

Guidelines for informed consent

These guidelines are made up of the following three sections: design decisions; guidance for broad consent participant information sheets and consent forms; and links to biobank-specific templates for participant information sheets and consent forms.

A2.1 Design decisions

This section contains useful points to consider when designing participant information sheets and consent forms for biobanks.

A2.1.1 Where do I start?

The templates for participant information sheets and consent forms listed in Section A2.3 are a good place to start to get an idea of the general contents of participant information sheets and consent forms.

A2.1.2 Will I provide the participant information sheet and the consent form as separate documents?

It is common practice to provide these documents separately, and this may be the most practical solution for biobanks in terms of the storage and distribution of these documents. However, in clinical trials that involve biobanking, the two documents are often combined, which ensures that the participant information sheet and the consent form used are stored together.

A2.1.3 Will I require that the participants initial or tick the boxes on the consent form?

It is recommended that biobanks follow best practice in clinical trials, which requires that participants initial the boxes on the consent form. It is worth making this requirement clear on the consent form itself.

A2.1.4 Will I provide opt-in/opt-out statements on the consent form?

The most critical thing to consider before providing opt-in/opt-out statements is whether the biobank can support this. For example, allowing the participant to opt out of research that involves animals but not being able to enforce this when distributing samples will cause problems for the biobank. The most common problem is that the biobank database does not record the participant's decisions, resulting in a time-consuming search for the consent form each time a sample is distributed. If opt-in/opt-out statements are provided, add two boxes, marked with "yes" and "no", to the consent form so that it is clear that these statements are optional. See the information on dynamic consent in Table A2.2 for examples of possible opt-in/opt-out statements.

A2.1.5 Should I consider what might happen to the samples in the future?

It is very important that when the participant information sheets and consent forms are being developed, the biobank should carefully consider the possible future use of the samples and data, so that the biobank can inform the participant at the outset and will not need to re-contact them for further permissions. Some examples of areas to consider are: issues that are potentially ethically or legally challenging, such as transfer of samples or data across national borders or use of samples and data by commercial researchers (see the recommendations in Section 3.1.2.3); return of results and incidental findings (see Section 3.1.4); access to and sharing of samples and data (see Section 3.1.5); when participants might need to be re-contacted; and whether the participants need to receive information or give consent via an interpreter. If an interpreter is needed, lines may need to be added to the consent form to allow the interpreter to sign the form.

A2.2 Guidance for broad consent participant information sheets and consent forms

Table A2.1 provides information on the headings that would be expected on a biobank participant information sheet aiming for a broad consent approach. The optional sections apply only to specific types of biobanks or specific types of research being conducted.

Table A2.1. Sections for inclusion on a biobank participant information sheet, indicating whether these are optional or mandatory; the initial statements or questions can be used as titles in the participant information sheet

Section	Mandatory or optional?
Why are human tissues and body fluids vital for research?	Mandatory
What is the purpose of the biobank? Answering questions such as: • What is the aim of the biobank? • Is the biobank disease-specific? • Is unspecified future research (secondary use) planned?	Mandatory
Who has approved the research?	Mandatory
Why am I being invited?	Mandatory
What will happen if I agree to participate? Answering questions such as: • Is access to medical or other health-related records planned?	Mandatory
Will my samples be used in genetic research?	Mandatory
What are the benefits and risks of taking part?	Mandatory
Who will have access to my samples and data? Answering questions such as: • Can the samples and/or data be transferred to/used by/shared with other researchers/biobanks/institutions? – Is this individual-level/aggregated/genetic data? – Will the samples be shared? • Can the samples and/or data be transferred to/used by/shared with researchers in other countries? • Will the data be included in a public database? • Can the samples be accessed by commercial organizations?	Mandatory

Table A2.1. Sections for inclusion on a biobank participant information sheet, indicating whether these are optional or mandatory; the initial statements or questions can be used as titles in the participant information sheet (continued)

Section	Mandatory or optional?
How will my samples and data be stored? Answering questions such as: • What are the privacy/data protection mechanisms?	Mandatory
How long will my samples and data be stored?	Mandatory
Will I find out results of the research? Answering questions such as: • Will any results (general or individual) be returned to the participant? • How will any return of results take place? • What options does the participant have?	Mandatory
What if I change my mind? Answering questions such as: • What withdrawal options are there? • What happens to samples and/or data after withdrawal?	Mandatory
Contact details for the biobank	Mandatory
Will my cells or tissue be used for research involving animals?	Optional
Will my cells or tissue be used to create cell lines?	Optional
Will my cells or tissue be used for research linked to reproduction?	Optional
Can I donate cells or tissues after death?	Optional
Will I receive any compensation for being involved?	Optional
Detailed explanations about tissue, cells, and DNA: Human cells and tissues DNA and genes How cells and tissue are collected Use of human tissue and fluids for medical education and audit Details for specific types of tissues or donors (e.g. stem cells, healthy donors)	Optional
Detailed information about biobank governance Answering questions such as: • What type of committee reviews applications for access to biobank samples and/or data, and who serves on this committee? • What type of contracts must those accessing the biobank samples and/or data complete (e.g. Material Transfer Agreements)? • How is the biobank governed?	Optional
Detailed information for postmortem donors	Optional
Information about whether samples and/or data are collected from vulnerable persons or populations and how that works Answering questions such as: • Can samples and/or data be used after children participating in the study become adults?	Optional
Preferences for re-contact (see Table A2.2)	Optional

Table A2.2 provides information on the consent statements that might be expected on a biobank consent form aiming for a broad consent approach. Some of these consent options may be required by the legal system in a particular country, for example the need to gain specific consent to access medical records. In addition, legal requirements may mean that consent is needed to transfer samples or data across national borders if this may occur in the biobank. Opt-in/opt-out statements should be included only when these are recordable, actionable by the biobank, and practicable.

