



Registered Membership Examination (ICR Exam) Information Booklet

Contents

1. Background.....	2
1.1. Background to the Institute of Clinical Research	2
1.2. Background to the examination	3
1.3. Becoming a Registered Member (RICR)	3
1.4. Benefits of becoming a Registered Member (RICR).....	4
1.5. Demonstration of Knowledge	5
2. Syllabus	5
3. How do I acquire the knowledge?	6
3.1. Recommended Reading by Syllabus area:.....	6
3.2. The Books.....	8
3.3. Other sources of information.....	10
4. Exam Format	111
4.1. Paper I: Multiple Choice.....	111
4.2. Paper 2: Short Answer Questions.....	112
4.3. Passing the Examination	112

Appendix 1: Self assessment Form

Appendix 2: Registration Form

1. Background

1.1. Background to the Institute of Clinical Research

The Institute of Clinical Research (ICR) is the oldest and largest not-for-profit organisation formed originally in 1978, and is the professional body for clinical research personnel.

The aims of the ICR are

- To enhance the professional identity of Members of the Institute
- To facilitate communications between Members by providing a forum for discussion
- To promote good relations with other healthcare related groups
- To provide opportunities for learning and development to enhance professional competence
- To enhance public confidence and understanding of clinical research

The membership is drawn from the pharmaceutical industry, the support service sector (contract research organisations and others) and research personnel at the study site (study site co-ordinators, research nurses, pharmacy staff and other allied healthcare professionals). During the development of the organisation, it has attracted new categories of members associated with clinical research. These include pharmacists, clinical research statisticians, data managers and clinical trial administrators. All categories of membership have grown remarkably in the past few years and membership now stands at approximately 6,000.

With the significant achievement of gaining Institute status, a number of developments have been made and more recently the membership levels were restructured. The movement between levels will depend on academic achievement, experience in clinical research and demonstration of continued professional development. One way to facilitate movement between the affiliate and registered member (RICR) categories is the ICR Registered Membership Examination (ICR Exam).

1.2. Background to the examination

This ICR Exam has been designed to provide:

- An alternative route into Registered Membership (RICR)
- A route for those wishing to demonstrate their knowledge of clinical research
- A method of formal assessment that can be used as a follow up to a learning program

The content of the ICR Exam was designed to test the candidate's broad overview of the essential aspects of clinical research not just guidelines and regulations. It will also test the candidate's ability to apply that knowledge.

The ICR Exam was prepared by a group of individuals from blue chip pharmaceutical companies, Clinical Research Organisations, study sites, data management/statistical and device companies.

1.3. Becoming a Registered Member (RICR)

To become a Registered Member (RICR) of the ICR there are three distinct routes.

Membership structure of the Institute of Clinical Research



1. Those holding a clinical research academic qualification a BSc (life science), an equivalent nursing qualification or NVQ Level 4 in a clinical discipline.
2. Those holding a cognate degree. There are a number of scientific degrees that will contain the basic concepts and scientific reasoning. In order to ascertain if a degree is cognate the candidate is asked to complete the self-assessment form, which will be reviewed and checked against a list of cognate degrees.
3. Those who take and pass the ICR Exam

Any person wishing to apply to become a Registered Member (RICR) must have at least one year's experience in clinical research. As a Registered Member (RICR) you will have the benefit of gaining recognition of your experience and achievements amongst your peers in the clinical research community.

The ICR Exam is designed in two parts. Part I (certificate) may be taken once the theory and basic principles of clinical research are acquired. Part II (diploma) requires a degree of application of those principles and is to be taken 6-12 months after candidates have been working in clinical research.

It is envisaged that some of the candidates may not be working in a traditional CRA role but may be working at a clinical trial site, in data management and the ICR exam is designed to accommodate this group by giving a choice of questions in Part II (dip.) of the exam.

It is also recognised that there is a growing number of clinical trials taking place in the medical device field and this is also taken into consideration in the examination. Part I (cert.) incorporates the ICH GCP equivalent ISO 14155. Part 2 (dip.) allows a question choice that is suited to those working with devices.

1.4. Benefits of becoming a Registered Member (RICR)

There are many physical benefits of being a Registered Member, such as access to the members only section of the website and voting rights. Ultimately it is the professional recognition of your experience and achievements amongst peers in the clinical research community.

1.5. Demonstration of Knowledge

Members of the ICR can choose to take the ICR Exam to demonstrate their knowledge of clinical research. The examination will have to be taken at one of the recognised examination centres on the dates determine by the ICR. Initially there will be two examinations held April and October each year.

