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## INTRODUCTION TO CLINICAL RESEARCH AND GOOD CLINICAL PRACTICE (GCP) INCORPORATING INTEGRATED ADDENDUMS (E6R2)

## Overview

This one day course is relevant to Principal Investigators, research nurses and associated research site personnel who have not undertaken GCP training within the previous 2 years.

This course incorporates the Integrated Addendum to ICH GCP Guideline E6 (R2) adopted by the EMA in December 2016.

The following content is included:

- ➤ Introduction to Drug Development and Clinical Research
- > Research Ethics and Clinical Research Governance
- Principles of Good Clinical Practice
- Investigator Responsibilities
- Regulatory Inspection

The course has Category 1 Approval from the Nursing & Midwifery Board of Ireland (NMBI) - 6 CEUs. It also 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

	Monday 13 <sup>th</sup> February 2017 & Thursday 20 <sup>th</sup> July 2017.
Dates &	RCSI Education & Research Centre, Smurfit Building, Beaumont Hospital
Venues	<b>Thursday 23<sup>rd</sup> November 2017</b> , RCSI, St Stephens Green, Dublin 2
	Additional training dates can be facilitated at alternative locations for groups of 10 or more.
Cost	€100.00 (Clinical/Academic rate); €300.00 (Industry rate).
Registration	Please contact Deirdre Hyland: Director of Research Nurse Education
	(01) 809 3785 dhyland@rcsi.ie