QUALITY SOP 3

Application for support of clinical research in the Clinical Research (Support) Unit

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QUALITY SOP 3

Application for support of clinical research in the Clinical Research (Support) Unit

Note:

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Reviewed By	HRI CRSU Clinical Operations Manager HRI Operations Manager
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SOP History:

Version	Date	Reason for Change	Author
1.0	July 2018	Initial Release	Maria Ryan
2.0	January 2021	2 year review: • Changed UL logo to HRI logo • Changes to title • Changes to Board approval • Changes to front page note • Updated Responsibilities section • Changes to the process for application • Addition of new application forms, LOA & CRU study log to appendices	Marie-Therese Hayes Maria Ryan

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for applying for support of studies by the Clinical Research (Support) Unit

2. Objective

To ensure that all studies carried out in the CR(S)U are deemed to be suitable, in every respect according to their protocols for that environment, are adequately funded and to ensure that the Investigator has adequate resources to meet the requirements of the study, as per section 4.2 ICH GCP (***Appendix i***) whilst keeping a complete record and documentation surrounding approved supports.

3. Responsibility

- The Principal Investigator (PI) is responsible for completing and submitting the *Application for Support form* (***Appendix ii***) with sufficient information to enable the review to take place. The PI should also submit any substantial amendments that result in significant changes to how the study is conducted or that introduce an element of risk that was not present in the original protocol.
- The Clinical Operations Manager (COM) along with designated CR(S)U staff will be responsible for review and commentary on the study protocol and all other required information prior to submission to the Clinical Research Unit (CRU) Management Board. The COM is responsible for the review of resources required for the study and will communicate this to the board prior to a decision being taken regarding the study support request.
- The CRU Management Board is responsible for reviewing applications submitted on the official form (***Appendix ii***) and providing an approval/rejection of the application with reasoning.
- The COM or designee is responsible for ensuring the decision is communicated to the applicant and that the CR(S)U study log (***Appendix iii***) is updated with the details of approved supports, if appropriate.
- The Quality and Regulatory Clinical Research Associate (Q&R CRA) is responsible for the processing of the *Application for Support form* and the correspondence and filing related to the above procedure.

4. Policy

It is the policy of the CR(S)U to work according to the applicable regulations and within the guidelines of the Declaration of Helsinki and Good Clinical Practice (GCP) as outlined in ICH Harmonisation Tripartite Guidelines for Good Clinical Practice.

5. Procedure

Application for CR(S)U support can occur at any stage. If it is during the early stages of the project and full details have not been formulated, the Principal Investigator (PI) may still begin a dialogue with the Unit and complete the CR(S)U application form (***Appendix ii***) with as much detail as possible.

An application form will not be required for requests for review of specific components of a Research Ethics Committee (REC) submission or for other general advice sought on the conduct of clinical research. This type of support can be approved by the COM and does not need to be added to the CR(S)U study log (***Appendix iii***) but a separate log of these types of communications and advice will be kept in the CR(S)U Quality Files.

5.1 Initial contact

- Anyone wishing to start a discussion about gaining CR(S)U support for studies and/or research projects will be advised that an application form will need to be completed and submitted for review by the CRU Management Board.
- If required, the CR(S)U team will provide information on available services and facilities the applicants should include in their request.

5.2 Review of application form and supporting documents

- Members of the CR(S)U will conduct a review of the Application to ensure it contains sufficient information for Board review, as well as to provide logistical, quality, budgetary, nursing/medical and all other relevant viewpoints for the Board to consider.
    - Studies that apply for support with no external funding will be reviewed using the following criteria: (i) alignment with the vision and strategic direction of the CR(S)U (ii) enhancement of the reputation of the unit, University Of Limerick (UL) or University Hospital Limerick (UHL) (iii) provision of a positive societal/public health impact (iv) CR(S)U resource capacity (v) Criticality of the study to a public health issue where funding is not immediately available but the public health need outweighs the funding consideration. A budgetary and capacity risk assessment will be conducted by the COM for the Board decision.
- The Application form and supporting documents will be reviewed by the CRU Management Board, to assess its suitability for CR(S)U support, based on scientific quality, capacity and funding.
- The PI or his/her designee may be invited to attend the CRU Management Board meeting to discuss the proposed study and his/her requirements if requested by the Board.
- Details of responsibilities and supports to be delegated to the CR(S)U should be described by the PI in the application form.
- If the study is approved the PI, along with the COM or designee, will review the resources required for the study to ensure adequate research staff resources versus the level of study activity, including devising contingency plans to cover study activities in the event of unexpected unavailability of personnel.

