Application for Access to the CRC and the Evaluation of Applications

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Author/Reviewed by: _____(Signature)

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Date Reviewed: _____19-Oct-2022_____

Approved by: _____(Signature)

Peter Doran, Director Clinical Research Centre

Date Approved: 16-Nov-2022

1. SCOPE

This SOP applies to the application and evaluation of proposals for access to the CRC facilities and supports.

2. PURPOSE

The purpose of this procedure is to describe the process for application for access for CRC resources by investigators and the evaluation of these applications.

3. POLICY

It is the policy of the UCD Clinical Research Centre to evaluate all applications for access to CRC resources, to ensure all research performed within the centre is completed in compliance with highest scientific, clinical and regulatory standards.

4. ROLES AND RESPONSIBILITIES

This procedure is applicable to all investigators applying for access to the UCD Clinical Research Centre and to all involved in the processing and evaluation of these applications. The CRC Director makes final decision on allocation of CRC resources.

5. DEFINITIONS

Standard Operating Procedures (SOPs) – Detailed written instructions to achieve uniformity of the performance of a specific function.

6. RELATED DOCUMENTS

CRC Application Form (Form STM-001)
CRC Operations Coordination Group Review Checklist (Form STM-002)
Investigator Agreement (Form STM-003)
Roles and Responsibilities (Form STM-004)
Sponsorship Oversight Committee Review Form (Form STM-005)

7. PROCEDURES

7.1. Application to CRC

7.1.1. All investigators intending to apply to the CRC for access to facilities and / or core supports are advised to contact the CRC early, to ensure their application is processed in a timely manner

7.1.2. All applications to the CRC must be made using the CRC Application form (Form STM-001)

7.1.3. Any expression of interest in a new study/project to be based at the CRC received by any CRC team member should be forwarded to the CRC Operations Manager and Business Development Manager.

7.1.4. The Operations Manager & Business Development Manager will initially assess each expression of interest. the Operations Manager will add the following project details to the CRC Clinical Trials Management tracker at a minimum:

7.1.4.1. Status of the Project:

7.1.4.1.1. Proposal Logged
7.1.4.1.2. Proposal Suitable
7.1.4.1.3. Proposal Unsuitable
7.1.4.2. Therapeutic Area
7.1.4.3. Timelines
7.1.4.4. Budget & Funding Source
7.1.4.5. Type of Study
7.1.4.6. Resources Requested

7.1.5. The project should remain at a status of Proposal Logged until the Operations Manager & Business Development Manager assesses the initial suitability of the project.

7.1.6. For those projects which are unsuitable to be supported by the CRC, the CRC Director will inform the investigator.

7.1.7. For those projects which appear to be initially suitable to be supported by the CRC, the details of the project will be forwarded by the Operations Manager to the CRC Operations Coordination Group to be evaluated fully. The Operations Manager will inform the investigator that the project is entering the evaluation process by the CRC Operations Coordination Group.

7.1.8. In addition, the following documents must be submitted once the project enters the evaluation process:

- Copy of full Study Protocol (or draft)
- Copy of Ethics Approval for the study (or draft of application) (if required/available)
- Copy of HPRA Approval (if required/available)
- Details of study funding

7.2. Evaluation of applications

7.2.1. All suitable applications will be reviewed by the CRC Operations Coordination Group.

7.2.2. The following list includes, but does not limit, the items which will be included as part of the evaluation process:

- Initial review of study design, protocol and feasibility
- Grant application, funding, budget review, contracts, insurance requirements
- Resource implications
- Regulatory requirements; Regulatory Authority/Ethics Committee requirements, Patient Information Leaflet, Informed Consent Form
- Laboratory requirements; Lab Manual
- Data Analysis requirements; IT systems, Case Report Forms, Statistical Analysis Plan

7.2.3. For applications requesting UCD sponsorship of Investigator Initiated Interventional Clinical Trials, a parallel review of the Application is required by the Sponsorship Oversight Committee. The recommendation of the

Sponsorship Oversight Committee review will be documented on the Sponsorship Oversight Committee Review Form (STM-005).

