Quality Control Document:

Protocol Template for non-CTIMPs & Studies

# Purpose

This document contains a template that can be used to create a protocol for non-Clinical Trials of an Investigational Product (non-CTIMPs) and studies.

This template is designed to be used in conjunction with the Protocol Development Tool for non-CTIMPs & Studies (UoB-ESD-QCD-003). For CTIMPs, see Protocol Template for CTIMPs (UoB-CLN-PRO-QCD-002).

# Instructions

1. Remove this first instruction page.
2. Update the header to include the project ID.
3. Update the footer to includes the protocol version number and date, retaining the document reference information relating to this quality control document.
4. Complete all sections of the template in line with your project’s requirements/design. Refer to the Protocol Development Tool for non-CTIMPs & Studies (UoB-ESD-QCD-003) for guidance on what should be included in each section.
5. Follow the procedures in the Essential Documents Development & Maintenance SOP (UoB-ESD-SOP-001) for submitting the protocol for approval and filing.

# Related documents

* UoB-CLN-PRO-QCD-002 Protocol Template for CTIMPs
* UoB-ESD-QCD-003 Protocol Development Tool for non-CTIMPs & Studies
* UoB-ESD-QCD-005 Essential Document Checklist
* UoB-ESD-QCD-006 Version Control Log
* UoB-ESD-SOP-001 Essential Documents Development and Maintenance

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

PROTOCOL

# Title page

## Full/long title of the project

## Short title/acronym

## Protocol version number and date

|  |  |
| --- | --- |
| **Protocol version number:** |  |
| **Protocol version date:** |  |

## Research reference numbers

|  |  |
| --- | --- |
| **IRAS number:** |  |
| **Sponsor/RG number:** |  |
| **REC reference number:** |  |
| **Public registry number:** |  |
| **Funder number:** |  |

# Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham’s sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

|  |  |
| --- | --- |
| **Full project title:** |  |
| **Protocol version number:** |  |
| **Protocol version date:** |  |

|  |
| --- |
| **Chief Investigator (CI)** |
| **Name:** |  |
| **Date:** |  |
| **Signature:** |  |

## Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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# Key contacts

|  |  |
| --- | --- |
| **Role/function** | **Contact details** |
|  |  |
|  |  |
|  |  |

# Project summary

# Funding and support in kind

|  |  |
| --- | --- |
| **Funder(s)** | **Financial and non-financial support given** |
|  |  |
|  |  |
|  |  |

# Role of sponsor and funder

# Roles & responsibilities of management committees/groups & individuals

## Patient & public involvement group

# Protocol contributors

# Key words

# Project flow chart

# Protocol

1. Background
2. Rationale
3. Theoretical framework
4. Research question/aims
	1. Objectives
	2. Outcome
5. Design and methods of data collection and data analysis
6. Project setting
7. Participant recruitment
	1. Eligibility criteria
		1. Inclusion criteria
		2. Exclusion criteria
	2. Sampling
		1. Size of sample
		2. Sampling technique
	3. Recruitment
		1. Sample identification
		2. Consent
8. Storage and analysis of human tissue
9. Safety reporting
10. Ethical and regulatory considerations

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* 1. Assessment and management of risk
	2. Research ethics committee (REC) and other regulatory review & reports
		1. Regulatory review & compliance
		2. Amendments
	3. Peer review
	4. Patient & public involvement
	5. Protocol compliance
	6. Data protection and confidentiality
	7. Indemnity
	8. End of study and archiving
	9. Access to the final dataset
1. Dissemination policy
	1. Dissemination policy
	2. Authorship eligibility guidelines and any intended use of professional writers
2. References
3. Appendices
	1. Appendix 1 – required documentation
	2. Appendix 2 – schedule of procedures
	3. Appendix 3 – amendment history

|  |
| --- |
| The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** | **Summary of amendment** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |