

Clinical trials in New Zealand are conducted in accordance with internationally accepted Good Clinical Practice (GCP) guidelines and each individual involved in conducting a clinical trial should be qualified by education, training and experience to perform his or her respective tasks. There is no formal register of research staff's mandatory GCP training.

- a register of completed GCP training has been instigated for Clinical Research Nurses, investigators and other research staff
- externally provided GCP Beginners and Refresher Courses are held at North Shore Hospital throughout the year

There is a paucity of research education clinics relevant to clinical trial management provided in-house for research staff.

- The idea of short (60-90min) research workshops was trialled in 2013:
- 5 clinics were held throughout the year with a total of 73 attendees from more than 20 different departments
 - 3 clinics were particularly successful and will be repeated in 2014
 - *When Research Involves Maori*
 - *Obtaining Informed Consent for Participation in Research*
 - *The Research Participant Experience*

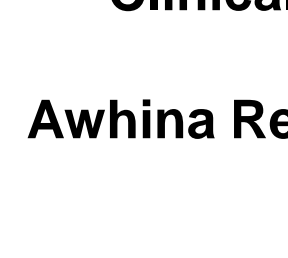
- Moving forward:
- GCP courses to be held regularly at NSH incl. Dangerous Goods Training (DGT) course
 - Mandatory course register (GCP and DGT) to be added to educational record on Kiosk
 - Continue 60min workshops/education clinics according to education needs using existing WDHB skill sets

Clinical Research Nurses (CRNs) are meeting every other month for one hour (February-October = 5 times per year). Attendance was variable and new ways of fostering a sense of "collective" needed to be explored.

- A group email list was set up and this is now used as the main means of communication within the group
- A group folder on G-Drive was created
- Meetings are formally minuted

- Moving forward:
- Formulate terms of reference for the Community of Research Practice

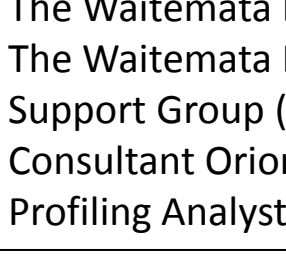
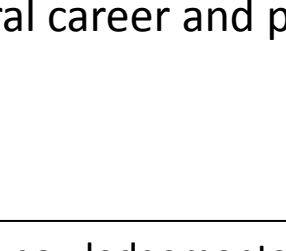
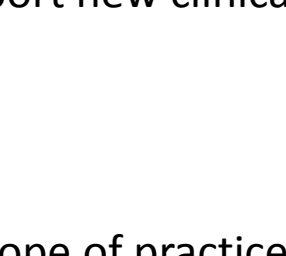
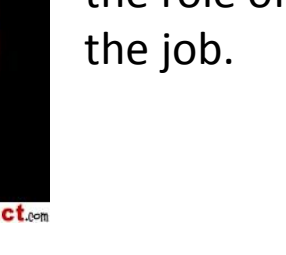
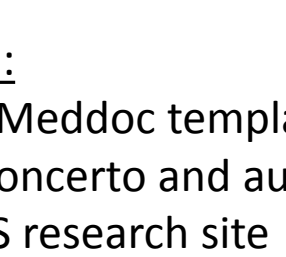
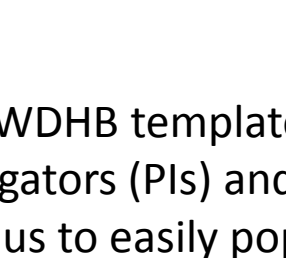
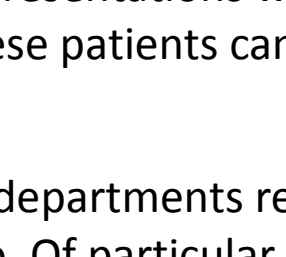
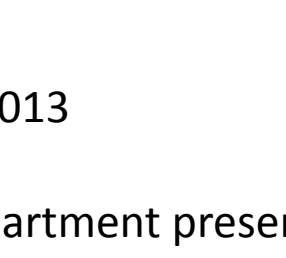
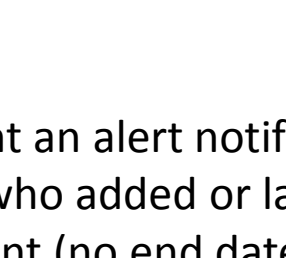
- Widen community to include investigators, cultural reviewers and clinical support services involved in research, ie laboratory and pharmacy
- consider setting up wider Community of Research Practice Email Group
- meetings should include educational aspects, eg case reviews, journal articles