7.2.4. The outcome of the review by the CRC Operations Coordination Group should be added to the CRC Operations Coordination Group Review Checklist (Form STM-002). The Operations Manager and Business Development Manager will request further information from investigator if required. Based on comments and feedback received, the recommendation of the CRC Operations Coordination Group will be documented on the CRC Operations Coordination Review Checklist (Form STM-002). the CRC Leadership Group will make a final decision on whether approval will be granted.

7.2.5. Projects which are not supported with external funding will be discussed by the CRC Leadership Group in order to make a decision about the feasibility of CRC supporting the particular project and the level of support provided to the project. The assessment will be based on the following criteria:

- therapeutic/investigation area
- clinical demand
- strategic importance for the University
- likelihood for the project to provide future funding

7.2.6. For those projects which are not approved for support the CRC Director will inform the investigator.

7.2.7. For those projects which are approved for hosting, the CRC Director will inform the investigator and detail the specific follow-up actions advised. Following Review, the Operations Manager will update the project status in the CRC Clinical Trials Management tracker to one of the following:

- Proposal Approved
- Proposal Approved, pending clarification
- Proposal Not Approved

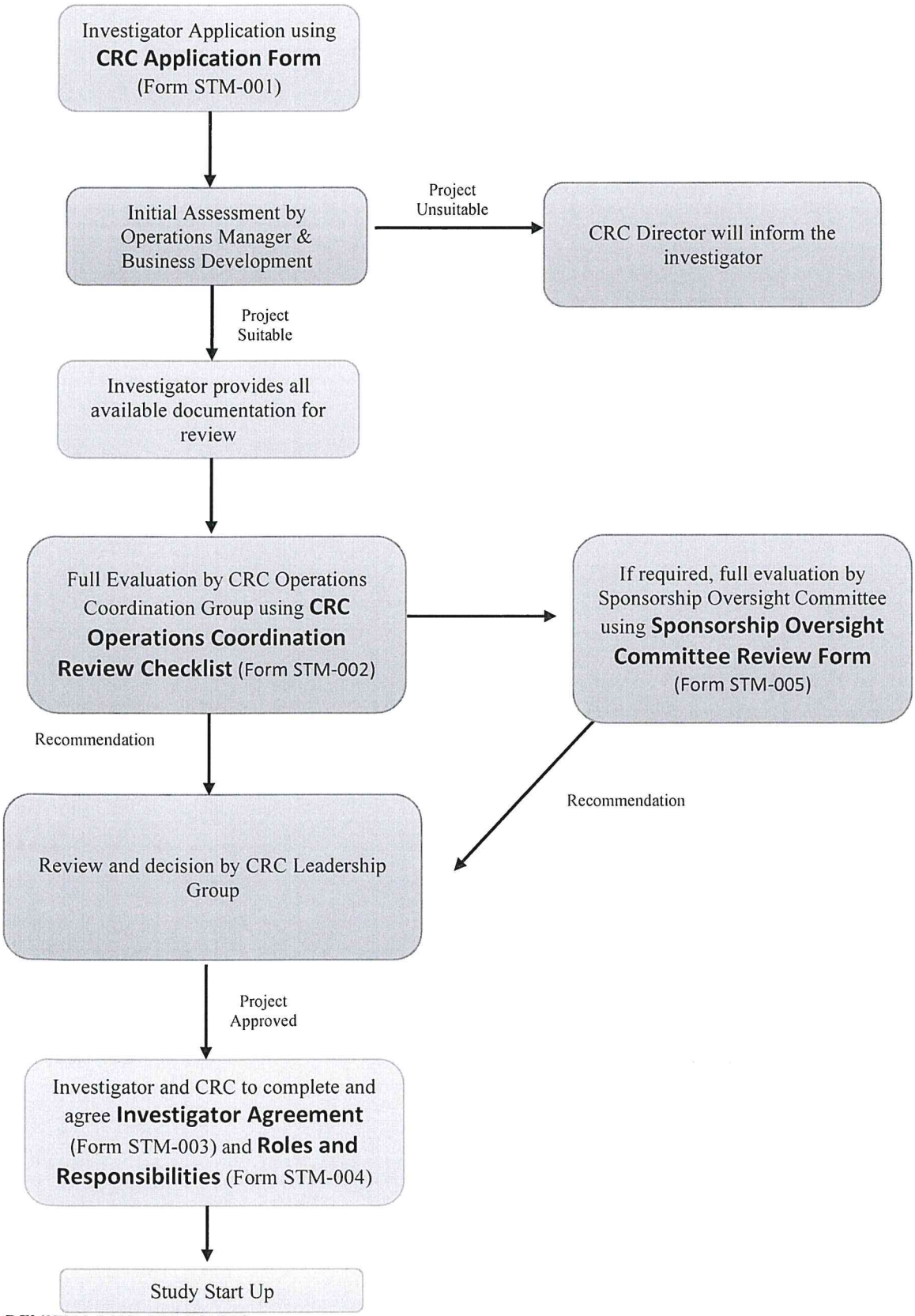
7.3. Study Start Up & Investigator Agreement