2. Syllabus

The examination is designed to test and prove the candidate's knowledge of the broad area of clinical research. To give a broad foundation to the clinical research environment the ICR Exam has been designed with consideration given to the three following areas:

Guidelines and Regulations

- ICH GCP
- EU Directive 2001/20/EC
- Awareness of ISO 14155 for medical device trials
- EU Directive 2005/28/E
- Basic process for achieving marketing approval / regulatory affairs

Design and Analysis of Clinical Trials

- Phases of clinical trials
- Basics of clinical trial design – randomisation, blinding, types of design
- Basic statistical aspects of clinical trials

Process of Conducting A Clinical Trial

- Drug development
- The process of ethical approval
- Pre study organisation
- Protocol design
- CRF design
- Informed consent
- Ethics approval
- Monitoring and Source Data Verification
- Safety reporting and adverse events
- Essential documentation
- Audit and inspections

3. How do I acquire the knowledge?






There are numerous methods to develop the knowledge for this examination. A recommended reading list is provided below that will provide a comprehensive overview of the relevant areas of clinical research to enable the candidate to complete this examination. Additionally some alternative information sources are listed.


3.1. Recommended Reading by Syllabus area:

Syllabus Area	
Guidelines and regulations	Recommended Reading
<ul style="list-style-type: none"> Monographs 	Please click here for a list of all our monographs
<ul style="list-style-type: none"> ICH Good Clinical Practice 1996 	<i>ICH GCP E6 Guidelines for Good Clinical Practice</i> . Published by: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
<ul style="list-style-type: none"> Other ICH guidelines 	<i>E3, E8 and E9</i> www.ich.org Published by: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
<ul style="list-style-type: none"> Medical Ethics 	<i>Declaration of Helsinki, 2004</i> . Published by: the WMA.
<ul style="list-style-type: none"> Awareness of ISO 14155 for medical device trials 	<i>ISO 14155</i> . Published by: BSI Global.
<ul style="list-style-type: none"> Clinical Trials EU Directive 	<i>EU Directive 2001/20/EC</i> . Published by: The Official Journal of the European Union.
<ul style="list-style-type: none"> GCP EU Directive 	<i>EU Directive 2005/28/EC</i> . Published by: The Official Journal of the European Union.
<ul style="list-style-type: none"> Basic process for achieving marketing approval 	<i>Clinical Trials Directive (2001/20/EC)</i> . <i>Principles of Clinical Research</i> . Published by: The Institute of Clinical Research.
Design and analysis of clinical trials	
<ul style="list-style-type: none"> Phases of clinical trials 	<i>Clinical Trial Design Monograph</i> .

<ul style="list-style-type: none"> Basics of clinical trial design – randomisation, blinding, types of design 	<p><i>Clinical Trial design Published by ICR publishing.</i></p> <p><i>Statistics in Clinical Research. Published by: ICR Publishing.</i></p>
<ul style="list-style-type: none"> Basic statistical aspects of clinical trials 	<p><i>Statistics in Clinical Research.</i></p>
<p>Process of conducting a clinical trial</p>	
<ul style="list-style-type: none"> The process of ethical approval 	<p><i>Clinical Trials Directive (2001/20/EC). In Fundamentals for CR book.</i></p> <p><i>ICH E6 Guidelines for Good Clinical Practice</i> www.ich.org</p>
<ul style="list-style-type: none"> Pre study organisation 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice. www.ich.org</i></p>
<ul style="list-style-type: none"> Protocol design 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice. www.ich.org</i></p> <p><i>Clinical Trial Design</i></p>
<ul style="list-style-type: none"> Informed consent 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice. www.ich.org</i></p> <p><i>Clinical Trials Directive (2001/20/EC).</i></p>
<ul style="list-style-type: none"> Monitoring 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice. Troubleshooting Monitoring</i></p> <p><i>ICR Publishing www.icr-global.org</i></p>
<ul style="list-style-type: none"> Safety reporting and adverse events 	<p><i>ICH GCP E6, ICH 2A, ICH2B Guidelines.</i></p>
<ul style="list-style-type: none"> Essential documentation 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice. www.ich.org</i></p>
<ul style="list-style-type: none"> Audit and inspections 	<p><i>ICH GCP E6 Guidelines for Good Clinical Practice.</i></p> <p><i>Draft notes to guidance EU Directive 2005/28/EC. Published by: the EMEA</i></p> <p><i>Engage Guidelines. Published by: European Forum for Good Clinical Practice.</i></p>

3.2. The Books

	<p>Title:</p> <p>Authors:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>Statistics in Clinical Research</p> <p>Trish Parry, Adrian Parrott (Editor)</p> <p>Paperback 39 pp (2004)</p> <p>ICR Publishing</p> <p>ICR</p>
	<p>Title:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>The Fundamental Guidelines for Clinical Research.</p> <p>Contains: ICH GCP 1996, Declaration of Helsinki 2004, EU Directive 2001/20/EC, EU Directive 2005/28/EC.</p> <p>Pocket book (2005)</p> <p>ICR Publishing</p> <p>ICR</p> <p><i>Also obtained from the relevant websites.</i></p>
	<p>Title:</p> <p>Authors:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>Troubleshooting Monitoring</p> <p>Zoë Binns (Editor)</p> <p>Paperback 84 pp</p> <p>ICR Publishing</p> <p>ICR</p>
	<p>Title:</p> <p>Authors:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>The Clinical Trial Protocol</p> <p>Sue Fitzpatrick (Editor)</p> <p>Paperback 48 pp</p> <p>ICR Publishing</p> <p>ICR</p>
	<p>Title:</p> <p>Authors:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>Clinical Trial Design</p> <p>Sue Fitzpatrick (Editor)</p> <p>Paperback 60 pp (2004)</p> <p>ICR Publishing</p> <p>ICR</p>