Proper clinical trial conduct involves investigator/institutional compliance with the study protocol, Good Clinical Practice (GCP) Guidelines, Standard Operating Procedures (SOP) and applicable regulatory requirements. SOPs are detailed, written instructions to achieve uniformity of the performance of a specific function. Waitemata DHB Research SOP's are scarce and departmental instead of organisation wide,

- Organisation wide "research" tab set up on Controlled Documents staffnet page
- 3 organisation wide SOPs written in 2013

- Moving forward:
- Build, categorize and review SOP library
 - Liaise with other research offices and clinical trial units
 - engage Community of Research Practice in process



Research staff need to monitor clinical trial participants closely for the occurrence of adverse events, eg unplanned hospital admissions. Despite iPM alerts in place for all research participants at WDHB, admitting clinicians do not consistently contact research staff.

Daily at midnight an alert notification is emailed to the modified user (staff member who added or last edited the alert) for each patient who has a current (no end date) alert under the *Clinical Trial Participant* category AND who has presented to the Emergency Department or as an inpatient or as an outpatient in the previous 24 hours.

- 22 November 2012 – 11 September 2013
- 175 emails generated:
 - 14 Emergency Department presentations (ED)
 - 96 Inpatient Presentations (IP)
 - 65 Outpatient Presentations (OP)

The majority of those 119 ED and IP presentations would have gone unnoticed by research staff before November 2012. Now these patients can be safety monitored adequately.

Inconsistency across departments regarding the documentation of clinical trial visits in Concerto. Of particular importance is the documentation of study medication and the presence of adverse events.

A standardised WDHB template was created with all specialties, Principal Investigators (PIs) and clinical trial short titles pre-loaded in drop down menus to easily populate the template and create a document in seconds.

- 29 studies and 11PIs across 11 specialties currently loaded

- Moving forward:
- Create WDHB Meddoc template to easily upload a study summary to Concerto and automatically send to GPs
 - Develop CeDSS research site

The Research CNS focuses on all aspects of clinical trial management. Central to the role are advanced nursing skills: patient assessment, treatment, safety monitoring, outcome assessment and follow-up liaising with the study and multidisciplinary team. Nurses new to the role often have little support and have to learn on the job.

The role of the Awhina Research CNS was established in July 2012. Key performance indicators for the role include developing opportunities to mentor and support new clinical research nurses and investigators.

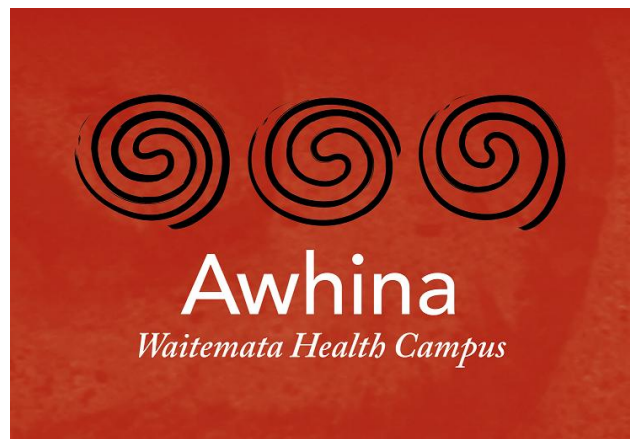
- Moving forward:
- Describe the scope of practice of the CNS Research against the New Zealand Nursing Council competencies for Registered Nurses
 - Develop an orientation programme for nurses new to the role
 - Outline a general career and progression plan which can be individualised

References:

Guideline on the Regulation of Therapeutic Products in New Zealand – Part 11 : Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements, Edition 1.2, April 2012, Medsafe, Wellington: Ministry of Health Retrieved 17 September 2012, from <http://www.medsafe.govt.nz/regulatory/clinicaltrials.asp>

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Optimising Clinical Trial Management to Enhance Patient Safety



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Waitemata
District Health Board

Best Care for Everyone

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