharing in your Open Humans account. You may continue to use other features of the Open Humans website without joining this study.

Are there any alternatives?

Your alternative is not to join this study.

How long does this study last?

This study is a long-term observational study with no end date.

B. Study procedures

What will this study do?

This study will allow you to publicly share research data you have added to your Open Humans account. You can choose which data to share and you may remove public sharing status for any given data set at any time.

When you share data publicly on the Open Humans website, it will be publicly visible and associated with your member profile. We anticipate researchers are likely to use this data, but there is no restriction: anyone may download it and it may be used for any purpose.

Data you choose to share publicly might include:

- Research data returned to you by researchers
- Data collected directly by Open Humans through online surveys and other methods
- Data you bring to Open Humans from third parties

To better understand sharing behaviors, practices, consequences, and impacts, this study might track the interactions that participants have within the Open Humans website. These interactions may include (but are not limited to):

- The content and frequency of questions submitted to support staff
- Which types of Open Humans data sets you publicly share
- How often you use certain features on the Open Humans website
- Access to and downloading of Open Humans data
- Participant responses to regular impact surveys

What will be required of me as a participant?

Our only requirement is that you keep your contact information *(e.g.* your email address) up-to-date. All other actions are optional.

Will this study collect samples or perform physical procedures?

No, participation in this study is performed through the internet.

Must I publicly share **all** research data imported to Open Humans?

No, you will decide which of your imported data you choose to share publicly. The decision to publicly share your data is always under your control.

How will you protect my privacy?

We do not guarantee privacy. The types of research data you choose to share through this study may be extremely identifiable. Publicly shared data will be connected to your Open Humans username. Many participants choose to share with their real name, but this is not required.

We will not remove all identifying features from your imported data. It will be your responsibility to determine when to share data you have received from other studies and activities. You should review imported data for the presence of personal information before choosing to make it public.

Information you share privately with this study and with the Open Humans website will be kept confidential (e.g. if you privately tell us your email or home address, we will not share these). In some cases, we may share confidential information with the Institutional Review Board which oversees this study, or in response to a legal request for information made by governmental agencies such as the US FDA (Food & Drug Administration).

What restrictions will you place on publicly shared data?

None. There are no restrictions placed on the access or use of data you publicly share through this study. We have developed a set of Data Use Guidelines to establish norms for Open Humans data, but these are not legal requirements and it’s possible that some people will ignore them.

Can I withdraw?

Yes, you may withdraw from this study at any time and request removal of your public data. We will remove public sharing for your imported data sets, and you will no longer have the option to publicly share your research data through the Open Humans website.

You should understand that others may have made copies of your public data, and we have no control over these. After you withdraw and your public data is removed from the Open Humans website, other copies of the data may continue to exist.

We reserve the right to remove individuals from this study at any time, without your consent, for any reason. This may occur if we are unable to contact you. If we do terminate your participation in this study, we will provide you with a reason for that decision.

Does it cost anything to participate? Will I receive compensation?

There are no costs to participate in this study. Participants are not paid and no medical care or treatment is provided to participants as part of this study.

Will you inform me of changes to study procedures if they occur?

You will be told about any updates to the content of this study's informed consent form, as this might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

C. Risks

What types of risks should I be aware of?

The potential risks of participation are related to data sharing. Because this type of public data sharing is a new activity, it is hard to anticipate all the risks of harm that may be involved. The foreseeable risks include loss of privacy and experiences of discrimination. We strongly encourage you to:

- Consider your own circumstances and how that might affect your personal risks
- Discuss potential risks of participation in this study with your immediate family members

If you are planning to share data while hiding your identity ("anonymously"), someone may determine your identity. Having your identity associated with your data has many risks, including risks of discrimination or embarrassment.

What do you mean when you say my research data is "identifiable"?

Even if you remove your name, research data could be connected to your identity. The risk of this varies depending on the type of data, but it is often surprisingly easy to identify people.

Some examples of identifiable data you may choose to share:

- **Demographic data.** Just three pieces of information - your birth date, sex/gender, and ZIP code - are enough to uniquely identify most individuals. If you share these, someone may use them to figure out who you are.
- **Genetic data.** Your genome data can be used to learn about your ancestors, and this information can be used to identify you. For example, a man’s Y chromosome can be used to predict his last name (or "family name") - this method has been used to identify individuals from "anonymous" genomes. Identifying people from genetic data is likely to get easier as genealogy tools become more powerful.
- **Location data.** Even a tiny amount of location data is enough to give a strong clue to someone's identity. Most people spend their time in two locations: work and home. That combination is often unique, and could be used to identify you.

Why can't researchers remove the identifying parts of my data?

