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|  | **POLICY -**  **retrospective clinical study protocol template**  |
| N° : AAHRPP-DSQ-033 / REV002 | N° ENGLISH VERSION : 025 |

***"Please do take into account that this is a translation of the original French version validated in the Quality Management System (QMS) of Cliniques universitaires Saint-Luc through the SharePoint PaCo GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"***

**INSTRUCTIONS FOR USE**

* This document is a protocol template based on the Good Clinical Practice Guidelines for Research (ICH GCP E6 R2 ).
* It should be used to write the protocol for a retrospective study.
* The parts proposed in this template can be adapted to your needs.
* The text in red that corresponds to the instructions for use should be removed, as well as this first page.
* The black text should be retained.
* You can change the headings and layout styles. Do not forget to update the table of contents.
* Each version of the protocol should be numbered and dated in the footer.
* The protocol can be written in French or in English (English version of the template available on request from the academic desk or on the website https://www.saintluc.be/fr/recherche-clinique-etudes-academiques).
* Final format: PDF

The title page should contain the following information:

* Protocol title
* Acronym
* If not apparent from the title, a brief (one to two sentences) description giving design, duration, procedures, and patient population
* Name and affiliation Sponsor
* Name and affiliation of principal investigator (address and phone number)
* Version and date of protocol

Version History

| **Version** | **Approval Date** |  | **Changes**  |
| --- | --- | --- | --- |
| 1  |  | Original |  |
| 2 |  | Amendment  |  |
| 3 |  | Amendment |  |
| 4 |  | Amendment |  |

1. Signature page

**SPONSOR REPRESENTATIVE**

 Name Signature Date

**INVESTIGATOR(S)**

I agree to conduct this study in accordance with the design and specific provisions of this protocol and will make changes to the protocol only after informing the sponsor.

I understand that I may terminate or suspend study enrollment at any time if necessary to protect the best interests of the study subjects.

I agree to personally conduct or supervise this study and to ensure that all associates, colleagues and employees involved in the conduct of this study are informed of their obligations to comply with these commitments.

I will conduct the study in accordance with the protocol, good clinical practice, the Declaration of Helsinki and the moral, ethical and scientific principles that justify medical research. The study will be conducted in compliance with all relevant laws and regulations concerning patient protection.

I will ensure that the requirements for ethics committee review and approval are met.

I will promptly report to the Ethics Committee any changes in the research activity and any unforeseen problems involving risks to human subjects or others. In addition, I will not make any changes to the research without the approval of the sponsor and the Ethics Committee, except where necessary to ensure the safety of study participants.

 Name Signature Date

 Name Signature Date

1. Protocol synopsis

|  |
| --- |
| Name of Sponsor |
| Title of Study |
| Service(s) in which the experimentation is taking place |
| Publication (reference) |
| Period during which data were collected from patients (source data) :from ...................... (DD/MM/YY) to ........................(DD/MM/YY)Period during which data will be retrieved from files and analyzed by the investigator:from ...................... (DD/MM/YY) to ........................(DD/MM/YY) |
| Objectives: - Primary - Secondary |
| Hypotheses |
| Study Design  |
| Number of planned patients |
| Main criteria for inclusion (inclusion/exclusion criteria) |
| Statistical Considerations |

Table of contents to be updated

In order for your headings to be included in the table of contents, you must use the heading styles configured in the document. Use the headings provided in the Word document toolbar or create your own heading styles.

Table of contents

[1. Signature page 4](#_Toc138434724)

[2. Protocol synopsis 5](#_Toc138434725)

[3. List of abbreviations and definitions 7](#_Toc138434726)

[4. Ethics 8](#_Toc138434727)

[5. BIBLIOGRAPHIC REFERENCES 9](#_Toc138434728)

[6. OBJECTIVES AND GOALS OF THE STUDY 9](#_Toc138434729)

[7. STUDY DESIGN AND METHODOLOGY APPLIED 9](#_Toc138434730)

[7.1. Design 9](#_Toc138434731)

[7.2. Description of the population 9](#_Toc138434732)

[7.3. Inclusion criteria 9](#_Toc138434733)

