In support of the *Framework for Responsible Sharing of Genomic and Health-Related Data*, P3G-IPAC* prepared 3 consent tools for the Global Alliance for Genomics and Health. The first, Legacy Consent and International Data Sharing (A), covers situations where researchers have collected data using older "legacy" consents. The second, Clauses for International Data Sharing (B), addresses situations where researchers wish to add clauses on international data sharing to their existing consent document(s). The third, Generic International Data Sharing Prospective Consent Form (C), provides a generic template for studies moving forward prospectively. All require adaptation according to local social, cultural and legal specificities.

*Public Population Project in Genomics and Society: International Policy interoperability and data Access Clearinghouse

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A. LEGACY CONSENTS AND INTERNATIONAL DATA SHARING

Prepared for the GA4GH by the P3G-IPAC

Many will ask whether legacy collections of data can be used for international data sharing. Legacy collections refer to data and samples previously collected for research or during medical care, but where the consent may not cover the proposed study. To help projects conform to the principles of the *Framework for Responsible Sharing of Genomic and Health-Related Data*, we suggest examining the adequacy of legacy consents by asking the following questions:

1. When was the original consent obtained and under what conditions?
2. Was international data sharing foreseen?
3. Was access to the medical record foreseen?
4. Was genetic/genomic research foreseen?
5. Was potential commercialization foreseen?

If there is uncertainty regarding the adequacy of legacy consent, researchers should consult their local ethics committee for advice regarding re-consent. They might be able to obtain a waiver from having to re-contact individuals and re-consent. If the decision is to re-contact and re-consent the participants, the Generic International Data Sharing Prospective Consent Form may be of assistance (http://www.p3g.org/resources/ipac).

B. ADDITIONAL CLAUSES FOR INTERNATIONAL DATA SHARING

Prepared for the GA4GH by the P3G-IPAC

1. Additional clauses for introduction into already existing consents:

This project is guided by the *Framework for Responsible Sharing of Genomic and Health-Related Data* **[cite URL for relevant website]**.

This project has been reviewed by **[name of relevant committees].**

2. Participate in international research

[**name of project**] is recruiting participants [or accessing data on already consented participants] for future as yet unspecified biomedical research which has received ethics approval:

- The project will include personal and health data as well as data from your medical record;
- Your data will be studied by researchers from around the world;
- [Where applicable: The project will be based on the data from your stored tissues using a process called sequencing.]

3. Privacy/Security

Your data will be stored in online secure databases (i.e. a server/cloud provider) that meet international security and safety standards. Your data will be shared and used by approved researchers around the world. Safeguards are in place to keep your information confidential, in particular:

- Personal identifiers will be removed (i.e. name/date of birth);
- Your personal details will be kept separate;
- Your data will be coded; and
- Stringent security measures will prevent unauthorized access or misuse.

We will not identify you at conferences/meetings, nor in any publications.

4. Storage

Data will be kept for a period of [number of years/identify period OR indefinitely] unless an ethics committee **[or other oversight body]** decides otherwise. Should data be transferred [state conditions that will apply].

5. Withdrawal

You can withdraw your data at any time by contacting **[name of relevant person]** free of charge at **[information]**. Data sent to other researchers around the world cannot be withdrawn if already used or published.

For other common basic elements to include see: P^{3}G-IPAC Generic Clauses Database (http://www.p3g.org/resources/ipac).

C. GENERIC INTERNATIONAL DATA SHARING PROSPECTIVE CONSENT FORM
Prepared for the GA4GH by the P3G-IPAC

The Global Alliance for Genomics and Health ('GA4GH') recognises that consent materials for research reflect local requirements, but also allow for international data sharing. Template text is offered below. The proposed text conforms to the principles of the GA4GH *Framework for Responsible Sharing of Genomic and Health-Related Data*.

A 'Consent Policy' from the GA4GH Consent Policy Task Team will provide more detailed consent-specific principles as well as procedures.

The text below can be adapted as necessary. Projects are invited to include or delete elements indicated by square brackets ([ ]). Content may change according to the nature and administrative requirements for each project. Further information can be found at the P3G-IPAC Generic Clauses Database (http://www.p3g.org/resources/ipac). It provides generic clauses designed to assist researchers in building ethical and legal policy documents.

[Name of Principal Investigator(s)]
[Name of organization]
[Name of funders & sponsors]
[Contact information]

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1. Introduction

We invite you to be part of the **[name of project]**. This project collaborates with researchers from around the world in studies approved and monitored by [research ethics review committee]. This project is guided by the ***Framework for Responsible Sharing of Genomic and Health-Related Data*** **[cite URL for relevant website]**.

The **[name of project]** will include some or all of the following: **[describe]**
(1) Data collected during the project;
(2) Some data from your medical file or other personal and health information; and
(3) Your self-reported health related data;
(3) **[where applicable:** Data from your stored tissues**]**.

Any data that may identify you will be kept in what are called controlled-access databases. This means researchers must have permission from **a review committee** to use the data that you and other participants have

provided (see section 8. *How will you protect my privacy?*). Such approved data may be shared online with researchers around the world. The results of studying your data will also be presented at conferences and in scientific publications. You will NOT be identified.

You can learn more information about the organization of this project and general results when they become available at: **[project website]**.

This project has been reviewed by **[name of relevant REB/committees]**

If you think you might want to participate in this project, please read the rest of this form and take as much time as you need to ask questions. **The decision about whether to participate is completely up to you.** Your decision to participate in the study will **NOT** affect your medical care.

