# LUMC Research Protocol (retrospective non-WMO research with body material/biobank)

# This page concerns general information, submission procedures/regulations regarding a Research Protocol (retrospective non-WMO research with body material/biobank)

**General information**

* Provide version number and date. All following versions (after feedback of Science Committee, LUMC Review Committee Biobank & biomaterials) should be updated by version number and date.
* All amendments will be given an updated version number and date. And changes to the protocol should be kept in track changes.

**First submission**

* Submission to Science Committee
* After approval, submission to LUMC Review Committee Biobank & biomaterials ([TCBio@lumc.nl](https://lumc.zenya.work/management/hyperlinkloader.aspx?hyperlinkid=2cea6b2a-95a9-487d-81b0-99faab1849da))
  + In case it concerns an extern collaboration, add agreements (MTA/DSA or other contracts: drafted in collaboration with LURIS).
* After approval material can be used for research

**Amendment submission**

A ‘substantial amendment’ is defined as:

* Request of 20% extra samples of the original request with the conditions:
  + the same research question;
  + the same study population.
* Extra clinical data of the studied population;
* Another type of body material;
* A new research question is defined; or
* Another patient population is added.

All substantial amendments will be notified to the LUMC Review Committee Biobank & biomaterials.

Non-substantial amendments will be notified to the Chair of the LUMC Review Committee Biobank & biomaterials.

**In case of a biobank with approved distribution protocol**

* Submission to chair of LUMC Review Committee Biobank & biomaterials ([TCBio@lumc.nl](https://lumc.zenya.work/management/hyperlinkloader.aspx?hyperlinkid=2cad85f6-9181-4508-9eb9-6242ab63cd6f)):
  + In case it concerns an extern collaboration, add agreements (MTA/DSA or other contracts: drafted in collaboration with LURIS).



# LUMC Research Protocol (retrospective non-WMO research with body material/biobank)

|  |  |
| --- | --- |
| **Title** | ***<Type full title of protocol>*** |
| **Version** |  |
| **Date** |  |
| **Biobank responsible/Biobank founder <in case of biobank>** | Name:  LUMC department:  E-mail: |
| **Coordinating investigator/project leader** | Name:  LUMC department:  E-mail: |
| **Co-investigator(s) within LUMC** | ***<please include names, department(s)>*** |
| **Co-investigator(s) outside LUMC (institution/company) <if applicable>** | ***<please include names, institution(s)>*** |
| **Type of research** | Clinical data (within the LUMC)  Clinical data (external collaboration, data stays at LUMC)  Clinical data (external collaboration, data outside LUMC)  Clinical data + biomaterial (within the LUMC)  Clinical data + biomaterial (external collaboration: analyses performed at LUMC)  Clinical data + biomaterial (external collaboration: analyses performed outside LUMC) |

# LUMC Research Protocol (niet-WMO research with body material protocol/biobank)

1. **Introduction and rationale**

*<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.>*

1. **Objectives**

*<Please specify the objective(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.>*

1. **Population**

Disease group(s) & number of subjects per group:

Control group & number of controls: <*In case of control population, the LUMC voluntary donor service (LuVDS) could be used.>*

Familial individuals, such as patients parents and/or other relatives & number of this group:

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 questions addressed. Also the size of detectable differences should be of clinical relevance.>*

Age of included subjects, and status (adults/minors/incapacitated):

≥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 included minors/incapacitated subjects (if applicable):

1. **Clinical data**
   1. **Variables**

*<Please specify the requested clinical data to answer the study objective(s). Provide all the clinical information necessary to answer your research question, such as social and/or demographic data, disease characteristics: age, gender, etc. In section 10 you describe who will provide this information.>*

☐Demographic data

☐Historical data

☐Questionnaire data

☐Risk factors

☐Genetic research/Heredity data

☐Familial data

☐Physical examination

☐Treatment

☐Pathological data

☐Lab data

☐Other, such as …………………………

* 1. **Data management**

*<Please describe the procedures for handling clinical data, how data are coded, who has access to the source data, by whom the key to the code is safeguarded, which steps are taken to ensure data security and how the subjects privacy is protected.>*

1. **Biomaterials** 
   1. **Type: volume/concentration/amount**

*<Please tick the box(es) of material that will be used. Include exact sample volume, or in case of DNA/RNA the concentration or amount of tissue blocks.>*

Whole blood Click here to enter text.µl

☐ DNA Click here to enter text.ng/µl

☐ ctDNA Click here to enter text.ng/µl

☐ RNA Click here to enter text. ng/µl

☐ Plasma Click here to enter text.µl

☐ Serum Click here to enter text. µl

☐ PBMCs Click here to enter text.million cells

☐ iPSCs Click here to enter text.

