Explanation for users of the Model Research Protocol Biobank

Aim Research Protocol

This protocol describes the use/distribution of body material and/or associated data from a sub-biobank. The research question is formulated in this protocol, which must include background information and rationale. It is also specifically stated which material is requested, which experiments will be carried out and how this benefits science. The same is done for data.

Explanation of typography: model can be used for a research protocol as follows from the next page:

1. Please use plain text as standard and only adjust it if it is not correct for the sub-biobank in question.
2. Replace [description/options] with the factual information OR choose the term that bet suits the nature of the sub-biobank.
3. Explanations can be found in the <*text*>. You can delete this explanation.

This model was created in NFU-project Mutual Recognition (Wederzijdse Erkenning). You can use the feedback form on the Health-RI website to report inaccuracies or bottlenecks.

General information about biobanks can be found on the Biobanken Netherlands website: Biomedisch onderzoek in Nederland | Biobanken Nederland.

Research Protocol sub-biobank

Title of project	
Version date	
Version number	
Name of the biobank	
Applicant	Name: [first- and last name] Department & function: [department and function] E-mail: [e-mail]
Internal coordinating investigator / project leader	Name: [first- and last name] Department & function: [department and function] E-mail: [e-mail]
External coordinating investigator / project leader	Name: [first- and last name] Department & function: [department and function] E-mail: [e-mail]
Co-investigator(s)	*<Please include name(s), department(s), institution(s)>*
Type of research	Will the planned research distributed material/data to different institutions? ☐ Not applicable, material/data will not distributed ☐ Non-commercial partner(s) ☐ Commercial partner(s)
Type of request	What is requested? ☐ Clinical data ☐ Biomaterial ☐ Biomaterial + Clinical data

Name	Signature	Date
Biobank responsible [First- and last name]		

ENCLOSE following documents (if applicable):

- Approval of scientific committee or other committee if protocol has previously been reviewed
- Patient information folder(s) and consent form that have been used (not signed forms)
- In case of WMO-study, add protocol
- In case of a collaboration, include agreement (M(D)TA, licensing agreement, or other

1. GENERAL INFORMATION	
Introduction, rationale and aim	*<Please specify background/rationale and hypothesis of the study. The protocol must contain an introductory section explaining why the research is to be carried out. The scientific relevance of the project should be indicated with references and/or convincing arguments should be given that there is not sufficient knowledge available to explain the problem or for the need to test what is known. It should be clearly stated which new information this study may add to what we already know.>*
Research question(s)	*<Please specify the research question(s) of the study. The objective(s) of the study are the questions that the study is intended to answer and are based on the scientific rationale and/or hypothesis formulated.>*
Outcome measure(s)/endpoint(s)	*<Describe the outcome measure(s). Indicate for each research question which outcome measure(s) the result(s) of the research will be displayed.>*
Study design	*<In vitro experimental, cross-sectional, longitudinal>*
Rationale of sample size	*<The number of subjects required for the study should be justified. The number of subjects should always be large enough to provide a reliable answer to the questions addressed. Also, the size of detectable differences should be of clinical relevance.>*
Analytic strategies	*<Please give a description of the procedures, techniques, methods and/or tests to be used to assess the defined objective(s).>*
Statistical analyses	*<Describe in general terms, how the data (categorical data and/or continuous variables) will be presented (quantitative and/or qualitative), and how the data will be statistically analyzed. Eg. Univariate analysis (Pearson correlation coefficients, t-test, ANOVA (univariate), etcetera) or multivariate analysis (multiple linear regression, multiple logistic regression, proportional hazards (Cox), etcetera).>*
Relevance	*<Describe the potential relevance of this research.>*
Incidental findings	*<If it is possible that new data regarding the health status of participants may be discovered when participating in the proposed study, indicate this here. If unfiltered genome or exome analysis is done, there is always a risk of incidental/secondary findings.>*

