

Clinical Research Professional Development Resources

2010

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PROVIDENCE HEALTH CARE
Research Institute



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This resource is intended for clinical research coordinators. It was developed by the Clinical Research Professional Development Team to support research education and professional development for the clinical research coordinator. It includes key resources and contacts related to professional development that were known at the time of publication. Updates will be produced as needed. Contact your local institutes' education representative if you have queries or wish to provide feedback regarding this document.

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CLINICAL RESEARCH PROFESSIONAL DEVELOPMENT (CRPD)

Introduction

The CRPD is an education initiative led by a group of individuals committed to developing a program that supports the professional development of clinical research coordinators from the Lower Mainland's teaching hospitals' research institutes.

Members of the CRPD team include:

- Manager, Research Education, Child & Family Research Institute (CFRI) (Sandra Elias, selias@cw.bc.ca)
- Manager, Clinical Trial Support Unit, Centre for Health Evaluation and Outcome Sciences, Providence Health Care Research Institute (PHCRI) (Erin Cherban, erin_cherban@mail.cheos.ubc.ca)
- Coordinator, Research Education, Vancouver Coastal Health Research Institute (VCHRI) (Kerri Abramson, kerri.abramson@vch.ca)
- Representative from the University of British Columbia Office of Research Ethics (Jeffrey Toward, jeffrey.toward@ors.ubc.ca)
- Representative from Research Administration and Development Office, Fraser Health Authority (Susan Chunick, susan.chunick@fraserhealth.ca)
- Senior Clinical Research Coordinator/Manager from CFRI, PHCRI or VCHRI (Vesna Popovska, Research Manager, Neurosciences, BC Children's Hospital vpopovska@cw.bc.ca)

Education Program

The education program includes a curriculum of seven core topic areas. A minimum of four workshops are offered each year. The topics chosen rotate with Good Clinical Practice offered annually. There is no particular order in which the workshops should be completed however it is recommended that coordinators complete a minimum of one workshop in each core area.

In addition to the core areas, supplementary sessions may be added to the curriculum as needed.

Education sessions take place at one of the three research institutes (see calendar on next page). Advertisements are sent via email from CFRI, PHCRI and VCHRI. In addition, events are listed on the CFRI Training website Event Calendar (www.cfri-training.ca).

Registration and payment for each session will be organized by the host institute. In the event of insufficient registrations, sessions may be cancelled.

Attendees of the CRPD workshops will receive a certificate of attendance for documentation of their participation for continuing education purposes.

The CRPD Education Curriculum includes workshops in the following core areas.

- Good Clinical Practice (GCP) – components of compliance, principles and practical applications of ICH-GCP, investigator and sponsor responsibilities in clinical research.
- Ethics and Regulatory Issues – role of ethics in health research, informed consent/assent and current regulatory issues.
- Recruitment – simple and efficient recruitment plans, strategies to enhance retention, the consenting process, understanding factors that contribute to participant withdrawal.
- Budgeting and Finance – reviewing protocols to calculate and identify research costs, creating recruitment budgets and presenting budgets to sponsors.
- Human Resources – writing job descriptions, interviewing and hiring staff, terminations and disciplinary processes.
- Communication Skills – effective interpersonal communication skills including conflict resolution.
- Project Management – defining and managing project scope, project schedules, basic communication management, and project management terminology.

CRPD Timetable (2010)

Jan-Mar	Apr	May	June	July-Aug	Sept	Oct	Nov	Dec
No Workshops offered	Good Clinical Practice (PHCRI) Friday April 9 Project Mgmt (Interm) (VCHRI) Thursday April 22	Human Resources (CFRI) Date: TBA	Recruitment (Royal Columbian Hospital) Friday June 18 Project Mgmt (Intro) (VCHRI) Wednesday June 2 Project Mgmt (Interm) (VCHRI) Wednesday June 30	No Workshops offered	Budgeting (CFRI) Date: TBC		Good Clinical Practice (PHCRI) Date: TBC	No Workshops offered

Site specific events held throughout the year including:

- CRC Lunch and Learn (CFRI) monthly September-June
- Clinical Coordinator Network meetings (PHCRI) quarterly
- Coordinators' Network (VCHRI) quarterly
- Transporting Dangerous Goods (VCHRI) Spring and Fall, odd years

For further information on the site specific events contact your local education representative (page 3 for contact details).

