| Version | Version Date | Author | Final Approver |
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## 1.0 Purpose

The purpose of this SOP is to describe the procedures to be followed, to gain approval to carry out patient focused research studies, sponsored by the University, in University College Cork (UCC).

## 2.0 Scope

This SOP applies to patient focused research studies conducted by UCC staff which do not have an external sponsor. In the absence of an external sponsor all PF research studies carried out by UCC Staff and approved by the CRRO are *de facto* sponsored by UCC.

## 3.0 Responsibilities

This SOP applies to personnel in UCC Sponsor Office and UCC Research who are involved in processes re: granting approval to carry out patient focused research at the University. These staff must read this SOP and follow the contents.

**Specific Responsibilities include:**

**3.1** UCC Research -Provide first line contact with investigators/researchers who are applying for funding for patient focused research, point them to the Sponsorship request form (SRF) on UCC Research website, inform Sponsor office if funding is granted for the study and (post funding) – follow up on relevant actions noted by CRRO including setting up agreements.

**3.2** Sponsor Office Administrator (SOA) – Sets up and maintains a PF study tracking workflow log (for each year). Assigns sponsor number and creates an electronic folder for each study. Files all relevant documentation into study folder, inputs study details onto UCC Insurer's pipeline, updates study status on Insurer's pipeline when relevant and submits Insurer's pipeline to OCLA for review on a yearly basis.

**3.3** CRRO – Reviews SRF (prefunding), PFQ (post funding) and other relevant documents. Classifies PF research studies, decides on any necessary actions. Communicates same to PI and all stakeholders including UCC Research, UCC Data Protection Officer for research (RDPO) and Office of Corporate and Legal Affairs (OCLA) etc.

**3.4** Quality and Regulatory Affairs Director (QRD) – Follows up on relevant actions noted by CRRO including carrying out sponsor greenlight, setting up study monitoring with Clinical Research Facility-University College Cork (CRF-UCC), Sponsor study audits, assists CRRO in reviewing PIL/ICF, obtains status updates on UCC interventional trials and acts as CRRO designee when required.

## 4.0 Procedure

### 4.1 Prefunding:

**4.1.1** Initial contact by investigator is to UCC Research. To ascertain if the research is patient focused research (as defined by Sponsor office UCC). Research Staff will initially ask the investigator 3 standard questions as follows:

*Q1: Does your research involve engagement with patients as subjects/participants including collection of patient/health data? (Examples: interviewing patients, observing patients, giving questionnaires to patients, testing a product on patients, testing an intervention using patients etc.)*

*Q2: Does your research involve engagement with healthy subjects (including health data on human subjects) where outcome of same could have a clinical impact?*

***If the answer to either of these questions is yes, research staff will ask the third question:***

*Q3: Do you wish to request that UCC Sponsor your study? (i.e., you do not have an external sponsor such as a pharmaceutical company, medical device company or SME who will provide insurance etc)*

If the answer to Q3 is yes, research staff will advise the researcher/ PI to complete a **Sponsorship request form** (SRF) and submit it to UCC Research. SRF is available on UCC Research Website https://www.ucc.ie/en/research/support/policies/patient-focused-research/

This short form captures the minimum amount of information needed by UCC Research and Sponsor office at prefunding stage.

All UCC staff who wish to carry out Patient Focused Research that does not have an external sponsor, **must request sponsorship of the proposed study from UCC Sponsor office** to assure UCC oversight of the study and adequate insurance for study participants.

If the researcher is unable to answer any of the questions (1 to 3 above), they will be advised to contact UCC Sponsor office (PFRSponsor@ucc.ie) who will assist the researcher in determining if their research falls into the category requiring review and assessment by Sponsor office.

**4.1.2** When UCC Research receives the completed Sponsorship request form, research staff will forward it to UCC Sponsor office

(PFRSponsor@ucc.ie) for review and assessment. UCC Research may also include other documents considered relevant to the review.

