Terms of Reference
UCC Quality Working Group (QWG) for Patient Focused Research

Agreed by UCC QWG for Patient Focused Research Signature of Chairperson: Ruben E. Kearney	5 February 2019
Approved by UCC Sponsor representative (CRRO) Signature:	08 FEB 2019

1. Introduction / Background

Patient focused research is carried out over a broad range of departments, research centres and units at University College Cork. The conduct of regulated Clinical Trials of Investigational Medicinal Products (CTIMP) and Clinical Investigations of Medical Devices are governed by Irish and European laws, directives and guidelines, thus clear expectations of the quality standards which must be complied with for such trials are available.

However, there is no defined quality standard for the conduct of non-regulated patient focused research, including observational research and non CTIMP interventional trials. Such interventions may include food products, nutritional supplements, vitamins, physical (e.g. physiotherapy, exercise) and psychological (e.g. Cognitive Behaviour Therapy) interventions. The vast majority of patient focused research which is carried out in UCC is of this non-regulated type.

Table one bellow shows the number and type of studies for which patient focused research questionnaires (PFRQs) were submitted to UCC Sponsors office in 2017 and 2018.

New trials started in	CTIMP (regulated)	CI Medical Device (Regulated)	Observational	Interventional
2018	0	0	138	16
2017	0	0	86	17

Table 1: PFRQs submitted to UCC sponsors office in 2017 and 2018

Sponsor audits carried out by the Quality and Regulatory Affairs Manager of HRB-CRF-C from 2015-2018 indicated that the quality of these non-regulated studies varied enormously. Audit findings included issues relating to consenting of patients, ethics approvals, training of site staff and study

documentation. Some departments/centres/units had full quality management systems in place and were well placed to carry out all types of patient focused research (including regulated trials) while others did not have any written quality processes in place.

In 2018 the office of the VPRI requested a survey to determine what quality processes were in place in the department/centres/units which carry out patient focused research in UCC. The Quality and Regulatory Affairs Director of HRB-CRF-C (whose role includes that of Sponsor QRD) carried out this survey and submitted results to Clinical Research Reporting Officer (CRRO) at UCC sponsor's office and to the Vice President of Research and Innovation (VPRI). Survey Results indicated a lack of quality processes in many locations and a lack of knowledge and resources among researchers around basic quality processes and documents for patient focused research.

The idea of a UCC Quality Working Group for Patient focused research was thus proposed to support the conduct of patient focused research in UCC with the mission and objectives outlined below.

2. Mission and objectives

The mission of the QWG is to improve the quality of both regulated and non-regulated patient focused research in UCC ensuring that harmonisation is promoted, duplication is avoided and available resources are maximised.

The objectives of the QWG are as follows:

1. Agree minimum standards for quality systems for patient focused research in UCC.
2. Develop and share 'Generic' Standard Operating Procedures and Forms which researchers can use and adapt for their own patient focused research.
3. Promote harmonisation and avoid duplication of effort by sharing of information regarding systems, procedures, processes, experiences, audit and inspection findings (as appropriate).
4. Provide a source of skilled quality professionals who can support researchers by carrying out audit or quality reviews when requested.
5. Support the provision of training and mentoring in patient focused research in UCC.
6. Provide considered opinion on the approach to implementation of new legislation/standards relating to patient focused research.
7. Carry out horizon scanning activities, ensuring changing legislation and guidance is identified in advance
8. Engage with interested stakeholders, on relevant issues, as necessary.

3. Composition and Membership

3.1 Chairperson

Meetings will be chaired by the QRD of HRB CRF-C

If QRD is absent, another member will chair the meeting. In this case, the chair will be selected for that meeting by consensus from other members.

3.2 Membership

Initial Membership is composed of the following:

- QRD of HRB CRF-C- Chair,
- Quality Representatives from the INFANT Centre, APC Microbiome Ireland (APC), Clinical Research Facility-Cork (CRF-C), Oncology Clinical Trials unit, Food and Nutritional Sciences, Epidemiology and Public Health.

Quality representatives from other departments/ centres/ Units where patient focused research is carried out may request to join the group at any time. Depending on number and expertise in the group at the time of the request membership will be at the discretion of QRD and CRRO. This is in order to preserve a mix of skills and experience in the group and avoid overly large meetings.

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4. Meetings

4.1 Frequency and location: Meetings will be held monthly for the first 3 months and thereafter on a quarterly basis. Location will rotate to various UCC locations to facilitate the members.

4.2 Minutes: Minutes will be taken by one of the members (rota) and circulated to all members within two weeks of the meeting

5. Responsibilities:

5.1 Responsibilities of the Chairperson:

The Chairperson is responsible for the efficient conduct of the business of the group. She/he will

- send out a draft agenda before each meeting
- arrange meeting date and location
- ensure that minutes are taken and circulated.
- aim to achieve consensus on issues discussed
- decide in exceptional cases, when a vote is necessary
- coordinate the work of the UCC QWG with any other relevant bodies, as appropriate
- report on the activities of UCC QWG to the Sponsors office and senior management of University

5.2 Responsibilities of members

Membership implies a commitment to participate actively in the work of the UCC QWG and to attend meetings regularly.

- Members will communicate the views of the department/centre/ unit they represent when contributing to discussions and agreements.
- Members shall ensure that any relevant issues are discussed/ communicated within their department as appropriate.
- Members may identify and propose topics for discussion and consideration by QWG.
- Members shall follow up on any actions which they volunteer/ agree to carry out within the timelines agreed.
- Members will take part in drafting groups on specific topics as appropriate and as time and work load allows.

6 Contacts with interested parties

- Where relevant, the QWG will establish contacts, on an advisory basis, with parties concerned with clinical research.
- When considered appropriate, such parties may make oral or written presentations to Q