2. POPULATION	
Disease group(s)	*<Please specify, and add inclusion/exclusion criteria and numbers per group>*
Control group	*<Please specify, and add inclusion/exclusion criteria and number of this group>*
Familial individuals	*<Please specify, such as patients parents and/or other relatives, and numbers of this group>*
Age of included subjects, and status	☐ ≥16 years old, and able to give informed consent ☐ ≥16 years old, and incapacitated subjects ☐ 12-15 years old, and able to give informed consent ☐ 12-15 years old, and incapacitated subjects ☐ <12 years old

Rationale to include minors/incapacitated subjects (if applicable)	*<Why is it necessary to include this subject group?>*

3. CLINICAL DATA		
Clinical data categories	☐ Demographic data ☐ Historical data ☐ Questionnaire data ☐ Risk factors ☐ Genetic research/Heredity data ☐ Familial data	☐ Physical examination ☐ Treatment ☐ Pathological data ☐ Lab data ☐ Other, [specify]
Directly identifying (personal/communication) data	☐ Residence ☐ Zip code and/or address ☐ Date of birth ☐ Age	☐ Gender ☐ Race or ethnicity ☐ Patient and/or pathology number ☐ None
Identifying data	*<Specify what genetic or epigenetic data is used in and/or results from an analysis of a biological sample. Explain whether it concerns, for example, a partial profile, a complete profile or single mutations/single nucleotide polymorphisms (SNPs). Also indicate which technique(s) the data was/are generated (e.g. karyotyping, PCR, Sanger, array or NGS). Identifying data can also entails images, please describe which images are used and which analyses will be applied.>*	
Data management - Source (which one and who has access) - Coding (how and who) - Key (access and safeguarded) - Data security - Privacy of subjects	*<Please describe the procedures for handling clinical data, which electronic patient system or other source will be used, how data are coded, who has access to the source data (clinical data only by treating physician), by whom the key to the code is safeguarded (someone who is not involved in the study), which steps are taken to ensure data security and how the subjects privacy is protected. Keep in mind that the key file should be stored separately form the coded data.>*	
FAIR	*<Please describe FAIR.>*	

4. BIOMATERIALS			
Material type	☐ Whole blood ☐ DNA ☐ ctDNA ☐ RNA ☐ Plasma ☐ Serum ☐ PBMCs ☐ iPSCs	☐ Cerebrospinal fluid ☐ Saliva ☐ Cheek mucus ☐ Nasal mucus ☐ Urine ☐ Feces ☐ Ascites ☐ Bile	☐ Pancreatic fluid ☐ Tissue, [specify type] ☐ Other, [specify]
Quantity of material type	<Volume, amount, concentration>		

Processing and destruction	*<Describe how biomaterial is processed (fully traceable, coded etc.) and how leftover material is handled (destroyed or returned)>.*
Material origin	What type of material is used (please check what applies, multiple answers possible)? ☐ Pure left over material of regular care, no longer diagnostics possible ☐ Left over material that remains after treatment/diagnostics If so, please indicate how it is ensured that sufficient material for (additional) diagnostics remains available: [specify] ☐ Left over material from a WMO-research: [include reference number] ☐ Left over material from a nonWMO-research: [include reference number] ☐ Material from a biobank (de Novo Biobank): [include reference number] ☐ Historical collection ☐ Material from elsewhere: [specify]
Specific applications	☐ Research with fetal and/or embryonal tissue (including gametes) ☐ Research with data that are considered intrinsically traceable (e.g. WGS) and where the data is shared more widely than internal use* ☐ The amplification of body material into long-lived (stem)cells (e.g. iPSCs), cell lines and/or organoids* ☐ The amplification of body material into gametes and/or embryo-like structures ☐ Transfer of data and/or material to parties in countries outside the EU (excl. Norway, Liechtenstein and Iceland)* ☐ Research with a commercial party* ☐ The development of human-animal combinations* ☐ Health screening – *bevolkingsonderzoek** ☐ Material available after death* ☐ None of the above *Sensitive applications: Ask for explicit consent and otherwise describe why asking permission is no longer reasonably possible or can be required. Commercial use is not permitted if it is not possible to obtain explicit consent, unless the company provides a service, whereby the company does not acquire any rights to the body material and/or results.
3.1 Extra information specific applications	
Research with fetal and/or embryonal tissue	*<Which material is requested? Please justify why embryos, fetal tissue or germ cells are needed for this project.>*
Research that is considered intrinsically traceable (WGS)	*<Which material is requested? Please justify why a complete genome analysis is needed for this project. What are the risks of individual incidental findings and how will be handled if an incidental finding is found?>*
Amplification of body material into long-lived (stem)cells (iPSCs), cell lines and/or organoids	*<What material is requested and what will be produced? Please justify why this material is needed for this project. Are long-lived (stem)cells, cell lines and/or organoids being created? With what purpose?>*

