



P³G GENERIC INFORMATION PAMPHLET AND CONSENT FORM (2014)

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I. BACKGROUND

In order to ensure the continued utility of its online tools, the Public Population Project in Genomics and Society (P³G) undertook a revision of its 2007 generic information pamphlet and consent form.¹ The following generic template builds on the 2007 documents and incorporates new elements based on current concerns, biobanking practices and literature.

This document is designed as a template for those involved in prospective, longitudinal population studies. It is tailored to obtaining the consent of adult participants and does not include any additional considerations for the consent of minors or vulnerable populations. Specifically, this template should assist biobanks in drafting their information brochures and consent forms for individuals considering participating in their study. It identifies the core elements and clauses that should be included in an information pamphlet and consent form. Each biobank will necessarily need to include or delete elements according to its aims, cultural and ethical norms, and national legislation or policy. We hope that this document will provide a starting point and useful guide.

This document is drafted for biobanks to essentially fill-in the blanks where lines are provided. Explanatory notes may be provided within brackets, indicating the type of information the biobank should include. Moreover, optional and alternative clauses are included to reflect regional legislative requirements that govern biobanking, specific areas of focus identified by certain P³G members in 2007, or to reflect a topic that should be addressed by the biobank, depending on its nature.

II. GENERAL INSTRUCTIONS

The information brochure and consent form should be clear, in plain language, easy to read, and written in large fonts (size may vary according to the targeted population). The date of the version of the form should be identified in the footer of the document and pages should be numbered "Page x of y". Also, in the information pamphlet, the term "you" should be used to refer to potential participants. Inversely, the term "I" should be used in the consent form.

¹ Susan Wallace, Stephanie Lazor & Bartha M Knoppers, "Generic Information Pamphlet" (November 6, 2007).

[Insert logo & letterhead of Biobank]

INFORMATION PAMPHLET FOR PARTICIPANTS

[Name of Biobank/Title of the study]

[Name of Principal Investigator]

[Name of organization]

[Name of funders & sponsors]

[Contact information]

Preamble

We are inviting you to take part in the creation of a resource for research called: [Identify Biobank/title of study]. Your participation is voluntary. Before you decide whether or not to participate and sign the consent form, please take your time to read this information pamphlet. This document may contain information or words that you do not understand. Please ask us if there is something you do not understand, or if you would like more information. It is important that you fully comprehend what participation in this project entails.

1. Nature and objectives of the study

[Describe the study purpose, in addition to the actual and future scope of research.]

The [Biobank] is a resource that contains biological materials, such as DNA samples, in addition to health/lifestyle information and personal information (data) on a large number of people over time. It has been set up so that it can be used in the future as a resource for researchers undertaking a wide range of medical research.

Optional Clauses

- If applicable, provide specific information as to "large number of people involved";
- If applicable, specify types of future "medical research" (e.g. specific disease/research area).

[Biobank] is a long-term study which will run from/until [identify the duration of the biobank, whether it be a specific year or indefinite].

This [Biobank/study] has two main aims. The first aim is to gain a better understanding of the interactions between genes, the environment and our lifestyle that influence our health or cause diseases. The second aim is to use this understanding to develop new drugs, genetic tests and treatments, and to create public health strategies that will benefit everyone.

Your participation in this project involves you giving broad consent. This means that you allow your personal information and samples to be used for a variety of future medical research approved by an ethics committee, but which cannot be specified at the present time.

Optional Clauses

- If applicable, specify types of medical research that will use the biobank (e.g., specific disease area). If other types of research are indicated, add: *“Some future types of research may require your specific consent.”*

- If data linkage is foreseen, add: *“Your personal data will have to be regularly updated by being linked to your medical record and other sources of administrative health information. If, after reading this information pamphlet, you do not agree to any of these aspects, you should not take part.”*

2. Prospective participants

[Outline the total number of expected participants and explain why the individual was selected to participate.]

The [Biobank/study] involves the participation of [number] of people between [age range] years of age from [region].

You have been chosen from [identify database, registry, etc.] to be invited to participate.

