RCSI

INTRODUCTION TO CLINICAL RESEARCH & GOOD CLINICAL PRACTICE

14th September, 2023, 09.00 – 16.00

Venue: Tutorial Room 1,

RCSI Education & Research Centre, Beaumont Hospital

AGENDA

09:00 Introduction to Clinical Research and Drug Development

Lessons from the Past

10:00 Break

10:30 Research Governance

Principles of Good Clinical Practice in IMP Trials

Investigator Responsibilities

13:00 Break

13:40 Investigator Responsibilities (continued)

Quality and Safety Issues:

- Safety Reporting
- Essential Documents
- GCP Inspections

15:30 GCP Quiz

Data Privacy: In order to record attendance, and to provide certification of attendance for future reference, your contact details will be retained on a course attendance record for a period of 2 years. This information will be located on the RCSI server, with authorised access only. You may receive notification of future courses or be asked to complete audit forms. If you do not wish your data to be retained, or want to have it deleted or amended at any time, this will be fully respected.

Accreditation: This ICH E6 (R2) GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. The full GCP course is accredited by NMBI for 6 CTUs. Refresher accredited for 4 CTUs.

For further information, please contact Deirdre Hyland – dhyland@rcsi.com