2. What is the purpose of this research?

Genes are the basic "instruction book" for the cells that make up our bodies. All genes are made of DNA. The DNA of a person is more than 99% the same as the DNA of any other person, but no two people have exactly 100% the same DNA except for identical twins. The complete set of DNA in your body, including all its genes, is called your genome. Although our DNA is very similar to each other, your genomic data is entirely unique. Variations in the genome explain some of the physical differences between people, and partly explain why some develop diseases like cancer, diabetes, asthma, and depression, while others do not. At present, it is generally not possible to predict which changes in DNA lead to disease or health.

We have also found important differences in DNA between population groups. Only by comparing your DNA and medical data with that of other people can we identify patterns and relationships in the genes, together with the environment, to help us better understand health and disease. Thus, the purpose of **[name of project]** is to **[description of project]**.

This is research, and not medical care. You should see a physician for any health problems or medical questions you might have.

3. What will you ask me to do if I decide to participate?

We will first ask you a few questions to determine whether you can participate. If yes, we will need access to your medical record and ask you to complete some questionnaires **[about…] [and access to data from stored tissue where applicable].**

4. What will happen with the data I give you?

Your data will be stored in controlled-access databases (i.e. a server/cloud provider) that meet international security and safety standards. Your data will be used for international research and may be moved and stored in different countries.

Over the next **[number of years]**, researchers will:

- analyse your genetic information using a process called 'sequencing'; and
- study DNA variation

Your data will be shared with other researchers around the world and used in future biomedical research projects after ethics approval. These projects can take place in universities, hospitals, non-profit groups, companies, and/or government laboratories. All researchers must respect the laws and ethical guidelines for biomedical research.

Your data will be kept for a period of **[number of years/identify period OR indefinitely]**.

5. Will I be paid to participate?

[No OR You will be reimbursed for any inconvenience such as travel time]. Some of the research done with the information stored in the databases may one day lead to the development of software, tests, drugs, or other commercial products. If this happens, you will not receive any of the profits.

6. Are there any benefits to participating in the project?

You will not benefit personally because research usually takes a long time to produce medically useful results. However, your participation may help others in the future.

7. What are the risks of participating?

Much like fingerprints, it is possible to identify someone if certain data are put together. While we use very strict data security measures to protect your privacy, there is always a small risk that your data may lead to you being re-identified. As technology advances, there may be new ways of linking data back to you that we cannot foresee today. Like other medical information, this may one day affect your insurability or employment.

8. How will you protect my privacy?

Your data will be stored online, in controlled-access databases. Only approved researchers will have access. An independent committee will determine whether to grant researchers access to your data. Numerous safeguards are in place to keep your information confidential. In particular,

- Personal identifiers will be removed (i.e. name, date of birth, etc.);
- Your personal details will be kept separate;
- Your data will be coded; and
- Stringent security measures will prevent unauthorized access or misuse.

These safeguards make it difficult to know which personal information came from you or any other participant. However, we cannot guarantee that you will never be re-identified.

Researchers who wish to access the database will be required to apply to **[Name Data Access Office]** who will examine their credentials and data security plan. They will also make sure the proposed research project is consistent with your consent. You will not be identified if findings from your data are presented at scientific conferences or appear in scientific publications. **[Name Data Access Officer]** will notify you immediately in the event of a problem with privacy.

9. Can I change my mind after I decide to participate?

You may choose whether or not you wish to take part in this study. You are also free to withdraw at any time from the project. If you withdraw, your data will no longer be used. However, data that has already been used for research i.e. now part of a dataset or is already published cannot be destroyed or removed.

You can withdraw by **[disclose ways for participant to indicate their withdrawal, e.g., by telephone, by email, by mail and whom to contact]**. You will also receive a letter confirming your withdrawal.

10. How can I find out about the results of the research?

It will probably take a long time to interpret the data accurately. You can check the project's web site at **[cite URLs for relevant websites]** to read about the project's progress and to see if there are any general results. **[Include the local policy on return of individual health results/incidental findings and role of physician where applicable]**

11. Re-contact

[With your permission, we may re-contact you to invite you to update your questionnaire, to provide additional data, or to be involved in new research projects by other researchers.] [Include local language for re-contact].

12. Who can I contact if I have questions or concerns?

If you have any questions or concerns, please contact **[name of person]** free of charge at **[insert telephone number]** or by mail/email at **[insert mailing address and/or email address]**. If you wish to make a complaint about any aspect of this study at any time, please contact **[name of person]** free of charge at **[insert telephone number]** or by mail/email at **[insert mailing address and/or email address]**. We take all comments seriously and will get back to you as soon as possible.

CONSENT TO PARTICIPATE

Consent and Signature

Please read the information below, and sign if you agree.

I have been provided all the information I need to make a decision. I have been able to ask questions if I did not understand the information.

I agree:

- that my personal, medical and genetic data can be deposited in online, controlled-access scientific databases;
- that my data be studied by researchers from around the world;
- that I will not be identified in scientific publications and at conferences;
- that I will not receive any profits if commercially valuable product(s) result from these studies;
- that my data cannot be removed if it is already used in a dataset or published; **[and]**
- **[to give access to data from my stored tissues for study where applicable]**.

I know that participating is my choice. I understand that I may withdraw at any time without having to give a reason.

I agree to be re-contacted to update my data, or to be involved in new research projects**:**

□ **Yes** □ **No**

[I agree to be re-contacted if medical information is found that could be useful to me and my doctor:

□ **Yes** □ **No] [Insert local policy on return of individual results]**

If yes, your email/address: _____

Your Signature _____ Date _____

Researcher Signature _____ Date _____

Copy given to participant: _____Yes