



ACRP

Association of Clinical
Research Professionals



CLINICAL NETWORK SERVICE (CNS) Pty Ltd

FREQUENTLY ASKED QUESTIONS

1. WHO ARE THE COURSE FACULTY?

Each course being delivered by a faculty of ACRP **certified and accredited trainers**. **Trainers have sat the ACRP certification exam**, are currently certified and accredited by a process of evaluation.

2. WHAT REGULATIONS ARE COVERED?

Locally applicable regulations and guidelines such as the TGA Regulations, NHMRC National Statement, STOTT Report and international FDA Code of Federal Regulations (CFR), the European Directives, and the International Conference on Harmonisation (ICH) the guideline, based on the Declaration of Helsinki.

3. WHAT ARE THE COURSE OBJECTIVES? – GCP for Research Professionals

2 day Course

- Review the evolution of Good Clinical Practice, from its origins to currently acceptable standards. Understand the imperative of keeping abreast of changing practices and regulations.
- Define the major steps and phases of the drug development process.
- Describe the regulations governing the practice of clinical research and other applicable guidelines.
- Examine the legal, professional and ethical constraints on various clinical research processes, such as the management of informed consent, ethics committees, disclosure of financial interests and electronic signatures.
- Identify the tools and techniques for successfully managing and executing trials.
- Analyse the principles of ethical conduct and subject protection together with examples of acceptable and non-acceptable norms.
- Arm the clinical research team with knowledge and tools to enable a high level of GCP compliance

4. WHAT ARE THE COURSE OBJECTIVES? – GCP Applications Workshop

1 day course

Review

- Essentials of Participant Information & Consent Form writing
- Essentials of the Ethics submission process
- Informed Consent issues and how to manage subjects
- Adverse Event Reporting requirements
- Methods of Standard Operating Procedures (SOP) Writing

5. ARE THERE ANY DISCOUNTS?

Group discounts are available for groups of 4 or more.

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|---------------------------------|--------------------|--------|
| GCP for Research Professionals: | -\$895 | \$810 |
| GCP Practical Applications: | -\$495 | \$425 |
| Both Courses | -\$1390 | \$1320 |

6. ARE THERE ANY REWARDS?

A Certification Review Package voucher will be awarded for "Refer a Friend" registrations. Please ask registrant to nominate you at the time of application.

7. REVIEWS and TESTIMONIALS

Hear What Participants Had To Say!



"As we progress medical care into the future, we need to do so with an understanding of clinical evidence.

Research governance is essential in implementing GCP. The framework is one which protects patients, researchers, clinicians and providers.

Therefore, education is key to ensuring our evidence is sound and Australia is a desirable environment to undertake clinical research."

**Dr Fiona Wood AM, Australian of the year (2005)
Director of the Royal Perth Burns Unit**

"I believe this course should be a pre-requisite to staff conducting trials. Practice in the 'real world' needs to reflect standards educated through GCP and your course". **Coordinator, new in the industry**

"Targeted, local, practical knowledge", **Project Manager, 8yrs experience**

"This course has been invaluable in providing me with resources and tools to conduct safe & effective research", **Coordinator, less than 2 years in the industry**

"Excellent background (and) introductions to requirements for involvement in clinical trials from perspective of many parties involved in clinical trials", **Biotech Director, 3 years experience.**

8. WHO ACCREDITS THESE COURSES?

Accreditation

The Royal College of Nursing Australia provides continuing education hours for this course. The University of Melbourne provides credit in their Graduate Program in Clinical Research.