PROFESSIONAL DEVELOPMENT RESOURCES

Professional Associations & Organizations

The resources listed below are a sample of professional associations and organizations relevant to the clinical research field intended for informational purposes and do not constitute an endorsement by the CRPD team.

Association of Clinical Research Professionals (ACRP) <http://www.acrpnet.org/>

ACRP is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. Their aim is to provide global leadership to promote integrity and excellence for the clinical research profession. For membership information and application forms click on the Membership tab on the ACRP website.

Clinical Research Professionals of BC (CRPBC) <http://crpbc.org/>

CRPBC is a group of clinical research professionals who work primarily in the Lower Mainland. They provide networking and professional development opportunities for those working in the clinical research profession, grant funded or industry sponsored.

Society of Clinical Research Associate (SoCRA) <http://www.socra.org/>

SoCRA is a non-profit, professional organization dedicated to the continuing education and development of clinical research professionals. SoCRA membership is available to all clinical research professionals who work with cooperative research groups, academic and private institutions, pharmaceutical and biotechnology companies, device manufacturers, CROs, SMOs, independent research and development organizations, and those who are involved in the management of clinical trials. For membership information and application forms click on the Membership tab on the SoCRA website.

There is a Vancouver Chapter of SoCRA that serves the Pacific Northwest (BC, WA). The chapter chairperson is Erin Cherban, GCPconsultants@shaw.ca.

Society of Research Administrators International (SRA) <http://www.srainternational.org/>

SRA is a non-profit organization for individuals who work in research administration in hospitals, universities, non-profit groups, and federal government. The organization is dedicated to the education and professional development of research administrators and in the advancement of research administration as a profession around the world. For membership information click on the 'Join Us' tab on the SRA website.

The following resources are a sample of training tutorials and reference books relevant to the clinical research field. Other than the requirement by UBC's REBs to complete the Tri-Council Ethical Conduct for Research Involving Humans, the resources listed here do not constitute an endorsement by the CRPD team.

Online Training Tutorials

Ethics / Human Protection

- Tri-Council Ethical Conduct for Research Involving Humans www.pre.ethics.gc.ca/english/tutorial/?action=start
- NIH Human Protection Tutorial <http://phrp.nihtraining.com/users/login.php>
- RISE Tutorials <http://www.ors.ubc.ca/> (click on RISE, then on the Tutorials tab)

Good Clinical Practice

- Collaborative Institutional Training Initiative (CITI) <http://www.citiprogram.org/>
- US Food & Drug Administration www.fda.gov/oc/gcp/guidance.html
- ASKA Research <http://www.askaresearch.com/products/index.htm>

Reference Books

The following books are listed under www.crc.washington.edu/Resources/OngoingTraining.aspx

- **Clinical Research Coordinator Handbook** by Deborrah Norris
- **The CRC's Guide to Coordinating Clinical Research** by Karen E. Woodin.
- **Good Clinical Practice: Standard Operating Procedures for Clinical Researchers** by Josef Kolman, Paul Meng and Graeme Scott (Editors)
- **Clinical Trials and Human Research** by Fay A. Rozovsky and Rodney K. Adams
- **Principles and Practice of Clinical Research** by John I. Gallin and Frederick P. Ognibene
- **Protecting Study Volunteers in Research** by Cynthia Dunn and Gary Chadwick.

Responsible Research: A Guide for Coordinators by Carol A. Fedor, Phillip A. Cola and Christine Pierre (Editors). A comprehensive resource for coordinators (experienced and new), monitors, and other study site professionals. It provides practical information on the activities and responsibilities of the modern coordinator. The international authorship ensures that content is relevant to the global body of research coordinators.

The Manager's Role as Coach by William Hendricks (Editor).

This guide is for those in management roles; and is not specific to clinical research. It offers an introduction to and explanations of the key aspects of mentoring/coaching staff; including how to mentor, motivating others, and step-by-step techniques on how to increase your effectiveness as a manager.

Essentials of Qualitative Inquiry by Maria Mayan (Left Coast Press, 2009).

