Course Title	GOOD CLINICAL PRACTICE: SPONSOR RESPONSIBILITIES - INCORPORATING INTEGRATED ADDENDUMS (E6R2)

Overview:

A one day course aimed at investigators, project managers and associated research team members involved in investigator-led clinical trials, representatives from the pharmaceutical industry and research officers from academic institutions. **This course incorporates the Integrated Addendum to ICH GCP Guideline E6 (R2) adopted by the EMA in December 2016.**

The following content is included:

- Clinical Research Governance: Background, Rules and Regulations
- Principles of Good Clinical Practice
- Sponsor Responsibilities
- Regulatory Inspections (Sponsor Perspective)

Dates and Venues	**Monday 8th May 2017** RCSI Education & Research Centre, Smurfit Building, Beaumont Hospital
Cost	€100.00 (Clinical/Academic rate); €300.00 (Industry rate).
Registration	Please contact either: Deirdre Hyland: Director of Research Nurse Education (01) 809 3785 dhyland@rcsi.ie or Carole Schilling: Quality & Regulatory Affairs Manager (01) 809 3789 caroleschilling@rcsi.ie