7.3.1. Prior to any project formally commencing in the CRC, a detailed Investigator Agreement (Form STM-003) will be completed.

7.3.2. The CRC Director will ensure the appropriate resources are assigned to the project as agreed.

7.3.3. The Business Development Manager will agree contracts and payment schedule with relevant parties as required.

7.4. Appendix A: Project Application & Evaluation Process



8. REVIEW AND REVISION

This SOP shall be reviewed at least every two years. It may be reviewed and reissued earlier if considered necessary

9. DOCUMENT HISTORY

Version Number	Effective Date:	Summary of changes from previous version:	Edited by: (name and role)
01	01-Apr-2013	Initial Document	
02	21-Dec-2015	Minor updates such as change to HPRA from IMB	Rabia Hussain, QRAM
03	20-Mar-2017	Sec 6.: addition of reference to Form STM-003 & STM-004 Sec. 7.1, 7.2, 7.3 : Substantially updated & added content in sections 7.1, 7.2 & 7.3 Sec 7.3.: Changed title from "Investigator Agreement" to "Study Start Up & Investigator Agreement" Sec 7.4 (App A): Newly added	Brenda Molloy, Data & IS Manager
04	17-Dec-2020	Sec 6.: addition of reference to STM-005, update to STM-002 Sec 7.2.3: update to reference of STM-002 Sec 7.2.4: additional point added in relation to Sponsorship Oversight Committee review Sec 7.2.6: additional text added in relation to management of unfunded studies Sec. 7.4 (App A): updated to include Sponsorship Oversight Review Committee step Updates made to the responsibilities for Business Development Manager and CRC Director, and clarification on review process	Brenda Molloy, Data & IS Manager
05	01-Dec-2021	Sec. 6: Update to STM-002 Sec. 7.1.3, 7.1.4, 7.1.5: updated to include Operations Manager	Anna Malara, Business Development Manager

		Sec. 7.1.7, 7.2.1, 7.2.3: updated to change from CRC Management Team to CRC Operations Coordination Group **Sec 7.2.5, 7.2.6: updated to include step of CRC Leadership Group review** **Sec. 7.4 (App A) updated to include CRC Leadership Group step**	
06	**16-Dec-2022**	**Sec 7.1.4: updated to include Operations Manager** **Sec. 7.1.7 updated to change from Business Development Manager to Operations Manager** **Sec. 7.2.2 typographical error removed** **Sec 7.2.3 deleted; part of wording moved to sec. 7.2.4** **Sec. 7.2.7 updated to include Operations Manager**	**Anna Malara, Business Development Manager**