A brief guide that introduces novices to the key elements of qualitative research methods including the essentials of theory building, research design, methods, data collection and analysis, writing, ethics, rigor and proposal writing.

NATIONAL AND INTERNATIONAL AGENCIES, GROUPS AND NETWORKS

Health Canada

- **Clinical Trials Manual**

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_intro-eng.php

This manual is based on Health Canada's Guidance for Clinical Trial Sponsors: Clinical Trial Applications and other applicable guidance documents. It is designed to provide tools and relevant links in order to facilitate the successful filing of a Clinical Trial Application (CTA) to Health Canada.

- **Food and Drug Act**

<http://laws.justice.gc.ca/en/ShowTdm/cs/f-27///en>

Network of Networks (N2) <http://www.cihir-irsc.gc.ca/e/34791.html>

N2 is a national initiative that brings together multiple existing disease networks and other stakeholders willing to join forces to enhance Canada's research capability and capacity.

Panel on Research Ethics <http://pre.ethics.gc.ca/eng/policy-politique/tcps-eptc/>

The Interagency Advisory Panel on Research Ethics was established in 2001 by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council, to support the development and evolution of the Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans (TCPS).

Canadian Association of Research Ethics Boards (CAREB) <http://www.careb-accr.org/>

CAREB is a national membership organization that represents the interests of Research Ethics Boards. They host an annual conference and provide various online services.

Office for Human Research Protections (OHRP) <http://www.hhs.gov/ohrp/>

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.

RESOURCES AT UBC

Research Services

UBC Office of Research Service provides assistance with the research grant application process including the provision of institutional signatures, establishing research accounts, ensures compliance with government regulations and granting agencies, and establishes inter-institutional arrangements for transferring funds. www.ors.ubc.ca

UBC Office of Research Ethics All research conducted at UBC facilities (including UBC's affiliated hospitals) or undertaken by individuals connected to the University, that involves human subjects, animals or bio-hazardous materials must be reviewed and approved by a UBC sanctioned Research Ethics Board or Committee. www.ors.ubc.ca/ethics

Research & Trust Accounting ensure all sponsored research and specific purpose funds at UBC are administered in compliance with funding agency, university, and accounting policies. They also maintain financial records for these funds and submit periodical financial reports to sponsors. Together with ORS and UILO provide assistance to researchers and departmental administrators with respect to research project funding issues. www.finance.ubc.ca/rtai/index.cfm

Health Research Resource Office (HeRRO) fosters and promotes the formation and building of investigator-driven and multidisciplinary health research at UBC by providing researchers with the following core services: Internal Review, Grant Support Services, Workshops, RFA Support, FRED (Facilities and Research Equipment Database), and CED (Chemical Exchange Database). www.herro.ubc.ca/

University Industry Liaison Office (UILO) facilitates the exchange of knowledge between UBC, its affiliated hospitals, industry, and the community. They help form relationships between university and industry, and assist with technology transfer and material transfer agreements. www.uilo.ubc.ca/

Professional Development/Other

Association of Administrative & Profession Staff (AAPS) Professional Development provides annual funds for professional development www.hr.ubc.ca/odl/funding/AAPS.html

MOST offers workshops designed to develop knowledge and skills, and enhance self-understanding for UBC faculty and staff. www.hr.ubc.ca/odl/most/

UBC Science Co-op utilizes an integrated approach to learning by combining university studies with relevant and paid working experiences. The program provides employers access to highly qualified and motivated undergraduate science students for 4, 8, 12 or 16 month work terms. www.sciencecoop.ubc.ca/employers/why

UBC Work Study and Work Learn Program provides UBC faculty and staff subsidies to support undergraduate students in work positions during the Winter (10 hrs/wk) and Summer (20 hrs/wk). <http://www.students.ubc.ca/careers/students/work-and-volunteer-opportunities/work-study-work-learn/>



CRPD PARTNERS

The following is a list of the CRPD partners currently aligned with the Clinical Research Professional Development Program.

