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Clinical Research (Support) Unit Quality Policy Statement

Reviewed and approved by:

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11 December 2020

Prof Paul Burke
Chairman, CRU Management Board

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Note:

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Reviewed By	CRU Management Board
Approved by	Chairman, CRU Management Board
Approval date	11 December 2020
Effective date	11 December 2020
Review date	July 2022
Version	Version 2.0

Document History:

Version	Date	Reason for Change	Author
1.0	July 2018	Initial Release	Maria Ryan
2.0	November 2020	2 year review: 1. Changed UL logo to HRI logo 2. Corrected name of CRSU Board of Management to CRU Management Board 3. Updated expected date Clinical Trial Regulation will come into effect 4. Updated expected date the MDR will come into effect 5. Addition of reference to HRR	Maria Ryan

The Clinical Research (Support) Unit (CR(S)U) recognises that Clinical Research requires its own unique Quality Management System (QMS) with a defined organizational structure, a set of procedures, processes and resources operating under a distinct mission statement influenced by externally imposed regulations and ethical principles. The QMS provides the tools needed to implement quality control, quality assurance and quality improvement for clinical research.

The CR(S)U is committed to following regulations and legislation that relate to any service or activity it carries out. The CRU Management Board:

- are committed to ensuring the integrity of research carried out by the CR(S)U
- are committed to the continuous improvement of the quality of its processes
- will ensure that the QMS is regularly reviewed to ensure it remains up to date and effective
- are committed to incorporating risk assessment and management into CR(S)U processes

When carrying our clinical research studies on human subjects involving Investigational Medicinal Products and/or medical devices the CR(S)U 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 **Although the Clinical Trials Regulation EU No 536/2014 entered into force on 16 June 2014 the timing of its application depends on the development of a fully functional EU clinical trials portal and database, which will be confirmed by an independent audit. The Regulation becomes applicable six months after the European Commission publishes a notice of this confirmation. The entry into application of the Regulation is currently estimated to occur in 2021.*
- EU Directive 2005/28/EC – GCP Directive
- S.I. No. 190 of 2004
- S.I. No. 374 of 2006
- ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good Clinical Practice
- EU Medical Device Directives, Medical Device Regulation (MDR), In-vitro Diagnostic Devices Regulation (IVDR) along with their associated Statutory Instruments in Ireland. **The new MDR and IVDR came into effect at the end of May 2017 but they have a staggered transitional period with some aspects becoming legally binding after 6 months, full application of MDR by May 2020 and full application of the IVDR by May 2022 and so the EU Medical Device Directive will be observed also until full application is realised. The MDR was due to become fully applicable on 26 May 2020 after a three-year transition period. However, due to the global outbreak of Covid-19, full application of the MDR has been postponed and will become fully applicable on 26 May 2021. The IVDR will be fully applicable on 26 May 2022, after a five-year transition period*
- World Medical Association Declaration of Helsinki
- General Data Protection Regulation (GDPR) 2018
- Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018)

The service that the CR(S)U 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 CRU Management Board will, under the direction of the Clinical Operations Manager and the Quality & Regulatory CRA:

- operate a QMS to integrate the organisation, procedures, processes and resources. The QMS will lay out the tasks, offer templates and provide methods for measuring quality
- maintain a Quality Manual which details how this policy is met
- ensure commitment to staff recruitment, training, development and retention to provide a full effective service to its users and to adhere to the required regulations as outlined in the Quality Manual
- ensure that staff working in the CR(S)U are appropriately qualified and experienced in the area of their responsibility or in a designated training post working under supervision until trained to the required level
- ensure staff are familiar with this policy statement, the Quality Manual and the overall QMS