Amplification of body material into gametes or embryo-like structures	*<What material is requested and what is produced? Please justify why the development of gametes or embryo-like structures are needed for this project.>*
Research with privacy risks (outside EU)	*<What privacy risks are there? What is the justification for taking these risks? Is body material and/or data derived from it shared with parties outside the EU (excl. Norway, Liechtenstein and Iceland)? If different privacy rules apply there: how is material/data protected in an appropriate manner as in the Netherlands? What is the justification for sharing body material/data with these parties?>*
Commercial party involvement	*<Does it concern a distribution of material/data to or a collaboration with a commercial party? And what exactly does this release/collaboration look like? To what extent is the applicant involved? Provide justification for collaborating with, or release material/data to, commercial party.>*
Development of human-animal combinations	*<Which material is requested? Please justify why the development of human-animal combination is needed for this project.>*
Health screening	*<Which material is requested? Describe the population survey in question.>*
Material available after death	*<Please explain how the material became available, how permission was given and by whom.>*

4. ETHICAL CONSIDERATIONS		
	Consent	**No consent**
Biomaterial	☐	☐
Clinical data	☐	☐
Specific consent in case of (sensitive applications)* *Ask for explicit consent and otherwise describe why asking permission is no longer reasonably possible or can be required. Commercial use is not permitted if it is not possible to obtain explicit consent, unless the company provides a service, whereby the company does not acquire any rights to the body material and/or results.	☐	☐
CONSENT IS GIVEN		
How was consent asked and given?	☐ WMO-consent ☐ nonWMO-consent ☐ Biobank-consent ☐ General consent (if applicable; *toestemming aan de poort*) ☐ Specific consent (retrospectively asked with consent form or note in the electronic patient file) *<In case of multiple answers, please provide which consent was given by which group/number of patients, and/or material type.>*	
NO CONSENT IS GIVEN		
Was there an opt-out procedure?	☐ No, there was no formal op-out system ☐ General opt-out	

	☐ Specific opt-out, namely *<Please give a description of the opt-out procedure and how objection is archived. Samples and associated data should be irreducible for the researchers, describe how this will be safeguarded.>*
Why is no consent asked?	☐ The address details of the subjects can no longer be traced (due to they moved or patients are not treated anymore); *<included how many subjects can be traced and how many cannot be traced>* ☐ Majority of subjects have passed away; *<included how many are still alive and how many subject have passed away>* ☐ Asking consent cannot reasonably be expected because of the larger number of subjects ☐ Asking for consent is too burdensome for the subjects; *<provide a substantiation, preferably with references>*
Rationale and description why consent was not asked	*<Provide information/rationale why consent was not asked. Please provide also the information about sensitive applications. Included as much information as possible.>*
Additional questions	1. Why does the research serve the general public health) interest? *<provide information>* 2. Argue that all personal data are necessary to carry out research. *<provide information>* 3. How is direct or indirect identification of the participant reasonably prevented? *<provide information>*

References

<Include all references published in peer reviews journals that are relevant for the study.>