

**STUDY DAY SCHEDULE RCSI CLINICAL RESEARCH CENTRE 2018**

Additional training dates or courses may be added subject to demand. Training courses may be facilitated at alternative locations for groups of 10 or more.

<b>Course Title</b>	<b>Overview</b>	<b>Dates &amp; Venues</b>	<b>Booking Information</b>
<b>Introduction To Clinical Research</b>	<p>A one day course developed for induction of newly recruited research nurses, study coordinators and research assistants, this programme covers the following topics:</p> <ul style="list-style-type: none"> <li>➤ Introduction to Clinical Research (Short History of Clinical Research and Research Governance; Types of Clinical Research)</li> <li>➤ Clinical Trial Coordination (Who's Who and the Study Coordinator Role; Site File Management; Documentation &amp; Data Management; Clinical Informatics &amp; Data Protection)</li> <li>➤ Quality and Regulatory (Approval Processes; Monitoring &amp; Quality Management; Informed Consent)</li> </ul> <p>This course has Category 1 approval from the Nursing &amp; Midwifery Board of Ireland ( NMBI ) for 5.5 CEUs</p>	<p><b>Thursday 22<sup>nd</sup> February 2018</b> RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital.</p>	<p><b>Cost:</b> €60.00</p> <p><b>Contact:</b> Deirdre Hyland: Senior Research Nurse/Director of Research Nurse Education (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>
<b>Course Title</b>	<b>Overview</b>	<b>Dates &amp; Venues</b>	<b>Booking Information</b>
<b>Introduction To Clinical Research And Good Clinical Practice (GCP) Incorporating Integrated Addendum (E6R2)</b>	<p>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. The following content is included:</p> <ul style="list-style-type: none"> <li>➤ Introduction to Drug Development and Clinical Research</li> <li>➤ Research Ethics and Clinical Research Governance</li> </ul>	<p><b>Tuesday 13<sup>th</sup> March 2018; Monday 16<sup>th</sup> July 2018; Tuesday 20<sup>th</sup> November 2018.</b> RCSI Education &amp; Research Centre, Smurfit Building, Beaumont</p>	<p><b>Cost:</b> €100.00 (Clinical/Academic rate) €200.00 (Industry rate)</p> <p><b>Contact:</b></p>

	<ul style="list-style-type: none"> <li>➤ Principles of Good Clinical Practice</li> <li>➤ Investigator Responsibilities</li> <li>➤ Regulatory Inspection</li> </ul> <p>The course has Category 1 Approval from the Nursing &amp; 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</p>	<p>Hospital.</p> <p>Additional dates can be facilitated at alternative locations for groups of 10 or more.</p>	<p>Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>
Course Title	Overview	Dates & Venues	Booking Information
<p><b>Good Clinical Practice (GCP) Refresher Course - Incorporating Integrated Addendums (E6R2)</b></p>	<p>A half day course relevant to Principal Investigators, Research Nurses and associated research site staff who have attended a full GCP training day within the last two years. The following content is included:</p> <ul style="list-style-type: none"> <li>➤ Clinical Research Governance (Revision &amp; Updates)</li> <li>➤ Principles of Good Clinical Practice</li> <li>➤ Investigator Responsibilities</li> <li>➤ Regulatory Inspections</li> </ul> <p>The course has Category 1 Approval from the Nursing &amp; Midwifery Board of Ireland (NMBI). All attendees are eligible for 4 CEUs on completion. 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.</p>	<p><b>Tuesday 17<sup>th</sup> July, 2018.</b> RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital.</p>	<p>€50.00 (Clinical/Academic rate)</p> <p>€100.00 (Industry rate).</p> <p><b>Contact:</b> Deirdre Hyland: <b>(01) 809 3785</b> <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

Course Title	Overview	Dates & Venues	Booking Information
<b>Good Clinical Practice: Sponsor Responsibilities - Incorporating Integrated Addendums (E6r2)</b>	<p>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. The following content is included:</p> <ul style="list-style-type: none"> <li>➤ Clinical Research Governance: Background, Rules and Regulations</li> <li>➤ Principles of Good Clinical Practice</li> <li>➤ Sponsor Responsibilities</li> </ul> <p>Regulatory Inspections (Sponsor Perspective)</p>	<p>Thursday 15<sup>th</sup> March, 2018, HRB/Wellcome Trust CRF St James's Hospital;</p> <p>Tuesday 2<sup>nd</sup> October 2018, RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital</p>	<p><b>Cost:</b></p> <p>€100.00 (Clinical/Academic rate) €200.00 (Industry rate)</p> <p><b>Contact:</b></p> <p>Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>
Course Title	Overview	Dates & Venues	Booking Information
<b>Good Clinical Practice In Medical Device Research</b>	<p>A one day course aimed at investigators, project managers, research nurses and other research team members involved in the conduct of medical device research at a clinical research site. It is also relevant to sponsors and device manufacturers involved in conducting clinical investigations. This course includes the following content:</p> <ul style="list-style-type: none"> <li>➤ Principles of Good Clinical Practice</li> <li>➤ Medical Devices (What is a Medical Device?; Types &amp; Classification; Medical Device Legislation; Clinical Investigations)</li> <li>➤ Good Clinical Practice in Device Trials (Ethical Issues; Conduct of a Clinical Investigation; Safety Reporting in Device Research)</li> <li>➤ Monitoring &amp; Audit</li> </ul>	<p><b>Tuesday 27<sup>th</sup> February, 2018; Tuesday 11<sup>th</sup> September, 2018;</b> RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital</p>	<p><b>Cost:</b></p> <p>€100.00 (Clinical/Academic rate) €200.00 (Industry rate)</p> <p><b>Contact:</b></p> <p>Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

**BOOKING FORM**

Course: \_\_\_\_\_

Name: \_\_\_\_\_

Address/Workplace: \_\_\_\_\_

Role: \_\_\_\_\_

**Please indicate if paying course fee by:**

(a) Cash or Cheque: \_\_\_\_\_; or (b) Invoice to employer/institution \_\_\_\_\_.

**If invoice required please provide details of payee:**

Name: \_\_\_\_\_

Billing Address: \_\_\_\_\_

\_\_\_\_\_

**Grant Code** \_\_\_\_\_ **or Purchase Order Number** \_\_\_\_\_ (as applicable).

Refreshments may be provided. Please indicate if you have any dietary allergies or intolerances:

\_\_\_\_\_.

**Return completed booking form to:**

Deirdre Hyland ([dhyland@rcsi.ie](mailto:dhyland@rcsi.ie)) or Carole Schilling ([caroleschilling@rcsi.ie](mailto:caroleschilling@rcsi.ie))