[7.4. Exclusion criteria 9](#_Toc138434734)

[7.5. Data Management Responsibilities 9](#_Toc138434735)

[7.6. Data breach 10](#_Toc138434736)

[7.7. Statistical Analysis 10](#_Toc138434737)

[7.8. Protocol Amendements 10](#_Toc138434738)

[8. End of study 10](#_Toc138434739)

[9. Archiving 10](#_Toc138434740)

1. List of abbreviations and definitions
2. Ethics
* *This protocol, any amendments to the protocol and any other relevant documents (e.g. recruitment posters) will be submitted to the Ethics Committee (EC) for formal approval to conduct the study. The decision of the EC regarding the conduct of the study will be communicated in writing to the sponsor.*
* *The study will be conducted in accordance with the Good Clinical Practice Guidelines (International Conference on Harmonisation 1996), and the latest version of the Declaration of Helsinki (World Medical Association).*
* *The identity of the participant will be kept confidential in accordance with the General Data Protection Regulation of 27 April 2016 (in application on 25 May 2018), the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data and the Belgian law on patient rights (22 August 2002). Personal data will be coded. Subjects will not be identified by name or in any other recognizable way in any records, results or publications related to the study.*
1. BIBLIOGRAPHIC REFERENCES
* Scientific explanation to define the question: discussion of the literature and important data relevant to the study and providing the context for the study.
* Justification of the study in the light of current knowledge: literature references and previously obtained results or data that are relevant to the study and serve as the basis for the study.
1. OBJECTIVES AND GOALS OF THE STUDY
* Statement of the research question (+ definition of variables)
* Objectives
1. STUDY DESIGN AND METHODOLOGY APPLIED
	1. Design

Definition of the characteristics of the research by standard terms:

* Type of study
* Expected duration (Period during which data will be retrieved from files and analyzed by the investigator)
* Methods of data collection for the evaluation of the study objectives
	1. Description of the population
* Patient population to be studied. Characteristics of the subjects to be included: age, sex, weight, height, race, medical history, biological parameters, definition of pathology and listing of its characteristics.
* Number of patients expected.
	1. Inclusion criteria

Indicate that subjects must meet all inclusion criteria in order to participate in the study and list each criterion.

* 1. Exclusion criteria

Indicate that all subjects meeting any of the exclusion criteria at baseline will be excluded from participation in the study and list each criterion.

* 1. Data Management Responsibilities

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification.

Instructions concerning the recording of study data:

* Name of used database – REDCap is recommended for studies sponsored by CUSL
* Describe how data will be collected

The data collected will be processed in accordance with the General Data Protection Regulation (GDPR) and the Belgian Data Protection Act of July 30, 2018.

* 1. Data breach
* A description of the measures taken to comply with the rules in force relating to the protection of personal data, and in particular the technical and organizational arrangements that will be applied to prevent unauthorized access, disclosure, dissemination, modification or loss of the information and personal data processed
* A description of the measures that will be applied to guarantee the confidentiality of the information and personal data of the participants
* A description of the measures that will be applied in the event of a data security breach, in order to mitigate the possible adverse effects

The Sponsor or designee must report to ethics committee, serious data breaches : transgressions against the [study](https://www.ema.europa.eu/en/glossary/clinical-trial) protocol or the regulation that are likely to significantly affect the safety and rights of a subject or the reliability and robustness of the data generated in the study.

* 1. Statistical Analysis
* Reasons for the sample size selected, statistical power of the study, level of significance to be used
* Describe planned analyses, comparisons and statistical tests
* Reasons for excluding subject from an analysis
* Planned monitoring of the results
	1. Protocol Amendements

If amendments to the protocol turn out to be necessary, they will be submitted to the opinion of the Ethic Committee having examined the initial protocol.

1. End of study

The study end date corresponds to the date on which analysis of the data collected is completed.

This is intended *to indicate the planned completion date*

1. Archiving

Personal data is kept for no longer than is necessary for the purposes for which it is recorded (Law of July 30, 2018, chap V Art 111).

For this study, data will be kept for *specify period in months/years.*

Specify where study documents and collected data are archived, as well as access conditions.