Optional Clauses

- If applicable, specify targeted disease or specific illness.

- If applicable, add: *“You are being asked to participate because you are a patient at [name of hospital/Institution]”* or *“You have been identified by your personal doctor as someone who is in the correct age bracket and meets the relevant criteria to participate.”*

However, please note that you should not participate if [enumerate exclusion criteria].

3. Researchers and Institutions conducting the study

[This section should also disclose any conflicts of interest.]

[Biobank] is a joint research effort between [identify Institutions]. It is coordinated by [Institution]. This institution is responsible for the practical aspects, such as data collection and secure storage of samples and data. It will be the point of contact for you, and for the researchers who use the biobank. The person who has overall responsibility for the management of the biobank is [name of executive director]. If you need to contact the biobank for any reason, please telephone [name] at [phone number], email [email address] or write to [mailing address].

The [Biobank] is supported by [Institution(s)] and is funded by [sponsor(s)/Government Agency]. The [study] has received approval from [name of research ethics committee].

4. What does participation involve?

[Outline study procedures; what participants are expected to do throughout the course of the study; include types of information being gathered (sample and data); amount of information gathered; tests to be performed (manner of acquiring samples); questionnaires; length of time; location...]

If you choose to participate, you will be asked to:

- 1) Undergo a physical assessment which involves you:
 - attending an appointment at [location], which will last approximately [duration of appointment];
 - providing a [blood, urine, saliva...] sample of [amount/ measures of samples taken] which the biobank will store;
 - answering a questionnaire on [e.g., your health and lifestyle, family and medical history] that will take approximately [length of time];
 - allowing our staff to perform basic measurements, including [e.g., measuring your weight, height, blood pressure].

The physical assessment will be conducted by [qualified health professionals, e.g., nurses, physicians]. In total, it should take approximately [duration of entire assessment].

- 2) Allow your samples and data to be stored and used in coded form by researchers for many years; and
- 3) Allow your personal information contained in your administrative health records to be accessed now and in the future. We may continue to access these records even if you become unable to make decisions for yourself or after your death.

5. Study risks

[List possible disadvantages or risks, e.g., discomfort, malaise, stress, transportation costs, time...]

Your participation entails few risks. The physical assessment involves little risk. The taking of a blood sample for DNA analysis may cause some bleeding, bruising, dizziness and/or discomfort. You should be aware that certain physical measurements that will be taken [e.g., your weight] and/or some of the questions you will be asked in the questionnaire may be personal in nature. The storage of your samples and the extraction of DNA involve minimal risk, as rigorous security measures are in place (as described below) and all samples will be kept in a high security facility.

Unless required by law or a court order, access to this information will not be offered to third parties such as employers, insurance companies or other family members. Only authorized staff members will have access to your information. For requests for access by researchers, they will

not be given any information that would allow them to identify you. The utmost care will be taken to ensure the confidentiality of all data.

6. Potential study benefits

You will not directly benefit by taking part in this study, as the most important health benefits will be realized many years from now. Rather, your participation will contribute to the advancement of scientific knowledge and help future generations, as your participation is expected to improve our understanding of genetic and non-genetic factors that affect the health of the population.

However, any immediate, life-threatening condition will be reported to you immediately so that you can obtain emergency care.

7. Privacy and confidentiality

[Specify who will have access to the participants' personal information and the types of information.]

The information in your file could include your past and present medical history, in addition to information about your life and test results from exams and procedures done during this study. Your file could also contain information such as your name, sex, date of birth and ethnic origin.

All information collected about you will remain confidential. No one will have access to your directly identifying information, that is, information that identifies you through specific identifiers such as your name, social insurance number and your personal health number.

To protect your privacy, your information will be coded. Coded means that your information has been stripped of any direct or indirect identifiers, which are replaced by a numerical code. A list that links the coded information with your identity will be kept secure, to allow for your re-identification in certain circumstances. Your unique code will enable us to link the information from different datasets to you, but at the same time, will enable us to keep your identity confidential when we give your data to other researchers to use.