Table A2.2. Items for consideration on a biobank consent form, including options that may be provided as consent statements and possible opt-in/opt-out statements

Area	Example of statement on consent form (<i>italic means that text must be adapted</i>)
The participant confirms that they have read and understood a particular participant information sheet	I have read and understood the information pamphlet [<i>version/date</i>]. 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 participant confirms that they have had the risks and benefits of participation explained to them	The risks and benefits of my participation have been explained to me.
The participant understands that participation in the research is voluntary	I understand that my participation is voluntary. I am free to withdraw at any time, without giving any reason.
Use of samples and data by commercial researchers	I understand that some of these research projects may be carried out by commercial organizations and that I will not benefit financially if this research leads to new treatments or medical tests.
Use of samples for genetic research	These samples may be used for genetic research.
Access to medical records	I give permission for information about me, provided by me or found in my medical and other health-related records, to be supplied to and stored by [<i>name of biobank</i>] for research purposes. <i>or</i> I give permission for access to my medical and other health-related records, and for long-term storage and use of this and other information about me, for health-related research purposes (even after my incapacity or death).
Contacting general practitioner for information	My general practitioner can be contacted for information relevant to my condition and current treatment.
<i>Possible opt-in/opt-out statements (to be used when these are recordable, actionable by the biobank, and practicable)</i>	
Re-contacting participants to ask for further information or about participation in new studies	We may like to re-contact you in the future to ask for further samples or information that may be of use to researchers, or for further permissions relating to the use of the samples and information you have already donated. I agree that [<i>name of biobank</i>] may re-contact me in the future to ask me to provide additional samples or information related to [<i>name of biobank</i>] or to invite me to participate in a new study. I understand that this does not oblige me to provide the samples or to participate in further research.
Re-contacting participant with information arising from the study The text included here in the consent form will depend on the biobank's policy in relation to return of study results	<i>These are the areas where permission may be requested, if relevant:</i> <i>A. Agreement or opt-in/opt-out to receiving general research project results, for example in the form of a newsletter or email.</i> <i>B. Agreement or opt-in/opt-out to receiving the results of any physical examination conducted as part of the sample or data collection, in which case also briefly explain the circumstances under which this may take place and the mechanisms by which it would be achieved.</i> <i>C. Agreement or opt-in/opt-out to receiving the results of any tests for infectious diseases conducted on the samples. Briefly explain the related circumstances and mechanisms, as in B.</i> <i>D. Agreement or opt-in/opt-out to receiving individual-level research results or other incidental findings arising from the research. Briefly explain the related circumstances and mechanisms, as in B.</i>
Transfer of samples or data across national borders	Do you give permission for samples to be sent to centres outside [<i>name of country</i>]?
Experiments involving animals	Do you give permission for your samples to be used in experiments using [<i>animal type, e.g. rodents (rats or mice)</i>]?
Creation of cell lines from the tissue	These samples may be used to create cell lines.

A2.3 Links to biobank-specific templates for participant information sheets and consent forms

The documents and links listed below can be used as reference materials to produce biobank participant information sheets and consent forms.

1. World Health Organization (WHO):
 - WHO Informed Consent Form Templates: http://www.who.int/rpc/research_ethics/informed_consent/en/
 - WHO Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples: http://www.who.int/entity/rpc/research_ethics/Informed%20consent%20for%20sample%20storage.doc?ua=1
2. Public Population Project in Genomics and Society (P3G):
 - P3G-IPAC Generic Clauses/Agreements Database, to assist researchers in building documents: <http://www.p3g.org/resources/ipac>
 - P3G Generic Information Pamphlet and Consent Form (2014): http://www.p3g.org/system/files/biobank_toolkit_documents/P3G%20Generic%20Info%20Pamphlet%20and%20Consent%20Form%20for%20Biobanks_0.pdf
3. Global Alliance for Genomics and Health (GA4GH):
 - Consent tools in relation to international data sharing: <http://www.p3g.org/sites/default/files/site/default/files/GA4GH-Consent%20Tools-FINAL%20%281%29.pdf>
4. Human Heredity and Health in Africa (H3Africa):
 - H3Africa Guidelines for Informed Consent (2013), guidance for designing consent materials for genomic research in African contexts: http://h3africa.org/images/FinalPoliciesDocuments/H3A%20WG%20Guidelines%20Informed%20Consent_FINAL_01082013.pdf
5. Beskow LM, Friedman JY, Hardy NC, Lin L, Weinfurt KP (2010). Developing a simplified consent form for biobanking. PLoS One. 5(10):e13302. <http://dx.doi.org/10.1371/journal.pone.0013302>
6. Strategic Tissue Repository Alliances Through Unified Methods (STRATUM) project:
 - Consent Models Work Package tools, including a two-page combined participant information sheet and consent form template and an in-depth biobank participant information sheet template: <http://stratumbiobanking.org/consent.html>
7. UK Biobank:
 - Consent form: http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf
 - Participant information sheet: http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Participant_information_leaflet.pdf?phpMyAdmin=trmKQlYdjjnQlgJ%2CfAzikMhEnx6
8. Children's Cancer and Leukaemia Group (CCLG):
 - Information sheets for involving children in biobank research: <http://www.cclg.org.uk/tissue-bank/information-for-patients>