**4.1.3** At this (prefunding) stage, the study will not be added to the Sponsor office insurance tracking log as it may not proceed and does not yet require insurance cover. The study will be added to the 'studies assessed for funding' log, by SOA, for statistical purposes.

**4.1.4** The SRF will be reviewed by the CRRO who will carry out a risk assessment (to ensure that the study can be sponsored by UCC and that there are sufficient resources for governance/ oversight.

**4.1.5** After reviewing the SRF the CRRO will advise UCC Research whether they have any objection to UCC endorsing the application to the funding body.

**4.1.6** The applicant / researcher will be advised by SOA that further details of sponsorship requirements will need to be provided to sponsor office if the study is funded or if the study is going ahead in the absence of funding.

**4.1.7** If funding **is approved,** UCC Research will inform sponsor office (PFRSponsor@ucc.ie ) and the SOA will send out the PFQ to the PI for completion.

**4.2 Post Funding**:

**4.2.1** Sponsor Office Administrator (SOA) carries out duties (detailed above in 3.1) which records the approval status of each patient focused (PF) research study in a PF workflow tracking log (See Workflow log template attached). The PF tracking log is held at a secure location on a UCC Server (UCC NAS), and access is limited to relevant personnel in Sponsor's office, UCC Research, OCLA and CRF-UCC. The SOA maintains a list of the personnel who have access to this log and keeps it updated. Access to the log is granted only by OCLA or CRRO.

**4.2.2** PI or their designee will submit the completed Patient Focused Research Questionnaire (PFQ) to Sponsors Office to start the study approval process. PFQ is available on the UCC Research website: https://www.ucc.ie/en/research/support/policies/patient-focused-research/. The Sponsors Office dedicated email is: PFRSponsor@UCC.ie. The PFQ should be accompanied by the Patient information Leaflet / Informed Consent form (PIL/ICF) and study Protocol. These accompanying documents may be in draft format.

**4.2.3** After the CRRO receives fully completed PFQ and any relevant documents, the CRRO (or designee) will review the documents, classify the study using the UCC PF Classification table (See UCC PFQ). CRRO will send an email to PI and relevant others (UCC Research OCLA etc) indicating classification, and further actions (if any) to be taken. Actions may include creation of agreements (e.g Funding, Data sharing, Hospital agreements), Sponsor Greenlight Process, Indemnity of product etc or additional documentation. CRRO will cc SOA on the emails.

**4.2.4** CRRO will carry out initial risk assessment on data protection issues and indicate if study requires a DPIA and/or research DPO review (Per Research Data protection review SOPs). If CRRO indicates neither DPIA and DPO review are required, this is indicated (by the CRRO) on the PFQ and noted by SOA on the tracking log.

**4.2.5** Only when the PI has confirmed that all conditions will be met or are acceptable, will the SOA request evidence of UCC sponsor insurance from OCLA. Some Research Ethics Committees may require this, e.g Clinical Research Ethics Committee of the Cork Teaching hospitals - CREC. OCLA will issue email evidence of insurance directly to the PI and will cc- SOA, who will file same in study folder,

**4.2.6** If CRRO has indicated that study appears to be of low risk regarding Data protection issues, this will be documented in the insurance note from OCLA insurance, which PI submits with Research Ethics Committee (REC) Application. CRRO will discuss applications with Research DPO as necessary if risks regarding data protection are unclear.

**4.2.7** If CRRO has indicated that the study requires research DPO review/ and or DPIA, CRRO/SOA will forward PFQ to Research DPO and inform investigator of this. Research DPO will review the PFQ and any required documents e.g PIL/ICF. These will be available via UCC Sponsor office or directly from the Investigator. Research DPO review process is covered in DPO SOPs.

**4.2.8** SOA will assign a Sponsor number (Format YY001) to the study and enter it into the workflow tracking log. Fields in tracking log include Sponsor study number, Study name, study classification and CRRO's recommendations/requirements (if any) as indicated in 4.2.3 above. SOA will create electronic study folder (using Sponsor number as folder name) and will file relevant documents, emails received etc in this study folder.

