

Study Coordinator Training 2009

Introduction to Clinical Research

New Zealand



Day One

8.00 – 8.30 Arrival tea and coffee (course will commence promptly at 8.30)

8.30 – 9.00 Welcome and introduction

9.00 – 9.45 **Introductory Exercise**

9.45 – 10.30 **Module 1**
The drug development process

10.30 – 10.45 Morning break



10.45 – 12.45 **Module 2**

- Regulations governing clinical trials in New Zealand
 - ICH GCP
 - Medsafe regulations
 - SCOTT
 - GCRP
 - HRC/NEAC ethics standards
 - Declaration of Helsinki

12.45 – 13.30 Lunch



13.30 – 15.00 **Module 3**

- Ethics in Clinical Trials

15.00 – 15.15 Break



15.15 – 17.00 **Module 4**

- Informed Consent



Day 2

8.00 – 8.30 Arrival tea and coffee

08.30 – 10.00 **Module 5**
Quality in Clinical Trials

10.00 – 10.15 Morning break



10.15 – 12.30 **Module 6**

- Clinical Trial Management
 - Role/responsibilities of the Study Coordinator
 - Basic planning tools
 - Dealing with common trial management problems

12.30 – 13.15 Lunch



13.15 – 15.00 **Module 7**
Data collection

- Source Documents
- The CRF
- Prioritising Activities

15.00 – 15.15 Afternoon break



15.15 – 16.45 **Module 8**

- Safety assessments in clinical trials.
 - Managing adverse events

16.45 – 17.00 Action planning and close