Informed Consent Guide

Biobank and registry based research (prospective samples and data)

International soft tools, such as the Nuremberg Code states that free and informed consent should be obtained in research involving humans. The World Medical Association (WMA) declaration of Helsinki and WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks present the ethical principles for medical research involving human subjects, including research on identifiable human material and data. Further considerations are enclosed in other documents, such as Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa or the Committee of Ministers of the Council of Europe adopts Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. Each human subject in medical research must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, the anticipated benefits, potential risks of the study and possible discomfort.[1] Other guidelines also stress that participation needs to be voluntary and without inducement by financial or other personal gain.

The process of obtaining informed consent can stimulate dialog between researchers and potential participants. Hence, it goes beyond the mere signature…. The underlying values that informed consent serves to research participants are to have respect for persons and their autonomy.

This document is a proposal of an informed consent, developed by study and compiled/brought together various forms, templates and articles in the area.[2] Depending on the research question it can be formed so it fits its purpose and demands. For biological samples and registry based research, as opposed to research on human subjects directly, there are minimal, if any, physical risks to the research participants. The potential harm is related to sensitive information ending up in the wrong hands and being used to the disadvantage of a person.[3] Therefore it is important to have safe routines for the biobank and the data collected to minimize the risk of social, psychological, or economic harm. To ensure that, information about storage, analysis and use of biological materials for research participant is important to inform. Furthermore, it is essential to ensure the protection of informational privacy of research participants as provided in the international, regional and national protection frameworks, and comply with quality assurance procedures in research.

Informed consent

1. Title and information about the researcher responsible for the project

Title
Name and function of principal researcher for the project:
Name and function of collaborators:

[1] *World Medical Association. Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects ; October, 2008 [art. 24] latest version available electronically at http://www.wma.net/en/30publications/10policies/b3/17c.pdf.*

[2] E.g. *Eurobiobank, WP5 Informed consent form, 2007; EpiHealth, Informationsbroschyr, 2011; Deschenes et al., 2001.*

[3] *Eriksson, S. & Helgesson, G. (2005). Potential harms, anonymization, and the right to withdraw consent to biobank research. European Journal of Human Genetics 13, 1071–1076.*

Institution:
Project financed by:
Telephone number, address and e-mail of principal researcher:

2. Research project description

Introduction*: State that this involves research, what the purpose of the research is and the reason for the request to participate.* ***Use lay terms to explain research possibilities.*** *State that it is voluntary, that the person is free to withdraw from the study at any time, and that if so that the samples will be destroyed or rendered irreversibly anonymous (anonymized) as applicable. If the participant is in for treatment, inform that he/she can quit at any time without this affecting current treatment or healthcare.* ***If genetic research is a possibility, explain what this is and what implications for them. Explain your biobank's policy regarding research results and incidental findings.***

Background of the study: *Give an overview of the background of the research project and state that an ethics committee/advisory board has already approved of the research protocol/project and that it complies with the legal and ethical requirements. Provide further details of the approval (e.g. number of decision of the committee/board) in order for the participant to verify it if desired. Give information regarding who funded or sponsored the research (e.g. pharmacy industry, research grant etc.). Inform if further research collaborations may include both academic and commercial partners.*

3. Description of the procedures of the study

The participation

Give information of what will be requested from the participant, what methods will be used (e.g. tests, interviews, surveys) and the duration of the subject's participation. Inform that the samples will be stored in a biobank and only be used in research after ethical approval is granted by the relevant body. State if consent will be specific (only for a specific research project/protocol) or broad (e.g. for other projects, with other researchers, and if this implies that the individual will be re-contacted. If your biobank has a website inform them if the changes in the research scope are accessible through the website. If consent is broad inform that any future research project must be approved by an ethics review board and that all technical means and safeguards for the protection of their privacy, are in place. Inform about any other plan recontacting, in the future for additional samples or follow-up info about the subject's health or medical care and possible recruitment of other family members.
Inform participants that their sample will not be sold for profit.

