How to use this template

This template is made to help use human biospecimen and/or personal data in cases where the initial consent given by the donor/data subject at the collection of the material/data does not cover the now intended use.

First and overall important: asking for further consent assumes that the donor of the biosamples and/or data in question has given his prior consent to be contacted again by the institution now seeking further consent to use the biospecimen/data. This consent to be contacted is an indispensable prerequisite to use this template. If this requirement is not met, it would be a breach of privacy as such to use the contact details in order to seek consent to further use of the biospecimen/data.

Secondly, valid consent to the use of personal data including the use of human biosamples requires that the following conditions have been met:

The consent must be freely given. This means that potential donors must be sure that the decision will not affect any present or future health care or entail any other disadvantages. It is generally recognised that consent can only be given on the basis of proper information of the intended use and the rights of the donor, e.g. to withdraw the given consent at any time (“informed consent”). Therefore, the Information Sheet provided hereby should be a visible part of the consent declaration in order to underline that the participant has been properly informed before signing the declaration.

Informed consent includes the explicit indication of a specified research purpose. This requirement is one of the great challenges for biomedical research and even more for biobanks. A purpose is without doubt properly specified in cases where the use of biospecimen/data is limited to one single study with a clearly defined study purpose outlined in a study protocol. Beyond this, it is widely recognised that the indication of a certain disease that the intended research is to combat can be seen as sufficient in the sense of specification. The concept of “broad consent to medical research” which would be most helpful for research with regard to data protection concerns in cases of the use of human biospecimen and/or genetic data through biobanks is gaining ground within the EU in cases, where the aim of the consent seeking biobank cannot be limited to combat certain diseases. It can, however, not be seen as prevailing and is not a reliable form of consent. It is therefore
highly recommended to indicate the research purpose as precise as possible. Alternatively, the general aim of the biobank should be indicated in a most clear manner.

Anonymisation is still widely seen as remedy to avoid any data protection concerns, since anonymised data are no personal data anymore and thus do not fall into the scope of data protection legislation. It has to be noted, however, that anonymisation requires proper de-identification in the sense that the donor/data subject is not identifiable any more by reasonable means. Constant technical developments challenge the concept of anonymisation of biospecimen due to the fact that they regularly contain the full DNA and sequencing is getting more and more feasible and affordable. Genetic data as such are even more in danger of being retraced to the donor. In addition, anonymisation deprives the donor of his right to withdraw his consent and claim the remaining material. Therefore, data protection agencies are beginning to recommend that anonymisation should rather be avoided than to be used as means to protect the donor.

Incidental findings regarding undetected health risks or diseases of the donor raise the question whether there is an obligation to inform the donor. On the other hand, the “right not to know” must be respected. This conflict cannot completely be resolved, but at least duly handled through implementing an explicit declaration regarding incidental findings of the donor.

In order to take into account varying research purposes and remaining legal uncertainties, the template of the consent declaration is generic. It contains several paragraphs from which the donor/data subject can choose to consent to or not. Paragraph 1 to 3 are indispensable to any valid consent, whereas paragraph 4 to 7 extend the scope of the consent. As discussed above, the broad consent provided in paragraph 4 and the consent to anonymisation in paragraph 5 are not unquestioned and may be invalid under certain jurisdictions or in the future. But considering the fact that the concept of broad consent for medical research is gaining ground, it is recommended to collect consent in this sense to make future use of the specimen/data possible. It is however important to ensure that the currently intended use is covered by the scope of the consent under present applicable law.

At this stage, open access to or publication of the full genom of a human being requires specific unambiguous consent and is not included in this consent form.

The biosamples and the data have to be specified as precisely as possible. Great care should be used to ensure that the indication is correct and complete. Otherwise the risk that the consent does not cover the intended use is not properly met.

Please note, that this template is only a suggestion which has to be assessed and adapted to the aim of the biobank and/or database using it. The consent form eventually used should be in line with advice from appropriate ethics committees and national authorities, where applicable.
Information Sheet

You are being invited to take part in a major medical research project carried out by the “XXXBiobank” [fill in official name of legal entity that is authorized to enter into this agreement]. Before you decide whether to join, it is important for you to understand why XXXBiobank is being done and what is involved. Please take the time to read the following information carefully, and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please telephone XXX to talk to a member of the project team. More information about XXXBiobank is also available at www.XXXbiobank.xx. At the assessment visit, there will be a further opportunity to ask any questions that you might have.

Thank you for taking the time to consider taking part in XXXBiobank.

Contact details:… [fill in contact details]

What is the purpose of the XXXBiobank?