While study information could be printed in journals or shared with other people at scientific meetings or for teaching purposes, it will not be possible to identify you. Your identity will be kept confidential. All data will be presented as group data, rather than individual data.

To ensure the highest standards for protecting your privacy and the confidentiality of samples and data, a number of bodies oversee this process. This oversight mechanism is designed to ensure accountability, transparency, protection, security and control.

The **[Oversight Body]** monitors the development and operation of the biobank. The **[Oversight Body]** ensures that the use of the biobank by researchers is in the public interest, and that

researchers conform to your consent and to all relevant legal and ethical rules. You can see who is a member of the oversight committee and its terms of reference by consulting [\[website\]](#).

Also, specific rules regulate access to your data and samples by researchers. Researchers will not have access to any of your personal information.

8. Access to your data and samples

Only approved research studies can gain access to your [coded data and samples](#), in order to protect your privacy. An approved researcher can be from [\[outline approved users as per access policy, e.g., academia, a charitable organization, a private company or a public institution\]](#). All projects must be approved by the [\[identify access committee\]](#) who will essentially review whether the proposed study has received prior scientific and ethical approval by the relevant committees, that the study fits within the purpose of the biobank and meets other general requirements.

Researchers have to sign agreements that control their access to data and samples, and they are not permitted to disclose or transfer data or samples to anyone else or to use them for purposes other than those agreed to. Researchers must also agree that they will not attempt to re-identify you from your data and samples and should immediately report any re-identification of participants to the biobank.

We also expect to receive access requests from overseas researchers and international collaborators. These researchers must follow the same procedures as all other researchers. All access is subject to the strictest scientific and ethical scrutiny, as described above.

When transferred samples are [no longer needed for the purpose for which they were given to researchers](#), researchers must [\[return them to the Biobank or destroy them\]](#). Researchers must also return their research results to the biobank, so that those results are available for other researchers to use in the future. This facilitates future research and enriches [\[Biobank's\]](#) database.

9. Storage of your data and samples

[Specify where the data and samples will be stored (location) and how long they will be stored.]

Your data and samples will be stored in a database at [\[name of Institution/hospital and location\]](#). This is a secure facility, meeting international security and safety standards for laboratories. Also, in order to keep your information confidential, numerous safeguards are in place. In particular, we will:

- Remove personal identifiers such as your name or date of birth from your samples and records;
- Assign codes to your samples and records;
- Keep your personal details separate from your data and samples;

- Use stringent security measures to prevent unauthorized use, including: strict access controls, computer security and data encryption techniques, confidentiality agreements and staff training;
- Hold information in secure databases, which can only be accessed by the authorized staff and by approved researchers who will only have access to coded information;
- Have a decoding step that will allow us to re-link your personal details with your samples and information, should you want to withdraw from the study or in order to make sure the database records are correct.

Your samples and data will be kept for a period of [number of years/identify period of conservation]. After this period, your samples and data will be [destroyed or transferred], unless an ethics committee decides otherwise.

Optional Clause

If samples and data are transferred at the end of the period of conservation, specify where the data and samples will be transferred [name of Biobank].

10. Withdrawing from the study

[Indicate treatment (foreseeable use and storage procedures) of already collected data/samples.]

You may choose whether or not you wish to take part in this study. If you choose to take part now, you can change your mind later and withdraw, meaning stop participating at any time and for any reason.

You are free to withdraw from the study at any time. You can withdraw by [indicate ways for participant to signal his withdrawal, e.g., by telephone, by email, by mail and whom to contact]. You will receive a letter confirming your withdrawal.

If you withdraw, your identifiable samples and the data derived from your samples and other personal information will be destroyed if possible. Data that is already used for research cannot be destroyed or removed.

The code that enables us to re-link your samples and personal information will be deleted so that no further information about you will be collected. Only your signed consent form and a copy of the letter confirming your withdrawal will be kept as a record of your wishes. Such a withdrawal will prevent information about you from contributing to further research and analyses.