**4.2.9** To enable rapid location of study folders, SOA will keep an index of studies). Sponsor study number should be used in all communications from this point.

**4.2.10** Staff from UCC Research, UCC Sponsor Office and UCC OCLA will follow up on all actions specified by CRRO (e.g Agreements, Sponsor Greenlight etc) and inform SOA of completion of actions. SOA will then update the workflow log and file any relevant documents into the study folder.

The following types of studies will require preapproval by UCC Clinical trial insurers:

- Interventional Studies involving Children, Pregnant Women, Vulnerable populations
- Studies on HIV positive or Hepatitis B positive populations
- Any other studies considered by CRRO or Insurers to be of high risk

The categories of studies that need to be preapproved by the insurers are listed on PFQ, which Is available on the UCC Research website. If in any doubt, insurers/ broker should be consulted re preapproval.

If preapproval is required, OCLA insurance office will request pre-approval from Insurers/ brokers and communicate the result of this to CRRO, SOA and UCC Research. CRRO will communicate the decision to the PI. SOA will file relevant emails relating to Insurance pre-approval onto the study folder and update the tracking log.

**4.2.11** UCC Sponsored interventional studies may require services of the HRB-CRF-UCC to enable UCC Sponsor to fulfil its sponsor responsibilities. Such services may include (but are not limited to) monitoring, pharmacovigilance, clinical services, data management, statistical analysis and audit. Alternatively, these services may be contracted out to competent service providers if approved by Sponsor office. It is vital that the PI should ensure that all Sponsor activities are adequately budgeted for in funding applications.

**4.2.12** QRD will request status updates (from Quality representatives of RICU's) on all UCC sponsored interventional trials quarterly. QRD will forward updates to SOA who will update the insurer's pipeline and workflow tracking log. If a study has closed or is/not proceeding it will be shaded in grey to indicate this, but it will not be deleted from the log. If UCC Research become aware that a study has closed, they will inform the Sponsor office.

**4.2.13** SOA will review the study index on a biannual basis and delete any duplicates of studies, correct any errors (i.e. change in study name) etc.

## 5.0 List of Abbreviations used in this SOP:

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| **HRB** | Health Research Board |
| **DPO** | Data Protection Office |
| **CRRO** | Clinical Research Reporting Officer |
| **CRF-UCC** | Clinical Research Facility- University College Cork |
| **QRD** | Quality and Regulatory Affairs Director |
| **SOA** | Sponsor Office Administrator |
| **UCC** | University College Cork |
| **SRF** | Sponsorship Request Form |
| **OCLA** | Office of Corporate and Legal Affairs |
| **PFQ** | Patient Focused Questionnaire |
| **PI** | Principal Investigator |
| **SOP** | Standard Operating Procedure |
| **ICH GCP** | International Conference on Harmonisation Good Clinical Practice |
| **HPRA** | Health Products Regulatory Authority |
| **REC** | Research Ethics Committee |
| **CREC** | Clinical Research Ethics Committee of the Cork Teaching Hospitals |

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| **PIL** | Patient Information Leaflet |
| **ICF** | Informed Consent Form |

## 6.0 Related Documents and References

- CRF-UCC-SPN-1: UCC Patient Focused Research Quality System
- CRF-UCC-SPN-FM-6: Sponsorship request form (SRF) - to be used Pre-funding
- UCC Patient Focused Research Questionnaire (PFQ) to be used Post-funding) *(available on the UCC Research Website)*
- CRF-UCC-SPN-SOP-2 Clinical and IMP Green Light
- CRF-UCC-SPN-SOP-4: Risk Assessment and Risk Management of Sponsor Clinical Trial Activity at CRF-UCC
- Data Protection Assessment SOP (s) *(available on the UCC Research Website)*

## 7.0 Appendices (If Applicable)

N/A