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## Clinical research modules (2015/16)

The following stand alone modules, components of the Postgraduate Certificate in Nursing (Clinical Research) are offered through the School of Nursing and Midwifery, Royal College of Surgeons in Ireland. These modules are aimed at all personnel working in a clinical research environment, including study development and coordination, quality assurance, ethical review, data management and scientific processing and analysis

### Clinical Research Design and Methodology

The aim of this module is to introduce the student to clinical research, and to research methodologies - in particular quantitative statistical methods utilised in clinical research. Lectures are designed to provide the student with an appreciation of the purpose of clinical research, and a broad knowledge of study design. Students develop the skills needed to participate in protocol development and in the design and structure of relevant study documents.

Provisional dates: 3 study days in RCSI and 2 web-based days;  
09/09/15, 30/09/15, 29/10/15 (Study days); 16/09/15, 14/10/15 (Web-based)

### Ethics and Regulatory Affairs

In this module we explore the core ethical principles and ethical issues in clinical research. The module includes lectures on informed consent, organ and tissue retention, third world research, the role of ethics committees and preparing an ethics application. Also included are an introduction to healthcare law, Irish and EU regulations governing research, regulatory inspections, data protection and clinical indemnity. This module incorporates the Irish Clinical Research Infrastructure network (ICRIN) ICH GCP study day.

3 study days in RCSI and 2 web-based days:  
05/11/15, 25/11/15 (ICH GCP), 17/12/15 (study days); 18/11/15, 09/12/15 (Web-based)

### Clinical Research Practice & Management

This module explores the role of the Clinical Research Nurse or study coordinator in depth. It covers all aspects of study management, including study set-up, budgeting, essential documents, patient recruitment and visit management, medication management, handling and transport of biological samples, maintenance of site files, discrepancy management, study closeout and archiving. It also looks at the role of the CRA, and of Clinical Research Organisations (CROs), and the patient/public perception of clinical research.

3 study days in RCSI and 2 web-based days:  
13/01/16, 04/02/16, 02/03/16 (Study days); 27/01/16, 17/02/16 (Web-based days)

**Entry requirements:** The applicant is required to hold a primary degree or equivalent, with relevant experience and previous studies (each application will be considered on an individual basis). Computer skills and access to a computer and the Internet are essential.

**Cost:** €700.00 per Module

On-line Registration is now available; Prospectus and Application forms: <http://www.rcsi.ie/nursing>

### **For Further Information contact:**

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