11. Return of Research Results

[Outline biobank's policy as to returning results, including general research results, the results from the lab assessment, individual research results and incidental findings. If the biobank's

policy is to return individual results, indicate who has the obligation of returning these results and for how long.]

a) Results from lab assessment & initial physical assessment

You can choose to immediately receive your physical assessment results, such as [specify results that can be returned], from your [type of assessment, e.g., BMI, ECG, blood pressure]. These results will be provided with the appropriate explanations (e.g., your measurements alongside 'standard measures'). You can decide whether you want these measurements sent to you or not*. If, during the physical assessment, we find something that we feel should be explored further, we will advise you to see your personal doctor, as the assessment is not a clinical check-up.

Optional Clause

* "you can ask that they be sent to your personal doctor."

b) General research results

General research results, meaning aggregate results derived from the analysis of the data and samples of research participants, will also be made available to participants, researchers and any other people who might be interested through [website, newsletter...]. This is done to make data more readily available to researchers and encourage medical advances. Such data will not have any identifiers that will enable anyone to link the data to you. You can access these results through the biobank [specify how/where participants can find these results].

c) Individual research results & incidental findings

Individual research results are results discovered during the course of research, which concern you and have potential health or reproductive consequences.

Incidental findings are unforeseen findings about you that have potential health or reproductive consequences. While they were discovered during the course of research, they are outside of the study objectives.

Alternative Clauses

- Alternative clause 1: "We will not return any individual research results or incidental findings to you"; or
- Alternative clause 2: "With your consent, we will return research results or incidental findings to you, when they are scientifically valid, are clinically significant and there is a recognized therapeutic or preventive measure or way of changing the clinical course of the disease or condition. These results will be returned to you by [e.g., the principal investigator, a qualified health professional] for a period of [number of years]. After this period, the biobank will no longer return individual research results to you."

12. Re-contact

With your permission, we may re-contact you to invite you to update your questionnaire or to provide additional samples or to be involved in new research projects by other researchers that could require additional physical assessments, tests and questions.

13. Compensation

[Include traveling expenses and the procedure for reimbursement.]

Alternative Clauses

- If compensation is not offered, add: “Your participation is on a voluntary basis. You will not be compensated for your participation.”

- If compensation is offered, add: “Your participation is on a voluntary basis. However, as compensation you will receive [specific amount] for [type of visit, e.g., a visit to the clinic or a visit at home], traveling expenses and other inconveniences related to your participation.”

14. Possible commercialization

[Explain the potential uses of data and samples, including the development of intellectual property and commercial uses.]

[Biobank or specific committee] has been set up as [guardian/owner/custodian] of the database and sample collection. The use of your data and samples might someday lead to the commercialization of a medical or genetic test or product. This may be done by a university or hospital, a commercial company or both working in partnership. This means that researchers, including, potentially, commercial companies, may benefit financially. You will not derive any personal financial advantage from this commercialization.

15. Closure of the biobank

[Explain what will happen upon the closure of the biobank, whether the closure is scheduled or unplanned.]

If the [Biobank] were to close for whatever reason, [see alternative clauses].

Alternative clauses

Alternative clause 1: “all of the research results and information will be put into an archive that will be overseen by the [identify committee]”;

Alternative clause 2: “all of the samples and data will be destroyed”; or

Alternative clause 3: “all of the samples and data will be transferred to [identify existing biobank].”

16. Your 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.

Thank you for considering taking part in this study!

[Insert logo & letterhead of Biobank]

PARTICIPANT CONSENT FORM

[Name of Biobank/Title of the study]

Name of Biobank: []
Investigator(s): []
Sponsor(s): []

The goal of [biobank/study] is [provide a brief summary of goal].

