**Proposal for LIFE Project Agreements (LIFE PV)**

Version 2.6 from 07.11.2023

**Project number, to be assigned by LIFE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date received:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**A. General**

New application: [ ]  yes [ ]  no

A project prolongation is requested: [ ]  yes [ ]  no

A project extension is requested: [ ]  yes [ ]  no

|  |  |  |
| --- | --- | --- |
| **A1.** | **Responsible person / applicant** | **Further contact persons** |
| - Name, first name: |       |       |
| - Institute, organisation: |       |       |
| - Address: |       |       |
| - Tel. no.: |       |       |
| - E-mail: |       |       |

**A2. Project title**

- Short title:

- Long title:

**A3. Project type**Organisational evaluations are used for quality control.

Standard procedure: Used for scientific research and publications.

[ ]  Organisational evaluations [x]  Standard procedures

**A4. Connection to other projects**

[ ]  NO [ ]  YES, which number:

[ ]  not known

**A5. Scientific background and preliminary work**

(State of research, own preliminary work, max. 1 page)

- Please add project-related publication list as attachment

**A6. Scientific question, study design and analysis plan**

(Research hypothesis, specific objectives, max.1/2 page)

(Study design, case number justification, data preparation, analysis plan incl. information on statistical methods, max.1/2 page)

**Biometrician in charge:**

Name:

Institution:

**A7. Planned work programme**

- Workflow of the most important steps with duration

- Timetable and important milestones (e.g.: data set, evaluation, draft publication).

- Results to be achieved (e.g.: publication, patent specification, application for third-party funding).

**A8. Planned publications**

Aspired Journal:

Patents are sought? [ ]  YES [ ]  NO [ ]  still unclear

**A9. Participating partners / authors**

Please list all responsible participating scientists. The list has not to be complete in terms of co-authors of included publications.

All partners and scientists responsible for required assessments should be informed before submitting the proposal. DFG Guidelines and good scientific practice apply here. Please send any objections by e-mail to the LIFE office (info@life.uni-leipzig.de).

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Institution** | **Signature/ Acknowledgement** |
| **1**Responsible person, applicant |       |       |  |
| **2** |       |       |  |
| **3** |       |       |  |
| **4** |       |       |  |

Further partners/authors are attached: [ ]  NO [ ] YES

**A10. Planned applications for third-party funding**

Do you plan to apply for third-party funding on the basis of this project?

[ ]  NO [ ]  not foreseeable [ ] YES

If YES, when?

 With whom?

**A11. Comments on Section A**

Place for comments or questions by responsible scientists or members of the internal project commitee (PV Task Force) on the content of Section A.

[to complete by LIFE]

**B. Description of the data**

 (If questions B1 and/or B2 are answered with "yes", please **always** include a completed assessment list (DQP list) as an **attachment**).

**B1. Is data requested**? [ ]  Yes [ ]  No

(If "yes", please inform all assessment responsibles for the data you are interested in,

cc please to the LIFE office. )

**B2. Is laboratory data requested**? [ ]  Yes [ ]  No

(If "yes", please inform the person responsible for the laboratory and obtain consent if necessary)

**B3.** Person **entitled to receive the data**  [ ]  Applicant person **OR:**

Name, first name:

Organisation, Institute:

Address:

Mail:

**B4. Requested duration of data use (expected project duration)**

from:       until:

**B5. Cohorts to include**
(see [LIFE Datenportal](https://www.uniklinikum-leipzig.de/einrichtungen/life/life-forschungszentrum/life-datenportal) and for LIFE Child the [LIFE CHILD Datenportal](https://home.uni-leipzig.de/lifechild/datenportal/))

**ADULT**

[ ]  Adult Baseline
Data (examinations, interviews, laboratory, …) of **10,000** subjects recruited for baseline examination

[ ]  Adult Baseline Plus

Data from all baseline subjects, including test, feasibility and pilot subjects

[ ]  Adult 1st follow-up

Data from the 1st follow-up survey of the LIFE-Adult study (n= 5,500)

**Long Covid**

[ ]  Long Covid Baseline

Data (examinations, interviews, laboratory, ...) of all baseline subjects (n=270)

**HEART**

[ ]  B3 Baseline
Baseline recruitment study data (n=6995)

[ ]  B3 Baseline Plus
Study data of the 2nd study inclusion (n=26)

[ ]  NOBCAD2014
Study data of the NobCAD study (n=866)

**CHILD**

[ ]  Child Health cohort

Regular examinations from the 3rd month of life)