5.3 **Administration and oversight of CR(S)U support for studies**

- The CRU Management Board chair will sign and date the Board's decision on whether or not each particular application is deemed eligible for the support requested. A copy will be sent to the Research Support Office in University of Limerick (UL) for information purposes.
- The Q&R CRA will assign a study number. A log of approved studies and level of support provided by the CR(S)U will be kept in the CR(S)U Quality Files.
- For studies with a UL PI, a Project Authorisation form (PAF) must be completed by the PI and returned to the Research Office in UL for review and approval.
- For studies where the PI is a UL Clinical Adjunct a Clinical Adjunct Authorisation form (CAAF) must be completed by the PI and returned to the Research office in UL for review and approval

- The Clinical Operations Manager or their designee will send a Letter of Agreement (LOA) (***appendix iv***) to the PI outlining the terms of approval and the supports that will be provided. This LOA will also inform the PI that the study must receive Green Light status as per *CRU QTY-14 Green Light Process for CR(S)U Studies* prior to starting any study-related activities.
- These documents will be stored in the CR(S)U file specific to that study. All documentation and correspondence between the PI and the CR(S)U relating to that study are held in this file.
- Study co-ordinators will ensure regular study team meetings are held throughout the study and that there is documented evidence of these meetings.
    - The Q&R CRA will liaise with the study co-ordinator to ensure adequate CR(S)U oversight for obtaining metrics on numbers recruited, Serious Adverse Events (SAE)s reported, etc.

6. Abbreviations and definitions

Term	Definition
CAAF	Clinical Adjunct Authorisation Form
COM	Clinical Operations Manager
CR(S)U	Clinical Research (Support) Unit
GDPR	General Data Protection Regulation
ICH GCP	International Conference on Harmonisation Good Clinical Practice
LOA	Letter of Agreement
PAF	Project Authorisation Form
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
UL	University of Limerick

7. References

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (Amended version E6 2016).
ICH Harmonised Tripartite Guideline for Good Clinical Practice. Geneva, International Federation for Pharmaceutical Manufacturing Association.

CRU QTY-14 Greenlight Process for CR(S)U Studies

Appendix i.

Extract from Section 4, ICH GCP

4.2 Adequate Resources

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

ADDENDUM

4.2.5 The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

4.2.6 If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

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Health Research Institute

Appendix ii – CR(S)U Application for Support Form

Instructions
All applicants requesting either access to or support from (or both) the CR(S)U are required to complete this application form for review by the CRU Management Board. Please complete this form and return, with any queries to Marie-Therese Hayes Clinical Operations Manager CRSU Marietherese.hayes@ul.ie You may be contacted to arrange a short follow-up meeting to discuss the requirements for your study

1. Principal Investigator

Name		**Speciality**	[Click to Select Specialty]
Email		**Phone No.**	
Department/ Work Address			

2. Project Details

Full Protocol Title	Click here to enter text.
Study Title (Short)	Click here to enter text.

3. Project Description

Please attach a copy of the current protocol and/ or a copy of the completed REC application form

Please provide details of any funding associated with this study:

Proposed start date and duration for supports requested:

4. Project Type:

Research Study	☐	**Study Category**	Choose an item.	**If Other – please specify:**
Clinical Trial	☐	**Trial Category**	Choose an item.	

5. Research Team *including Sub-Investigators and other Research Staff*

Name	Job Title / Role	Email	Contact Number

6. Type of Support Required *(tick all that apply)*

Nursing	☐	**Statistical Support**	☐
Sample Processing	☐	**GCP Training**	☐
Ethics Committee Application Support	☐	**Regulatory Support**	☐
Clinical Rooms	☐	**Support through the HRB CRCI Feasibility & Study Start up programme**	☐
Data entry	☐	**Storage of clinical research documents and/or data**	☐
Protocol development	☐	**Assistance with grant application**	
Study document Development	☐	**Other:** *please specify*	☐

7. Applicant Details (if different from PI)

Applicant Name			
Contact Number:		**Email:**	

8. Signature

PI/ Applicant Signature		**Date:**	

CR(S)U OFFICE USE ONLY			
Confirmation Application reviewed prior to CRU MB submission	**Signature** _____	**Date:**	

CR(S)U OFFICE USE ONLY			
CR(S)U support approved / denied	**Signature** _____	**Date:**	

Appendix iii CRSU study log template

This log is to document the research studies and projects approved to be run through the CR(S)U along with the supports provided:

Date of approval	Study Title	Principal Investigator	Assigned CR(S)U number	Approved supports

Appendix iv CR(S)U Letter of Agreement (LOA) template

Clinical Research Support Unit,
Health Research Institute,
3rd Floor CERC Building,
University Hospital Limerick,
Dooradoyle.

Date

PI name and department

Study title application for CR(S)U support

Dear ***<insert PI name>***

I am writing to you to advise that the CRU Management Board has reviewed your application form for the above study dated X and have approved the following supports for the duration of the project/duration that the funding will cover:
(DELETE AS APPROPRIATE)

1. Quality & Regulatory CRA support with study start up activities
   - Ethics approval
   - Agreements
   - DPIA
   - Site file set up
   - Training of research team
   - Quality management throughout study
2. Research assistant support for:
   - Study co-ordination
   - Maintenance of essential documentation
   - Data collection from medical records
   - Data entry to electronic system
   - Co-ordination of shipping of samples

As this study is being supported by the CR(S)U it will be conducted in accordance with our processes and procedures as mandated by our Quality Management System. As such once all required elements are verified you will be issued with notification of the study Greenlight and a Site activation notification will be sent to you informing you that you may start the recruitment and data collection at that stage.

If you have any queries, please do not hesitate to contact the team in the CR(S)U

Kind regards,

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