BY SIGNING THIS CONSENT FORM, I AGREE TO PARTICIPATE IN [BIOBANK/STUDY] AND DECLARE THAT:

- I have read and understood the information pamphlet [version/date]. I have had the opportunity to consider the information it contains and to ask all the questions I had. I have obtained satisfactory answers to my questions.
- The risks and benefits of my participation have been explained to me.
- I understand that my participation is voluntary. I am free to withdraw at any time, without giving any reason. This can be done by contacting [name] at [insert phone number, email address and/or mailing address]. I will receive a letter confirming my withdrawal.
- I understand that I will not receive any personal financial benefit from any possible commercialization of a test or product developed by using my data and samples.
- I understand that my participation does not entail any direct personal benefit. However, any immediate, life-threatening condition will be reported to me immediately so that I can obtain emergency care.
- I understand that upon closure of the biobank, my data and samples will be [specify policy for closure: archived, destroyed, transferred to another biobank].
- I understand that unless access is required by law, only approved researchers will have access to my coded data and samples. Access is subject to ethics approval and oversight.
- I understand that general research results, meaning aggregate results, will be made available to participants, researchers and other people who might be interested through [website, newsletter...] in order to make data more readily available and encourage medical advances.

I AGREE TO:

- Undergo a physical assessment, including:
 - attending an appointment at [location], which will last approximately [duration of appointment];
 - providing a [blood, urine, saliva...] sample of [amount/measures of samples taken] which the biobank will store;
 - answering a questionnaire about [e.g., my health and lifestyle, family, medical history];
 - allowing staff to perform basic clinical measurements, including [e.g., measuring my weight, height, blood pressure].

- Allow my coded data and samples of [e.g., blood, cells, DNA, urine, saliva] to be used for various research purposes approved by the relevant research ethics committee.

Optional Clause

If specific disease/research area: "Allow my coded data and samples of [e.g., blood, cells, DNA, urine, saliva] to be used for [specify disease/research area] approved by the relevant ethics committee. My approval will be required for other types of research."

- Have my data and samples stored at [storage location] for [specify period of conservation]. All data and samples will be kept in a secure facility overseen by [name of individual or committee].
- Allow my data contained in administrative health records to be examined now and in the future. My records and samples will continue to be accessed even if I become unable to make decisions for myself or if I die.

Alternative Clause

Allow my data contained in administrative health records to be examined now and in the future. If I die, my records and samples will no longer be used.

RETURN OF RESULTS

a) Results from lab assessment & initial physical assessment

| | | |
|---|--------------------------|--------------------------|
| <i>Optional Clauses</i> | | |
| ➤ I wish to receive the measurements or other results taken during the physical assessment/lab tests. | YES | NO |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| [OR] | | |
| ➤ I wish to have the measurements or other results taken during the assessment and lab tests sent to my doctor. | YES | NO |
| | <input type="checkbox"/> | <input type="checkbox"/> |

b) Individual research results & incidental findings

Alternative Clauses

Alternative 1:

- I understand that I will not receive any individual research results or incidental findings.

Alternative 2:

- I agree to have individual research results and incidental findings returned to me when these results are scientifically valid, have clinical significance and are actionable (there is a recognized therapeutic or preventive measure or way of changing the clinical course of the disease or condition). YES NO

RE-CONTACT

- I agree to be re-contacted by [Biobank/study] to update my data (questionnaires or physical measures) or to provide additional data/samples. YES NO
- I agree to be re-contacted by [Biobank/study] to participate in new research projects conducted by other researchers that could require additional physical assessments, tests, questions or samples. YES NO

INVESTIGATOR OR HIS/HER DESIGNEE CONFIRMATION

I described the [Biobank/study], including the conditions of participation, to the participant. I explained the contents of the information pamphlet and consent form to the participant. Any questions were answered. I explained that participation was voluntary.

Investigator/Designee name _____ Signed _____ Date _____

Optional Clause

TRANSLATOR INFORMATION (if applicable)

I was present during the meeting between [identify the Investigator/designee] and the participant. I translated, for the participant, the consent form and all information presented regarding the research project.

Translator name _____ Signed _____ Date _____

PARTICIPANT INFORMATION

I AGREE TO PARTICIPATE IN [BIOBANK/STUDY] AND WILL RECEIVE A COPY OF THIS CONSENT FORM AFTER I SIGN IT.

Name: _____

Signed: _____ Date: _____

THANK YOU FOR PARTICIPATING! FOR MORE INFORMATION, PLEASE CONTACT: [add website, person to contact, phone number, email address].

To file a complaint regarding your participation, please contact: [name of person to contact, phone number, email address and mailing address].