HRB Clinical Research Facility Cork Quality Policy Statement

Document History	Effective Date	Rationale
V1.0	01 August 2014	Initial Version
V2.0	01 August 2017	1. Changes to legislation including ICH-GCP update to R2, Data protection Regulation (2018) and update of 3 Medical Device Directives to 2 Regulations. 2. Include concepts of Research integrity and risk management

The HRB Clinical Research Facility Cork (CRF-C) is committed to following national regulations and legislation that relate to any service or activity it carries out. The Senior Management Team (SMT) of the CRF-C:

- are committed to research integrity of research carried out by CRF-C
- are committed to the continuous improvement of the quality of its processes
- will ensure that the quality management system is regularly reviewed to ensure it remains current and effective
- are committed to incorporating risk assessment and management into CRF-C processes

When carrying out clinical research studies on human subjects involving Investigational Medicinal Products and medical devices, the CRF-C will adhere to relevant national and international regulations, laws and guidelines including:

- ICH Guideline for Good Clinical Practice E6 (R2)
- EU Directive 2001/20/EC – (Clinical Trials Directive)
- EU Directive 2005/28/EC- (GCP Directive)
- S.I No. 190 of 2004
- S.I No. 374 of 2006
- ISO 14155:2011
- EU Medical Device Directives and their associated Statutory implements in Ireland or Medical Device Regulations, as appropriate (*Changes are being implement at time of writing whereby the 3 Medical Device Directives are being replaced by two Medical Device Regulations with phased implementation.)
- WMA Declaration of Helsinki
- Data Protection Act 1988 and (amendment) 2003 - Up to May 2018
- General Data Protection Regulation – After May 2018

The service that the CRF-C provides will be of a high quality and will take into consideration the needs and requirements of its users.

In order to ensure these needs and requirements are met, the Senior Management Team of the CRF-C will:

- Operate a Quality Management System (QMS) to integrate the organisation, procedures, processes and resources.
- Maintain a Quality Manual which details how this policy is met.
- Are committed to staff recruitment, training, development and retention to provide a full effective service to its users and to adhere to the required regulations.
- Ensure that staff working in the CRF-C are appropriately qualified and experienced in the area of their responsibility or in a designated training post working under the supervision until trained to the required level.
- Ensure staff are familiar with this policy/ statement and the CRF-C Quality Manual.

The Senior Management Team of the CRF-C will ensure that the CRF-C will maintain an approved Master Documentation Log of all Standard Operating Procedures (SOPs) governing its essential processes. A training matrix will indicate the appropriate SOPs required for each role within CRF-C. Adherence to the relevant CRF-C SOPS is SOPs is compulsory.

Approved by:

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Professor Joe Eustace Date

Clinical Director, HRB-CRF-C