☐ Cerebrospinal fluid Click here to enter text.µl

☐ Saliva Click here to enter text.

☐ Cheek mucus Click here to enter text.

☐ Nasal mucus Click here to enter text.

☐ Urine Click here to enter text.µl

☐ Feces Click here to enter text.

☐ Ascites Click here to enter text.µl

☐ Bile Click here to enter text.µl

☐ Pancreatic fluid Click here to enter text.µl

☐ Tissue, such as Click here to enter text.

☐ Other, such as Click here to enter text.

* 1. **Collection of biomaterial**

Where/how is the material collected:

☐Pure left over material of regular care, no more diagnostics are possible

☐Left over material after diagnostics and/or treatment

If so, please indicate how it is ensured that sufficient material for (additional) diagnostics remains available: Click here to enter text.

☐Left over material of WMO-study (attach research protocol and patient information sheet)

☐Material from outside the LUMC

☐Historical collection of biomaterial, registered as nader gebruik biobank (further use biobank)

☐Biobank material

* 1. **Methods: Sensitive applications / Analytic strategies**

Sensitive applications:

☐Research and applications with a significant risk of individual incidental findings\*

☐Research and with data that are considered intrinsically traceable (e.g. WGS) and where the data is shared more widely than within the LUMC\*

☐Transfer of data and/or material to parties in countries outside the EU, where GDPR does not apply\*

☐Research with a commercial party, whereby results become available to that party\*

☐The amplification of body material into long-lived (stem)cells, cell lines and/or organoids\*

☐The development of human-animal combinations\*

☐None of the above

\*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. Sharing with countries outside the EU is also not possible without consent.

Procedure:*<Please give a description of the procedures, techniques, methods and/or tests to be used to assess the defined objective(s). Especially describe sensitive uses like creation of cell lines, use of embryonal or foetal tissue, development of organoids, GWAS/WES/WGS, etc.>*

* 1. **Storage location**

*<Describe where biomaterial is stored (fully traceable, coded etc.), which biomaterial information management system is used (e.g. SampleNavigator (in case of stored at Biobankorganisation)), who has access to this system and who has access to the biomaterials).>*

* 1. **Processing and destruction**

*<Describe how biomaterial is processed (fully traceable, coded etc.) and how leftover material is handled (destroyed or return to freezer)>.*

1. **Statistical analysis**

*<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 analysed. Eg. Univariate analysis (Pearson correlation coefficients, t-test, Anova (univariate), etcetera) or multivariate analysis (multiple linear regression, multiple logistic regression, proportional hazards (Cox), etcetera)>*

1. **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.>*

1. **Legal consideration**

*<When sponsor and/or another institution/company is involved, please include information about the contract.>*

1. **Ethical considerations** 
   1. **Consent and/or opt-out procedure**

Category of material and clinical data (please tick where appropriate, multiple options possible):

|  |  |  |
| --- | --- | --- |
|  | **WITH consent** | **WITHOUT 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. Sharing with countries outside the EU is also not possible without consent.

If there is **no consent** for the use of (part of) **biomaterial/data**, substantiate why consent is not asked:

|  |  |  |
| --- | --- | --- |
|  | **Biomaterial** | **Clinical data** |
| The address details of the subjects can no longer be traced (due to they moved or patients are not treated anymore) |  |  |
| Majority of subjects have passed away |  |  |
| By asking for consent a selection bias is expected, which will make the data no longer representative |  |  |
| 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*> |  |  |

Opt-out procedure (prerequisite if **consent is not available**):

No, there was no formal opt-out system (LUMC broad system is introduced November-2022)

Yes, LUMC-system (since November-2022)

Yes, an opt-out procedure is in place, 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.>*

1. **References**

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