For many types of data, it is impossible to make the data "de-identified". Methods to "scramble" or make data "fuzzy" can make identification more difficult, but also make the data much less valuable for research. Also, even "fuzzy" data becomes very identifying when combined with other data - e.g. when combined with other research data on your Open Humans public profile.

Methods for figuring out my identity sound difficult and obscure, isn't the risk actually pretty low?

Even if identification sounds difficult to you, it might be trivial for others to identify you, and it will become easier in the future. In some cases, identification can be performed automatically, using a computer program that cross- references different public records.

Theoretically, someone could create a website which automatically uses software to identify an Open Humans public profile. In fact, websites already exist which do this with public records, social networks, and other online content.

Okay, let's assume my name is attached. What is the risk of publicly sharing this data?

The risks of sharing data associated with your identity vary based on the type of data. Risks may include:

- **Identity theft.** The more information about yourself that you publicly share, the more likely it is that someone will be able to use that information to pretend to be you to access money, resources, and information.
- **Embarrassment.** Your data may contain information that you're not always comfortable with someone else knowing. When you share your data in a public space, you are taking a risk that someone will learn something about you that you would rather they not know.
- **Discrimination.** While there are laws protecting you from some types of discrimination, these protections have limits. It is also possible that someone will ignore the law and use your information in illegal ways.
- **Data may later become sensitive.** Data you are currently comfortable sharing might become sensitive later. Your personal circumstances might change, or your data might reveal things you didn’t anticipate. Research data is often not well understood, and later discoveries could reveal things about your data that weren’t previously known.

Some types of data also come with specific risks, for example:

- **Location data reveals your daily patterns.** Someone might be able to use daily patterns inferred from your location data to approach you unexpectedly.
- **Genetic data and crime scenes.** Genetic data could be used by police to match your identity - or one of your relatives - to evidence discovered at a crime scene.

It is important to recognize that not all risks are known or knowable: new or unanticipated risks may arise with advances in science and technology.

What are my alternatives to being in this study?

Your alternative is to not be in this study.

D. Benefits

How will participating in this study benefit me?

Participation in this study does not entitle you to financial compensation or other direct benefits. We do believe public data sharing by participants is likely to benefit society. This includes data sharing within this study, as well as data sharing through other groups that implement similar models after learning from this study. These advances may indirectly benefit you, as a member of society.

How might public data sharing by participants benefit society?

We believe that public research data, shared without legal restrictions, can have powerful potential benefits for society, such as:

- Researchers can check and confirm data analyses done by other researchers.
- Data from different sources is easily combined (it can be difficult to do this when data sets have different legal restrictions).
- Data can be re-used beyond the initial reason it was collected.
- Researchers can be inspired by the existing public data and build upon it with new research, including potentially recruiting participants to new research projects on the basis of their publicly shared data.
- Public data is a public resource that may serve important functions to diverse individuals not part of standard research groups, including software engineers, health care workers, educators, students, and citizen scientists.
- Participants can advance their own understanding and empowerment in research, as they can compare their own data with data shared by other participants.

E. Contact Information

How can I contact you to ask more questions?

Please contact the Principal Investigator (Madeleine Ball) if you have any questions about this study and your part in it, if you believe you have had a research-related harmful event, or if you have any general questions, concerns, or complaints about this research:

Study staff	Email:	oh-publicdatastudy@personalgenomes.org
Madeleine Ball, PhD	Email:	madeleine@personalgenomes.org
(Principal Investigator)	Phone:	(617) 383-4332

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120 Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research. WIRB will not be able to answer some study- specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

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F. Consent Statement for the Open Humans: Public Data Sharing Study

I have read this consent form. I have had a chance to ask questions, and my questions have been answered to my satisfaction. I understand that I can refuse to participate in this study. I have taken time to think carefully about my decision to participate. I freely consent to be in this research study.

To show that I have voluntarily given my consent to participate in this study, I have checked the boxes next to each statement below and have typed my name to electronically sign this form.

☐ *I understand the uncertainty and risk of research as stated in this consent form.*
☐ *I understand that data I choose to publicly share may be used for any purpose, including research purposes.*
☐ *I understand that once I authorize public data sharing, data privacy laws might not apply or no longer protect my information.*
☐ *I understand that I can withdraw data from Open Humans at any time, but copies of that data that have already been made by other people may remain.*
☐ *I am at least 18 years of age.*
☐ *By signing this consent form, I have not given up any of my legal rights.*
☐ *I am signing this form with my full legal name.*

Electronic Signature of Participant: ____

Date: ____

Open Humans User Data

Username: [USERNAME_HERE] Email: [EMAIL_HERE]