

## STUDY DAY SCHEDULE RCSI CLINICAL RESEARCH CENTRE: Jan – June 2020

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.

INTRODUCTION TO CLINICAL RESEARCH & GOOD CLINICAL PRACTICE (GCP)	Dates & Venues	Booking Information
<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> <li>➤ Principles of Good Clinical Practice</li> <li>➤ Investigator Responsibilities</li> <li>➤ Regulatory Inspections</li> </ul> <p>The course has Category 1 Approval from NMBI – 6.5 CEUs. It meets the minimum criteria for ICH GCP training identified by TransCelerate Biopharma as necessary to enable mutual recognition of Investigator Site GCP training by trial sponsors. It is also accredited as a component of the Postgraduate Certificate in Clinical Research Practices, RCSI School of Postgraduate Studies (2 ECTS)</p>	<p><b>Thursday 6<sup>th</sup> Feb</b> <b>07.30 – 15.00</b> Conference Room, RCSI Education &amp; Research Centre, Beaumont Hospital.</p> <p><b>Note:</b> This course will be video-conferenced to facilitate attendance by colleagues in RCSI Bahrain</p> <p><b>Wednesday 13<sup>th</sup> May,</b> Tutorial Room 2, RCSI Education &amp; Research Centre, Beaumont Hosp.</p>	<p><b>Cost (external attendees):</b> €100.00</p> <p><b>Student rate:</b> €30.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>
GOOD CLINICAL PRACTICE (GCP) REFRESHER COURSE	Dates & Venues	Booking Information
<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 3.5 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>Wednesday 29<sup>th</sup> January, 2020</b> <b>09.30 - 13.30,</b> Tutorial Room 2, RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital.</p>	<p><b>Cost (external attendees):</b> €100.00</p> <p><b>Student rate:</b> €30.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

GOOD CLINICAL PRACTICE: SPONSOR RESPONSIBILITIES	Dates & Venues	Booking Information
<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><b>Date and venue to be confirmed</b></p>	<p><b>Cost (external attendees):</b> €100.00</p> <p><b>Student rate:</b> €30.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>
GOOD CLINICAL PRACTICE IN MEDICAL DEVICE RESEARCH	Dates & Venues	Booking Information
<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>➤ Overview of Clinical Research</li> <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>This course is accredited as a component of the Postgraduate Certificate in Clinical Research Practices, RCSI School of Postgraduate Studies (2 ECTS)</p>	<p><b>Wednesday 10<sup>th</sup> June</b> Tutorial Room 2, RCSI Education &amp; Research Centre, Smurfit Building, Beaumont Hospital</p>	<p><b>Cost (external attendees):</b> €60.00</p> <p><b>Student rate:</b> €30.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

<p style="text-align: center;"><b>NEW ** NEW ** NEW</b></p> <p style="text-align: center;"><b>CLINICAL RESEARCH COORDINATION AND MANAGEMENT</b></p>	<p style="text-align: center;"><b>Dates &amp; Venues</b></p>	<p style="text-align: center;"><b>Booking Information</b></p>
<p>A three-day course designed to explore elements of the clinical research nurse/study coordinator role.</p> <p>This course will be delivered over 3 days using a combination of face to face (2 days) and online (equivalent to 1 day) teaching strategies.</p> <p>Topics included are:</p> <ul style="list-style-type: none"> <li>➤ Role of study coordinator</li> <li>➤ Study set-up – Budgets, feasibility, administration, site preparation</li> <li>➤ Patient recruitment</li> <li>➤ Patient study visit management</li> <li>➤ IMP and resource management</li> <li>➤ Documentation In clinical research</li> <li>➤ Data management, safety reporting and discrepancy management</li> <li>➤ Site file management</li> <li>➤ Study close-out and archiving</li> <li>➤ Preparing for Audit and Inspection</li> </ul> <p><b>Day 1:</b> Study Set-up (face to face)</p> <p><b>Day 2:</b> Managing Study Participant Visits (online)</p> <p><b>Day 3:</b> Safety and Regulatory Issues (face to face)</p> <p>This course has been accredited as an optional component of a Postgraduate Certificate in Clinical Research Practices, School of Postgraduate Studies, RCSI (5 ECTS). It is also accredited by the Nursing &amp; Midwifery Board of Ireland for 18 continuing education units (CEUs).</p>	<p><b>CRCM Day 1:</b> Wednesday 26<sup>th</sup> February, 09.00 - 16.30, Tutorial Room 1, RCSI Education &amp; Research Centre, Beaumont Hospital.</p> <p><b>CRCM Day 2:</b> <b>Online date TBC.</b></p> <p><b>CRCM Day 3:</b> Monday 6<sup>th</sup> April, 09.00 - 16.30, Tutorial Room 2, RCSI Education &amp; Research Centre, Beaumont Hospital.</p>	<p><b>Cost (external attendees):</b> €180.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

INTRODUCTION TO CLINICAL RESEARCH	Dates & Venues	Booking Information
<p><b>Overview</b></p> <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</li> <li>○ Short History of Clinical Research and Research Governance</li> <li>○ Types of Clinical Research</li> <li>➤ Clinical trial coordination: <ul style="list-style-type: none"> <li>○ Who's Who and the Study Coordinator Role</li> <li>○ Site File Management</li> <li>○ Documentation &amp; Data Management</li> <li>○ Clinical Informatics &amp; Data Protection</li> </ul> </li> <li>➤ Quality and Regulatory <ul style="list-style-type: none"> <li>○ Approval Processes</li> <li>○ Monitoring &amp; Quality Management</li> <li>○ Informed Consent</li> </ul> </li> </ul> <p>This course has Category 1 approval from the Nursing &amp; Midwifery Board of Ireland (NMBI) for 6.5 Continuing Education Units (CEUs).</p>	<p><b>TBC</b></p>	<p><b>Cost (external attendees):</b></p> <p>€60.00</p> <p>See booking form for further details, or contact Deirdre Hyland: (01) 809 3785 <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p>

## Course Booking Form

<b>Name:</b>	<b>Email:</b>
<b>Job Title:</b>	<b>Workplace or home address:</b>
<b>Course name:</b>	<b>Preferred course date:</b>
<b>External attendees:</b>	
<p>To reserve a place on your preferred course date please contact course coordinator, Deirdre Hyland <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a></p> <p>Please find below the web payment link to be used for making payments for the courses you are attending:</p> <p><a href="https://ubw.unit4cloud.com/ie_rcs_prod_incomemanager/NReg/QuickPay.aspx?GROUP=54">https://ubw.unit4cloud.com/ie_rcs_prod_incomemanager/NReg/QuickPay.aspx?GROUP=54</a></p> <p>Where there is a reduced cost for students you have the option of selecting NS (non-student) or S (student)</p>	
<b>RCSI staff &amp; students</b>	
<p>To reserve a place on your preferred course date please contact course coordinator, Deirdre Hyland <a href="mailto:dhyland@rcsi.ie">dhyland@rcsi.ie</a>.</p> <p>If applicable, payment as above, or please provide Grant or Department Code: _____</p>	
<b>Refreshments may be provided. Please indicate if you have any food allergy or intolerance</b>	
<p><b>Data privacy statement</b></p> <p>In order to process this application, 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, and will not be revealed to unauthorised persons. 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.</p>	
<p><b>Signature:</b> _____ <b>Date:</b> _____</p> <p>(can be typed or electronic)</p>	
<p><b>For further information, or to submit a booking form, please contact Deirdre Hyland -</b>  <a href="mailto:dhyland@rcsi.com">dhyland@rcsi.com</a></p>	