[Adapt, if necessary:] The purpose of this biobank is to improve the prevention, diagnosis and treatment of a wide range of illnesses (cancer, heart disease, diabetes, dementia) and joint problems and to promote health throughout society. By analysing answers, measurements and samples and health data collected from donors/data subjects, researchers may be able to work out why some people develop particular diseases while others do not. They may also detect unknown diseases and genetic defects. Thus progressive research objectives may emerge in the future and your biospecimen and/or personal data will be used for research purposes which at this stage cannot be indicated. This should help us to find new ways to prevent early death and disability from many different diseases.

XXXBiobank is not intended to help directly those who give their consent that their biospecimen and/or personal data can be used – but it should give future generations a much better chance of living their lives free of diseases that disable and kill.

How have you been chosen for invitation to XXXBiobank?

You were identified through your participation in [fill in name of project where the biosample/data has been collected] research project where you have given consent to be contacted again in case your specimen would be needed for research projects lying beyond the purpose of your given consent. The only information used, in confidence, for this purpose is your name and address. We do not know anything else about you, and have not seen any of your medical records.

How will your specimen be stored?

Your specimen will be stored under pseudonym or anonymised, if you consent to anonymisation. Your pseudonymised personal data and your pseudonymised specimen will be stored at different places and controlled by different persons in order to further impede abuse.

How will personal data kept confidential?
Access to personal information is restricted within XXXBiobank, and all staff sign confidentiality agreements as part of their employment contracts. Data or samples provided to researchers will not include personal identifying details. This should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than to support the project. Computer security to block unauthorised access (for example, by “hackers”) to the computers that hold personal information, is installed.

You do not give your consent to the publication of your full genom by signing this consent form. This would instead require your unambiguous renewed consent.

Why do we need your written consent?
Your donation of your biospecimen and/or personal data to XXX Biobank is entirely voluntary. By signing the consent form, you would be confirming your willingness to donate.

Can you withdraw?
You will be free to withdraw and to reclaim your specimen at any time without justification, unless the storage has been anonymised. In case of withdrawl, your specimen will be destroyed and your personal data deleted.

Will your specimen and/or data be shared with or transferred to other biobanks or databases?
The XXXBiobank is taking part in the European research project called [fill in]. We are establishing a databridge with our partner institute [fill in name and contact details]. The aim is to [fill in]. Therefore we need to [fill in extent and kind of possible specimen/data exchange]. Your specimen/data will be handled within this project under equivalent safeguards in order to ensure your privacy. The exchange will not affect your right to withdraw your consent (see above).

What are the risks for you?
Any collection, storage and transfer of data concerning your biospecimen or genetic information involves the general risk of re-identification in the future due to the constant progress in re-identification techniques and the permanent increase of publicly available information. These risks cannot completely be excluded. The risk would increase in case you make further genetic information available, e.g. for genealogy purposes. XXXBiobank declares to take all measures being state of the art to protect your privacy and to share and transfer your biospecimen and/or personal data only to those for research purposes who have an equivalent concept of data protection.
Declaration of consent

Thank you for reading the Information Sheet, and asking any questions that you might have had. If you would like to participate, please respond to each of the following questions and then sign the declaration.

The following specimen have been taken:… [fill in any biosample stored, e.g. blood sample, tissue etc. ]

The following data will be derived from your specimen: … [fill in, in particular when genome sequencing is intended]

The following data have been collected: … [fill in any personal data stored]

1. I have read and understand the information and have had the opportunity to ask questions.  
   Yes  No

2. I understand that my consent is voluntary and that I am free to withdraw at any time without giving any reason as long as the biospecimen has not been anonymised.  
   Yes  No

3. I hereby agree that my specimen and/or data as indicated above will be used in pseudonymised form by the biorepository (name and full contact details), which has the right to use and further transfer to other biobanks/databases and research institutes within Europe the specimen and/or personal data as indicated above for research purposes concerning the study …[fill in name, PI and reference number of the study] described in appendix 1 [add study protocol] or the disease …[fill in a disease, e.g. cancer] 
   I give permission for long-term storage and use of my biospecimen and/or my personal data as indicated above for this purpose. The usage of data comprises storage in an electronic data base and linkage to other research data.  
   Yes  No

4. I hereby agree that my specimen and/or personal data as indicated above can be used for general medical research purposes and transferred within Europe for this purposes.  
   Yes  No
5. I hereby agree that my specimen can be anonymised and used for general research purposes and transferred in anonymised form. I understand that my specimen will be used for many different research purposes and that reclaiming is excluded in case of anonymised transfer. I understand that storage of my specimen is unlimited in time and will last beyond death. I relinquish all rights to these samples which I am donating to XXXBiobank. Yes  No

6. I hereby agree that this institution may contact me at any time in future in order to ask me for further cooperation in specimen and/or personal data donation. My contact details may be stored exclusively for this purpose and in no case disclosed to any third party. Yes  No

7. I understand that no incidental findings will be given to me and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment). Yes  No

Signature of biobank  Signature of donor/data subject or of legal representative in case of minor or legally incapacitated donor