**Research Project Submission– LUCID National Data Stream**

***Please ensure that all sections are completed before submitting your research project.***

**Date of submission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Decision of the LUCID Executive Board: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **INTRODUCTION**
   1. **TITLE** [A brief, descriptive title that summarizes the main focus of the research project]
   2. **SUBTITLE** [Project Subtitle]
   3. **AREA**

* Research
* Quality Monitoring
  1. **ETHICS**
* Project submitted and accepted: \_\_\_\_\_\_\_\_\_\_\_\_\_(EC number)
* Project to be submitted
* Waiver obtained (add a proof in the Annex)
  1. **ADMINISTRATIVE INFORMATION AND NAME OF INVESTIGATORS**

|  |  |
| --- | --- |
| Name of the Primary Investigator(s): | Name of Co-investigators: |
| Name of Institutional Affiliations: |
| Email: | Email: |
| Telephone number: |
| Name of the Sponsor of the Study: | Sponsor (Institutional) Affiliations: |

* 1. **FUNDING AND BUDGET INFORMATION (IF AVAILABLE)**
  2. **TIMELINE**

1. **STUDY DESCRIPTION**
   1. Introduction

*Background information on the research topic. Statement of the problem or research question. Rationale for the study and its significance. Rationale for the use of LUCID Regsitry.*

* 1. Study Objectives

*Briefly describe clear and specific objectives of the research project. Hypothesis or research question that the project aims to answer*

1. **STUDY DESIGN**
2. *Describe research methodologies and techniques. Sample size and* ***inclusion/exclusion criteria, including whether general consent is needed****. Primary and secondary outcomes.*
3. *Describe the planned analyses for this study (mandatory), including the statistical tests that as well as any mock tables (optional) that will be generated to provide visual representation of the data*
4. **NEEDED DATA AND MATERIALS**

*Define Data that will be needed for the study in accordance with LUCID dataset.*

*Describe any necessary software, equipment or facilities. Procedures to maintain confidentiality and privacy of data/materia according to LUCID Registry description and regulation.*

1. **DISSEMINATION OF RESULTS**

*Plans for disseminating the research findings (publications, presentations, etc.). Plans for sharing the data/material with other researchers, if applicable. Authorship.*

1. **PUBLIC AND PATIENTS INVOLVEMENT**
2. *How do you intend to involve patients or public voice in the study? Did you receive feedbacks from patients on your research questions/methods, which one?*
3. *How do you intend to involve patients or public voice in the study? Please use and fill out the Involvement Matrix you find at the end of this document (Annex I)*
4. *We kindly ask you to prepare a lay summary (mandatory in English) of your research project with a maximum of 500 words.*
5. **DE-IDENTIFICATION EVALUATION AND RISK ASSESSMENT**

Please fill out the level of risk for your study based on the de-identification evaluation and risk assessment (template provided on the project page)

1. **THIRD PARTY USE**

Are the investigators belonging to one or more of the 5 University Hospitals (CHUV-Unil, HUG-Unige, Inselspital-Universität Bern, USZ-Universität Zürich, USB-Universität Basel) or the Fribourg Hospital-Université de Fribourg?

* Yes
* No

1. **REFERENCES**

*A list of sources cited in the proposal, formatted according to the appropriate citation style.*

1. **ANNEXES**
   1. [Annexe 1]
   2. [Annexe 2]

I hereby certify that the information provided in this research project submission is accurate and true to the best of my knowledge, and that the research will be conducted in accordance with the relevant ethical guidelines.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Annex I**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **ROLE IN PROJECT/RESEARCH** | | | | |
|  |  |  | **Listener**  *Is given*  *information* | **Co-thinker**  *Is asked to give*  *opinion* | **Advisor**  *Gives (un)*  *solicited advice* | **Partner**  *Works as an*  *equal partner* | **Decision-Maker**  *Takes initiative,*  *(final) decision* |
| **STAGE OF PROJECT/RESEARCH** | **Preparation** |  |  |  |  |  |  |
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| **Execution** |  |  |  |  |  |  |
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| **Implementation** |  |  |  |  |  |  |
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[Involvement Matrix (kcrutrecht.nl)](https://www.kcrutrecht.nl/involvement-matrix/)