

Lab ID:filled by ILM.....

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UNIVERSITÄT LEIPZIG – Medizinische Fakultät

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Order form of laboratory diagnostics for clinical studies with human material for external institutions

Project name:

Short description of the project: (if necessary use an additional sheet):

Study duration: from till

Principal Investigator (PI):

Institution:

Address:

Phone: Mail:

Study coordinator:

Phone: Mail:

☐ Contract research

☐ Scientific cooperation with ILM (Please attach the concept of the project and the study protocol)

Note: Before the initiation of the study, the allocation of the work during the study performance should be pre-discussed and agreed by the upper management of the ILM. ILM supports the project with standardized and research-based laboratory analysis and scientific support, whereas principal investigator is in charge of study design, selection of the method, study performance, and the analysis of the results. Responsible person(s) in ILM will share the authorship in the publication according to the rules of the German Research Society (DFG) for good scientific practice.

☐ I hereby confirm that the use of the biosamples for the research project has been checked by an **ethics committee** from an ethical, medical-scientific and legal point of view and that a positive ethics vote has been issued (where appropriate in the context of the approval of a clinical trial).

Ethics committee reference number/EU-CT-No.:
Date, signature **Principal Investigator**

Request for items of study organisation:

- ☐ Design and preparation of lab kits
- ☐ Design of laboratory request form (LRF)
- ☐ Design of barcodes
- ☐ Design of lab manual and/or flowchart
- ☐ Other:

Request for QM-documents:

- ☐ Certificate of external quality assessment test
- ☐ Reference values
- ☐ CV institute director

Laboratory Analysis

Note: No output of reference values without specifying the year of birth and gender.

Parameter	Material

☐ Sample storage Biobank (see Appendix I)

☐ Profile of parameters required

Sample shipment: ☐ single sample transfer (Monday – Friday 8 a.m. to 5 p.m.)

☐ transfer as batch at the end of the study

Estimated number of total analyses:

Number of subjects planned:

Number of samples per subject:

Immediate notification in case of pathological values expected?

If yes, please enter the name of a contact person and phone number:

Transfer method of lab report:

☐ post

☐ fax

☐ Mail per lab report (PDF)

☐ data query (additional costs)

Address for lab report transfer: Name:
street, postal code, city:
Fax: Mail:

Notes:

1. The processing time of this application is up to 6 weeks.
2. Cost quotation can only be prepared based on the complete order form.

Below here will be filled by ILM

Study feasibility: ☐ yes ☐ no

If yes:

1. Agreement preparation / responsible person at ILM:
2. Scientific supervision at ILM:
3. Comments: