This generic consent form is largely designed as a template for use by those involved in prospective, longitudinal population genomics studies and is based on approaches found amongst P³G members (www.p3gconsortium.org). The optional clauses have been added for those participating P³G members that have identified specific disease areas of focus or come from countries or regions with specific legislation governing their resources/biobanks.

This generic form is offered as a template to assist or inform interested persons. It is not intended to be proscriptive; projects are not required to include all of these elements in order to inform potential participants. It is designed to indicate the elements that may be considered when creating a consent form for a resource or biobank project. Each resource or biobank will necessarily need to include or delete elements according to, for example, the aims of their project, cultural norms, or national legislation or policy. We hope this form will provide a starting point and a useful guide for creating consent materials for population genomics studies.

Letterhead of (Population Genomics Resource/Biobank)

GENERIC CONSENT FORM
[Name of Resource/Biobank]

Name of Population Genomics Resource/Biobank:_____
Investigator(s): _____
Sponsor(s): _____

CONFIRMATION OF UNDERSTANDING OF THE INFORMATION PROVIDED

I confirm that I have read and understood the information pamphlet _____ [**PFI***] _____ __[version/date] ___. I have had the opportunity to consider the information it contains. The risks and benefits of my participation have been discussed with me. I have had the chance to ask questions. These questions have been answered to my satisfaction.

I understand that my taking part is voluntary. I am free to withdraw at any time, without giving any reason and without affecting my present or future medical treatment. This can be done by telephoning __ [Telephone] __ or by writing to __ [Address] __.

I agree to:

-Undergo a physical examination, including:

- Providing a __[blood, urine, saliva, other]__ sample of ___[Amount]___ (about [amount] tablespoons)
- Answering a questionnaire about ___[PFI, e.g. my health and lifestyle, family and medical history]___
- Allowing staff to perform basic clinical measurements, including ___[PFI, e.g. measuring my weight, height, blood pressure, etc]___

-Store my data and samples ___ [until year/indefinitely] ____. All samples will be kept in a secure facility overseen by _____ [PFI] _____. If the resource/biobank has to close they will be archived [Optional: destroyed].

-Allow my personal information (data) contained in [Optional: my medical records and] administrative health records to be examined now and in the future, even if I can no longer make decisions for myself, or after my death [Optional: stop using].

-Allow my personal and health information and of my __ [coded/anonymized] __ samples of __ [blood, cells, DNA, and urine] __to be used for research purposes approved by the relevant research ethics committee [Optional: for research in _ [PFI] __].

***PFI: Project fill-in** .

Version November 6, 2007 by Susan Wallace, Stephanie Lazor, and Bartha Maria Knoppers. Substantial comments have been made by Jane Kaye, Sue Gibbons, Alastair Kent, Tobias Schulte in den Bäumen, Naomi Hawkins and Adrienne Hunt.

-Allow ___[PFI]__ to re-contact me in the future to invite me to participate in follow-up research for the _ [PFI, resource/biobank] (e.g. providing additional samples or updating the questionnaire). yes ☐ no ☒

I understand that I can stay in the resource/biobank even if I do not wish to be re-contacted.

ACCESS

I understand that unless access is required by law or court order, only approved researchers will have access to the information and samples of the resource/biobank. Access to my samples and data is subject to ethics approval and oversight.

RESULTS

- My participation will not provide me with any direct personal benefits, but I understand that general research results are available at __ [PFI, e.g. website]___.
- I wish to receive the measurements or other results taken during the clinical assessment. *yes* ☐ *no* ☒

  OR

  I wish to have the measurements or other results taken during the clinical assessment sent to my doctor. *yes* ☐ *no* ☒

COMMERCIALIZATION

- I understand that with proper oversight, results and samples may be exchanged with researchers in other countries, including those from commercial companies, for use in specific biomedical projects. I will not receive any personal financial benefit from the commercialization of any test or product that may result.

AGREEMENT TO PARTICIPATE

_____ [Name of person] _____ has explained the ___ [PFI] ___ to my satisfaction. I agree to participate and will receive a copy of this consent form after I sign it.

PARTICIPANT INFORMATION

Name: _____

Signed _____ Date _____

INVESTIGATOR OR HIS/HER DESIGNEE CONFIRMATION

I described the___ [PFI] ___, including the conditions of participation, to the participant. Any questions were answered. I explained that participation was voluntary.

Investigator/Designee name _____Signed _____ Date _____

TRANSLATOR INFORMATION (if applicable)

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

Translator name _____ Signed _____ Date _____

APPROVAL

The ___ [PFI] ___ was approved by the __ [Research ethics committee] __ on __ [Date] __.

***PFI: Project fill-in** _____.

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Consentement accepté | Consentement refusé