- **Handling of data, confidentiality and results**

Give information about whether data/samples will be stored/used, as anonymous, identified or pseudonymised (rendered reversibly anonymous)) and if pseudonymised, that the key to the code that links the person to the sample will be stored in a safe place and accessed only by the PI or authorized by the latest, person who shall abide by confidentiality.

> *Explanation: Regarding anonymous samples, there are no links to the individual participant [although there may be general descriptions such as 'man, aged 50–55 years, cholesterol level 4240mg per 100 ml']. Identified samples are linked to*

the individual in a way that makes them immediately identifiable. Pseudonymised samples and data imply a direct link to the individual, usually through a random set of numbers or letters, or a bar code.

Inform about the duration of storage and where the samples will be stored, and if they may be sent abroad to be analyzed or stored. Explain implications of the decision. Inform of what will happen to samples after completion of the study (stored for future research, destroyed, anonymised). Inform the subject of the entitlement to have access to data/info about oneself, and who to contact. In case there is a Data Protection Officer (DPO) write his full contact details and also inform them that they can lodge a complaint at the Data Protection Authority (DPA) in case of privacy breach of their data in case your legislation provides such a right to the subjects (Under EU law, the General Data Protection Regulation-GDPR- lodging a complain at the DPA is a right of the individual). Inform where personal data will be stored and for how long and if certifications or other accreditations are obtained (e.g. ISO etc) state so. Inform if a privacy policy is in place and if your Biobank/Registry follows the SOP's. Inform who will have access the subject's data or name, who is responsible for the personal data and who has access to the subject's medical data. Set in place confidentiality agreements with your colleagues binding them with confidentiality in case they handle health data. Inform if individual and/or general results or incidental findings will be returned to the sample participant donor, and if so how they will be communicated. Give information that research results will be published in scientific papers, with no identifying data retained. Inform if personal data will be linked to other registries, who is responsible for the safety of data and if data will be shared with international partners. Inform about other informational privacy considerations as appropriate.

4. Risk or discomfort to the subject

Give information about risk or discomfort to the subject: physical risks, side effects, pain, long term effects, emotional effects, effects to integrity, socio-economic risks, risks concerning privacy breach and measures you have taken to avoid such breach. In that regard, you may need to account for the vulnerabilities associated with the group a participant could belong to.

5. Benefit to the subject or to others

Information about benefits associated with this research: to the subject, to the subject's family, further knowledge in the area of……..(write the area of your research), helping future patients, benefits to society as a whole.

6. Research results and incidental findings

- *Provide information regarding individual research results and incidental findings (whether or not they are going to be disclosed, if yes, how this will be done and whether the biobank intends to provide directly a genetic consultation to the participant or inform the participant's physician or the participant himself/herself on these findings). In the latest case ask the participant to provide the contact details of his/her physician.*

7. Insurance, repayment, costs

Describe if there will be any payment, or compensation, and if there is access to justice and remedy (a right to lodge complaint, recover compensation in money, or kind) e.g. if something happens you will be provided with medical care).

8. Conflict of interest

Inform about any conflicts of interest here.

9. Statement to read before signing

- I have been given sufficient information of the project, oral and written, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time.
- I approve that my samples and data are used as described in the informed consent information.
- I have received a copy of this informed consent.

10. Sign and contact to the responsible for the procedure of the study

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Date	Signature, subject	Name, subject
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Date	Signature, researcher	Name, researcher

11. Contact information to responsible persons

Give contact information to a person that the research participant can ask questions about his or her rights and if injury occurs. Also give contact information to the researcher responsible for the study.

DISCLAIMER: This is a Sample Template. The template is based on Jennifer Viberg Johansson and Mats Hansson template Version 1.6 2017-11-02, as modified by Santa Slokenberga, Jane Reichel & Olga Tzortzatou for the purposes of B3Africa project. Any use of this Sample Template is exclusive responsibility of the respective users.