Clinical Trial Essentials: A workshop for non-scientists

Friday 4th November 2011, 10am - 4pm, Darlington Centre, University of Sydney

Who should attend:
This course is designed primarily for a non-scientific member of a Human Research Ethics Committee (HREC), and secondarily for a non-scientific member of another Committee where there is a role in clinical trials (e.g. consumer representatives for cancer cooperative groups).

Course aim and objectives:
The course aims to have better informed non-scientists who have a role in clinical trials, by gaining:
- an understanding of the scientific basis and all the elements that are required in the conduct of clinical trials
- an appreciation of the issues in clinical trials as they relate to specific areas e.g. ethics, informed consent, translational studies
- an improved ability to participate fully as a HREC (or other Committee) member

Topics Covered:
I: Clinical Research
Importance of clinical trials, types of studies, trial design, randomisation, placebo controls, follow up

II: Study Materials
How to fully understand a Protocol and Patient Information and Consent Form

III: Ethical and Regulatory Requirements
An introduction to The National Statement, mutual acceptance and the HOMER initiative, ICH-GCP, TGA and jurisdictional issues, monitoring for safety, trial committees

IV: Translational Research/Substudies
Controversies related to tissue banking and future unspecified research, registries and data linkage studies, Quality of Life & Patient Reported Outcomes

Presenters:

Prof. John Simes
Recognised internationally for his expertise in the field of clinical trials, he is also professor at the University of Sydney and a specialist medical oncologist at Royal Prince Alfred Hospital.

A/Prof. Winston Liauw
Chair of CINSW HREC, he is heavily involved in research ethics and regulation. A practicing medical oncologist and clinical pharmacologist at St George Public & Private Hospitals, he is also principal or co-investigator on numerous industry & investigator initiated clinical trials.

Dr. Andrew Martin
A senior biostatistician from the University of Sydney with 15+ years experience in clinical trials research gained within both research-based pharmaceutical organisations & academia. A recent focus has been on promoting high quality investigator initiated research activities in underfunded areas.

To register, complete the form over the page, or contact:
The NHMRC Clinical Trials Centre:
courses@ctc.usyd.edu.au
Ph: 02 9562 5000
### ATTENDEE DETAILS

Mr / Mrs / Ms / Dr / Other: 

First Name: 

Surname: 

Preferred Name: 

HREC Name: 

Position on HREC: 

Address: 

Suburb: 

State: 

Postcode: 

Work Phone/Mobile: 

Home Phone: 

Email: 

Dietary Requirements: 

### PAYMENT DETAILS

Please find enclosed a cheque made payable in $AU to ‘The University of Sydney, NHMRC Clinical Trials Centre’

Or, please charge $55 to my: 

- [ ] VISA 
- [ ] MASTERCARD 
- [ ] BANKCARD

Card Number: 

Name on Card: 

Expiry: / 

Signature: 

* Your registration will not be confirmed until full payment is received

Please email, fax or post your registration to: 

**Email:** courses@ctc.usyd.edu.au 

**Fax:** 02 9562 5094

**Post:** Clinical Trials Essentials 

NHMRC Clinical Trials Centre 

Locked Bag 77 

CAMPERDOWN NSW 2050

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### Essential Information

- Registrations close **Friday, 28th October, 2011**
- Morning Tea, Lunch and Afternoon Tea will be provided, please ensure you outline any dietary requirements on your registration.
- This form is a valid tax invoice, please keep for tax receipts. No other receipt will be given.
- Parking: Limited car parking facilities are available at parking stations around the University. This parking is ticket parking, at $24 per day. See below for more details: 