[ ]  Child Obesity
Obesity sample and its control group - sub-cohort of the Child Health cohort

[ ]  CHILD Pregnancy
Data from around the 24th and 36th week of pregnancy

**CHILD Depression**

[ ]  Survey wave 1 (8 - 14 years)

 [ ]  Baseline examination (examination day 1, total sample)

 [ ]  Additional examination (examination day 2, EEG/TSST/Basiscortisol, subsample only)

 [ ]  Survey wave 2 (10 - 16 years, AMIS sub-project)

 [ ]  Survey wave 3 (Written survey, LIFE Child-Depression and AMIS)

**Head and neck tumours**

[ ]  Total sample

**Depression patients** (Günther & Suslow)

[ ]  Total sample

**ADULT Depression 40-60** (Jawinski & Hensch)

[ ]  Total sample

**B6. Specification of the requested sample**

(see [LIFE Datenportal](https://www.uniklinikum-leipzig.de/einrichtungen/life/life-forschungszentrum/life-datenportal) and for LIFE Child the [LIFE CHILD Datenportal](https://home.uni-leipzig.de/lifechild/datenportal/))

In the case of different cohorts, please specify the requirements.

 1) Age range of subjects (please specify):

 from      to       in years

 2) Further inclusion criteria (e.g. completeness of a target variable)

 3) Further exclusion criteria (e.g. specific group of drugs***)***

**B7. List of items/assessments from the assessment list (DQP list)**

[ ]  List of characteristics and justification for primary target variables (ZG) and for co-factors (KF) is attached.

Note: It is essential to provide specific justification for the characteristics, separately for primary outcome measures and for cofactors, due to the nature of the PV question.

**B8. Return of generated / calculated data to the LIFE research database**

[ ]  List of generated items is attached.

The responsible person (applicant) will sent the respective data to the LIFE research center until (anticipated date):

**B9. Data Transfer Agreement**

For external partners, a Data Transfer Agreement must be completed and sent to the LIFE office. Please contact the LIFE office before submitting this proposal (info@life.uni-leipzig.de).

[ ]  Data Transfer Agreement (DTA) is required and will be enclosed with the attachments.

**B10. Comments on Section B**

Under this item, comments or questions by assessment responsibles or members of the internal project commitee (PV Task Force) on the content of Section B can be added.

[to complete by LIFE]

**C. Description of additional laboratory analytics**

**C1. Does the project require the additional determination of laboratory values?**

 [ ]  YES [ ]  NO

Justification:

(If "yes", the **joint** submission of the project with the laboratory managers and the confirmation of funding, indicating the funding source, is binding for the activation of the project. )

**C2. Person authorised to receive the samples** [ ]  Applicant person **OR:**

Name, first name:

Organisation, Institute:

Address:

E-mail:

**C3. Description of requested sample material**

- Inclusion and exclusion criteria (precise specification for sample selection):

- Survey wave (please specify):

- Other filter conditions:

|  |  |  |  |
| --- | --- | --- | --- |
| Cohort | Sample size | Parameter | Sample material |
| Type | Quantity needed per subject | Concentration |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
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(The availability of the intended sample material must be checked **before** submitting the proposal. )

**C4. Laboratory analytics**

Laboratory method Responsible laboratory partners

[ ]  Clinical chemistry

[ ]  Mass spectrometry

[ ]  Cytometry

[ ]  Transscriptome [ ]  ARRAY [ ]  PCR [ ]  Seq

[ ]  Genotyping [ ]  ARRAY [ ]  PCR [ ]  Seq

[ ]  Epigenetics

[ ]  Other

**C5. Material Transfer Agreement**

For external laboratory partners, a Material Transfer Agreement must be completed and sent to the LIFE office. Please note that for legal and ethical reasons, any analysis of LIFE samples at industrial partners' sites requires consultation with the LIFE office prior to submission of this proposal.

[ ]  Material Transfer Agreement (MTA) is required and will be enclosed with the attachments.

**C6. Comments on section C**

Under this item, comments or questions by assessment officers or members of the internal project commitee (PV Task Force) on the content of Section C can be added.

[to complete by LIFE]

**D. Signatures**

Responsible person, applicant and other contact persons:

Cohort leader / PI:

Laboratory manager:

LIFE office:

LIFE Board:

**E. Attachments**

[ ]  Participating partners / authors

[ ]  Project-related publication list

[ ]  Assessment list (DQP list)

[ ]  List of derivatives likely to be created

[ ]  Data Transfer Agreement

[ ]  Material Transfer Agreement

[ ]