Child & Family Research Institute

www.cfri.ca

www.cfri-training.ca (click on the **Training Programs** tab for the Clinical Research Coordinators webpage)

Providence Health Care Research Institute

www.providencehealthcare.org/research

Vancouver Coastal Health Research Institute

www.vchri.ca

Fraser Health

<http://research.fraserhealth.ca>

http://research.fraserhealth.ca/clinical_trials/



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CFRI SERVICES

In addition to the information listed below visit www.cfri.ca and click on Research Support. FAQs are available under **Contracts, Research Ethics Board, and Financial Services** and further information relevant to coordinators and research staff is available under **Clinical Research Support**.

CFRI Research Education

The CFRI Training website www.cfri-training.ca includes information under **Training Programs** on research education events specifically for Clinical Research Coordinators.

Research Education organizes monthly lunch-time sessions for clinical research coordinators. Session topics include ethic applications, recruitment, budgeting, consents/assents and resources at CFRI/C&W relevant to clinical research.

Half-day workshops are offered throughout the year for coordinators. These are advertised through the CRCNet listserv (see page 11) and posted on the CFRI Training website event calendar.

Contact: Sandra Elias, Manager, Research Education selias@cw.bc.ca

CFRI Research & Technology Development Office

The RTDO provides expertise in strategic research planning, research design and grants crafting. In conjunction with CFRI Research Education they provide workshops on proposal writing, funding opportunities and presentation workshops for individuals actively involved in research onsite.

Contact: Dawn McArthur, Senior Research Development Facilitator, dmcarthur@cw.bc.ca

CFRI Communications

CFRI Communications produces Research Reporting (quarterly) and Upcoming Events (biweekly) to the research community onsite. To subscribe or submit an event or relevant research information for inclusion see contact information below.

CFRI Communications provides assistance and clarification on the use of logos for internal and external documents and produced the Study Recruitment Guide available on the Children's & Women's Health Centre of BC intranet <http://infosource.cw.bc.ca/cw/content/Home.asp> or by contacting CFRI Communications.

Contact: Stephanie Dunn, Communications Specialist, sdunn@cw.bc.ca

CFRI Finance and Contracts

The Finance Department assists investigators and research programs with their budgeting and financial record keeping. Financial forms, policies and procedures to assist investigators and research teams with financial management and reporting and frequently asked questions are available on the CFRI website under Research Support.

Contacts: Anita Chiu, Director, Finance achiu@cw.bc.ca
Joanna Ho, Research Legal Counsel jho@cw.bc.ca

C&W EDUCATION RESOURCES

A variety of resources are available onsite for C&W employees.

CRCNet

CRCNet is a C&W listserv available for clinical research coordinators at C&W. To join the listserv, email ajunker@cw.bc.ca. Once you are added to the list you are able to send emails to this group. CRCNet is found in the CW global address list. Sending an email to this address sends your message to all in the group. If you reply to an email sent via CRCNet your response will be automatically forwarded to all CRCNet subscribers. If you do not want your response to be sent to all members select the individual(s) you wish to communicate within the 'To' field.

A permanent copy of all CRCNet communication is stored in the CRCNet Folder in Microsoft Outlook. To access the CRCNet folder click on Folder list, scroll to the bottom of your folders to find Public Folders. Click to open Public Folders, then on Department, and finally on Research Institute. The CRCNet folder is found in the Research Institute folder. Drag this folder to your Favorites folder for quicker access.

Libraries

Various library resources, including access to online databases and the UBC Libraries, are available on the C&W intranet under Resources http://infosource/cw/content/cw_hamber.asp.

Learning & Development

Learning & Development is responsible for staff orientation, ongoing professional development, clinical, patient and family resource development and distribution, classroom bookings, and media, technology and graphics services including photography, video, desk-top publishing and eLearning. For more information go to <http://infosource.cw.bc.ca/ld/home.html>.

Rounds and Journal Club Schedules

The schedule for weekly and monthly rounds can be downloaded from the C&W intranet <http://infosource.cw.bc.ca/cw/content/Home.asp>. Many departments and research clusters organize journal clubs onsite. To view upcoming sessions visit the CFRI Event Calendar www.cfri.ca/news/event_calendar.asp.

Telethon Awards

This competition supports initiatives of staff of the Children's and Women's Health Centre of British Columbia that improve and/or enhance knowledge of, and promote excellence in, the practice of pediatric health care. For more information visit www.bcchildrens.ca/Research/Telethoncompetition/default.htm