	<p>Title:</p> <p>Authors:</p> <p>Detail:</p> <p>Publisher:</p> <p>Buy from:</p>	<p>The Pocket Guide to the EU Directive.</p> <p>Julie Meeson</p> <p>Paperback 52 pp (2005)</p> <p>ICR Publishing</p> <p>ICR</p>
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Other sources of information

Most Introductory courses should cover the areas covered in the syllabus. ICR's course *Introduction to Clinical Trials and Clinical Trials Practice* is ideal for gaining the required knowledge for sitting the ICR Exam.

Curriculum Summary of Introduction to Clinical Trials and Clinical Trials Practice

The course introduces the nature and concepts of Clinical Research, the Clinical Trial process and the regulating framework in which they operate. Practical work demonstrates the principles involved in the accurate reading of data and its presentation and need to work to standard set of principles – Standard Operating Procedures or SOPs. Lectures are highly informal and interactive so as to introduce individuals gradually to the industry requirements.

4. Exam Format

The ICR Exam will be in the form of two papers.

4.1. Paper I (certificate): Multiple Choice

This will consist of 60 (sixty) multiple choice questions covering all areas of the syllabus to be answered in 2 (two) hours. For each question there will be a choice of 5 (five) answers from which the candidate must choose 1 (one) and only 1 (one) answer.

Format 1 example question:

QUESTION

- 1) According to ICH GCP E6 guidelines drug accountability is the responsibility of:

OPTIONS

- a) The Monitor
- b) The Study Site Co-ordinator
- c) The Investigator**
- d) The Pharmacist dispensing the drug
- e) The Principal Pharmacist

Answer: c

Format 2 example question:

QUESTION

- 2) Which of the following are among the 20 elements of informed consent as listed in ICH GCP E6 guidelines?

OPTIONS

- i) 24 hours must be allowed for consideration of the information by the subject
 - ii) A subject may withdraw from the trial at any time
 - iii) Aspects of the that are experimental must be explained
 - iv) An explanation of the probability for random assignment to each treatment must be given
-
- a) i & ii
 - b) i & iv**
 - c) ii & iii
 - d) iii & iv
 - e) iv & v

Answer (b)

One mark will be awarded for each correct answer and no points will be deducted for an incorrect answer. The total mark achievable on the multiple choice paper is 60 (sixty) marks.

4.2. Paper 2 (diploma): Short Answer Questions

The candidate must select to answer short answer questions on 3 (three) areas of clinical research from a choice of 9 (nine). Each set of questions will be related to a scenario from the specific area of clinical research. The 9 (nine) areas of clinical research are broadly:

- Trial design
- Safety
- Site activities
- Drug accountability
- Monitoring
- Data handling
- Ethics and consent
- Essential Documentation
- Medical device trials

Candidates will be given 30 (thirty) minutes reading time at the start of the paper 2 examination to read and determine which areas of clinical research to answer questions on. The candidate will then have 3 (three) hours to complete the examination. Each scenario has 5 (five) component questions, each component question is worth 5 (five) marks unless otherwise indicated so each scenario is worth 25 (twenty five) and the total marks available for the paper is 75 (seventy five).

There is additional time incorporated into the examination to aid candidates whose first language is not English.

4.3. Passing the Examination

A specialist company uses a computer to mark the answer sheets for the MCQs. There are specific QC processes in place that evaluate the quality of the assessments as well as the standard of the candidates. The reports produced include twenty percentiles histogram which gives a visual check of the performance of the question (easy, difficult, good discriminator). The system is in use by many professional bodies including the Royal Medical Colleges and financial and commercial institutions.

Unlike the MCQs short answer questions are posed which require a short descriptive answer where there are no clues to the likely correct answer. An initial scenario is presented with more and more information required as the candidate proceeds through the case study questions. The marking of these papers is by academic and teaching staff who provide scoring schemes and key words to provide model answers that candidates can be assessed against.

The Board of Examiners will decide the pass mark in advance. The Board consisting of expert academic, professional body representatives and educationalists will review and approve the examination papers.

Candidates will be informed in writing within 6 weeks of the exam date if they pass or fail. There is no provision for grading of the performance i.e. no merits or distinctions only a pass or fail.

A candidate who has previously failed the examination is eligible to resit, however, there will be a nominal fee of £25 for administration. There will be provision for feedback to students who have failed but there will be no release of past examination papers.