## GCP STUDY DAY SCHEDULE RCSI CLINICAL RESEARCH CENTRE, 2019

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.

| Course Title  | Overview   | Dates & Venues  | Booking Information   |
|---|--|---|---|
| Introduction To<br>Clinical Research<br>& Good Clinical<br>Practice | <ul> <li>This one day course is relevant to Principal<br/>Investigators, research nurses and associated<br/>research site personnel who have not undertaken<br/>GCP training within the previous 2 years. The<br/>following content is included:</li> <li>Introduction to Drug Development and<br/>Clinical Research</li> <li>Research Ethics and Clinical Research<br/>Governance</li> <li>Principles of Good Clinical Practice</li> <li>Investigator Responsibilities</li> <li>Regulatory Inspection</li> <li>The course has Category 1 Approval from the<br/>Nursing &amp; Midwifery Board of Ireland (NMBI) - 6</li> <li>CEUs. It also meets the minimum criteria for ICH GCP<br/>investigator site personnel training identified by</li> <li>TransCelerate Biopharma as necessary to enable<br/>mutual recognition of GCP training by trial sponsors</li> </ul> | Monday 11 <sup>th</sup> Feb<br>& Tuesday 16 <sup>th</sup><br>July, 2019<br>RCSI Education &<br>Research Centre,<br>Smurfit Building,<br>Beaumont<br>Hospital.           | Cost:<br>€100.00<br>(Clinical/Academic<br>rate)<br>€30.00 (student rate)<br>€200.00 (Industry<br>rate)<br>Contact:<br>Deirdre Hyland:<br>(01) 809 3785<br>dhyland@rcsi.ie |
| Course Title  | Overview   | Dates & Venues  | Booking Information   |
| Good Clinical<br>Practice (GCP)<br>Refresher Course                 | <ul> <li>A half day course relevant to Principal Investigators,<br/>Research Nurses and associated research site staff<br/>who have attended a full GCP training day within the<br/>last two years. The following content is included: <ul> <li>Clinical Research Governance (Revision &amp;<br/>Updates)</li> <li>Principles of Good Clinical Practice</li> <li>Investigator Responsibilities</li> <li>Regulatory Inspections</li> </ul> </li> <li>The course has Category 1 Approval from the<br/>Nursing &amp; Midwifery Board of Ireland (NMBI). All<br/>attendees are eligible for 4 CEUs on completion. It<br/>also meets the minimum criteria for ICH GCP<br/>investigator site personnel training identified by<br/>TransCelerate Biopharma as necessary to enable<br/>mutual recognition of GCP training among trial<br/>sponsors.</li> </ul>               | Thursday 14 <sup>th</sup><br>Feb, 2019<br>Tuesday 16 <sup>th</sup><br>April, 2019<br>RCSI Education &<br>Research Centre,<br>Smurfit Building,<br>Beaumont<br>Hospital. | <pre>€50.00 (Clinical/Academic rate)  €100.00 (Industry rate). Contact: Deirdre Hyland: (01) 809 3785 dhyland@rcsi.ie</pre>   |

| Course Title      | Overview   | Dates & Venues                | Booking Information    |
|-------------------|--|-------------------------------|------------------------|
| Good Clinical     | A one day course aimed at investigators, project   | Thursday 18 <sup>th</sup>     | <b>Cost:</b> €100.00   |
| Practice: Sponsor | managers and associated research team members  | April, RCSI                   | (Clinical/Academic     |
| Responsibilities  | involved in investigator-led clinical trials,  | Education &                   | rate)                  |
|                   | representatives from the pharmaceutical industry   | Research Centre,              |                        |
|                   | and research officers from academic institutions.  | Smurfit Building,             | €30.00 (student rate)  |
|                   | The following content is included:   | Beaumont                      | €200.00 (Industry      |
|                   |  | Hospital                      | rate)                  |
|                   | <ul> <li>Clinical Research Governance: Background,</li> <li>Bulas and Begulations</li> </ul> |                               |                        |
|                   | Rules and Regulations  |                               | Contact:               |
|                   | Principles of Good Clinical Practice   |                               |                        |
|                   |  |                               | Deirdre Hyland:        |
|                   | Sponsor Responsibilities   |                               | (01) 809 3785          |
|                   | Regulatory Inspections (Sponsor Perspective)   |                               | <u>dhyland@rcsi.ie</u> |
| Course Title      | Overview   | Dates & Venues                | Booking Information    |
| Good Clinical     | A one day course aimed at investigators, project   | Tuesday 26 <sup>th</sup> Feb. | Cost:                  |
| Practice In       | managers, research nurses and other research team  | RCSI Education &              |                        |
| Medical Device    | members involved in the conduct of medical device  | Research Centre,              | €60.00                 |
| Research          | research at a clinical research site. It is also relevant                                    | Smurfit Building,             | (Clinical/Academic     |
|                   | to sponsors and device manufacturers involved in   | Beaumont                      | rate)                  |
|                   | conducting clinical investigations. This course  | Hospital                      | €30.00 (student rate)  |
|                   | includes the following content:  |                               |                        |
|                   |  |                               | €100.00 (Industry      |
|                   | Principles of Good Clinical Practice   |                               | rate)                  |
|                   | Medical Devices (What is a Medical Device;   |                               | Contact:               |
|                   | Types & Classification; Medical Device   |                               |                        |
|                   | Legislation; Clinical Investigations)  |                               | Deirdre Hyland:        |
|                   | Good Clinical Practice in Device Trials  |                               | (01) 809 3785          |
|                   | (Ethical Issues; Conduct of a Clinical   |                               | <u>dhyland@rcsi.ie</u> |
|                   | Investigation; Safety Reporting in Device<br>Research)                                       |                               |                        |
|                   | Monitoring & Audit   |                               |                        |

## **Course Booking Form**

| Name:   | Email:   |  |  |  |
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| Job Title:  | Workplace:                                     |  |  |  |
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| Course name:  | Preferred course date:                         |  |  |  |
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| Pay by cheque/bank transfer:  | Invoice to employer:                           |  |  |  |
|   | Name:  |  |  |  |
|   | Address:                                       |  |  |  |
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|   | Grant Code or Purchase Order number:           |  |  |  |
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| Refreshments may be provided. Please indicate if you have any food allergy or intolerance   |  |  |  |  |
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| Data privacy statement  |  |  |  |  |
| In order to process this application, and to provide certification of attendance for future   |  |  |  |  |
| reference, your contact details will be retained o  | n 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. |  |  |  |  |
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| Signature: Date:  |  |  |  |  |
| (can be typed or electronic)  |  |  |  |  |
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| For further information, or to submit a booking form, please contact Deirdre Hyland -   |  |  |  |  |
| dhyland@rcsi.com  |  |  |  |  |