

# Clinical Research Professional Development Resources

2011-2012

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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@cfri.ca](mailto:selias@cfri.ca))
- Manager, Clinical Trial Support Unit, Centre for Health Evaluation and Outcome Sciences, Providence Health Care Research Institute (PHCRI) (Michelle Jones, [mjones@hivnet.ubc.ca](mailto:mjones@hivnet.ubc.ca))
- Coordinator, Research Education, Vancouver Coastal Health Research Institute (VCHRI) (Kerri Abramson, [kerri.abramson@vch.ca](mailto:kerri.abramson@vch.ca))
- Representative from the University of British Columbia Office of Research Ethics (Jeffrey Toward, [jeffrey.toward@ors.ubc.ca](mailto:jeffrey.toward@ors.ubc.ca))
- Representative from Department of Evaluation and Research Services, Fraser Health Authority (Susan Chunick, [susan.chunick@fraserhealth.ca](mailto:susan.chunick@fraserhealth.ca) or Camille Viray [camille.viray@fraserhealth.ca](mailto:camille.viray@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](mailto: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. 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](http://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, setting expectations for staff, coaching, 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 (2011-2012)

Sept	Oct-Dec	Jan/Feb	Mar/Apr	May	June	July/Aug
<b>Human Resources – Project Team Building (PHCRI)</b>  Date: Sept 12	No workshops offered	<b>Ethics (VCHRI)</b>  Date: TBC	<b>Privacy in Research (CFRI)</b>  Date: TBC	<b>Intro to Research Coordinating (All sites)</b>  Date: TBC	<b>Fraser Health Authority Clinical Trials Research Symposium (Royal Columbian Hospital)</b>  Date: TBC	No workshops offered
<b>Site specific events held throughout the year including:</b> <ul style="list-style-type: none"> <li>• CRC Lunch and Learn (CFRI) monthly September-June</li> <li>• Coordinators’ Network (VCHRI) quarterly</li> <li>• Transporting Dangerous Goods (VCHRI) Spring and Fall, odd years</li> </ul> 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](mailto: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 SRA' tab.



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The following resources are a sample of tutorials, courses and references relevant to clinical research. Other than the UBC's REBs requirement to complete the TCPS-2 tutorial, resources listed here do not constitute an endorsement by the CRPD team.

## Training Tutorials and Courses

### Ethics / Human Protection

- TCPS-2 Tutorial Course on Research Ethics (CORE)  
<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>
- RISE Tutorials  
<http://rise.ubc.ca/tutorials.asp>
- UBC Office of Research Ethics Online Tutorials & Training  
<http://research.ubc.ca/ethics/online-tutorials-training>
- NIH Human Protection Tutorial  
<http://phrp.nihtraining.com/users/login.php>
- Ethics Decision-Support Guides – developed by the Alberta Research Ethics Community Census Initiative  
<http://www.ahfmr.ab.ca/arecci/areccitools.php>

### Good Clinical Practice

- N2 – Online GCP Modules
  - Go to [www.citiprogram.ca/](http://www.citiprogram.ca/) OR [www.citiprogram.org/default.asp?language=english&icat=7](http://www.citiprogram.org/default.asp?language=english&icat=7)
  - To access the online education program, create your own unique username and login.
  - To login you must be affiliated with the Providence Healthcare Research Institute, University of British Columbia, or Vancouver Coastal Health Research Institute.
  - Select either “Providence Healthcare Research Institute”, “University of British Columbia”, or “Vancouver Coastal Health Research Institute” from the list of Canadian Institutions presented. If you are also a member of one of the other organizations listed you can add them to your list in addition to your primary institution. Each institution will then receive confirmation when you complete the program. Completion of the course can be done at your own pace. You will need to receive a mark of 80% to complete the program.
  - If you require assistance with setting up your account or determining your institutional affiliation please contact one of the following individuals:
    - Providence Healthcare Research Institute – Michelle Jones at [mjones@hivnet.ubc.ca](mailto:mjones@hivnet.ubc.ca)
    - UBC - Jeffrey Toward at [jeffrey.toward@ors.ubc.ca](mailto:jeffrey.toward@ors.ubc.ca).
    - Vancouver Coastal Health Research Institute – Stephania Manusha at [Stephania.Manusha@vch.ca](mailto:Stephania.Manusha@vch.ca)
- US Food & Drug Administration – GCP Guidance Documents, Information Sheets and Notices  
[www.fda.gov/oc/gcp/guidance.html](http://www.fda.gov/oc/gcp/guidance.html)

## Clinical Trials

- Modules and FAQs on completing clinical trial applications  
[http://www.rochecanada.com/portal/ca/clinical\\_trial\\_applications](http://www.rochecanada.com/portal/ca/clinical_trial_applications)
- A number of online training tools, resources and education links (note this is an American website)  
<https://www.ctnbestpractices.org/resources> and <https://www.ctnbestpractices.org/education>

## Other

- **Phlebotomy Training**
  - Venipuncture course at BCIT [www.bcit.ca/study/courses/nmed1117](http://www.bcit.ca/study/courses/nmed1117)
- **Transportation of Dangerous Goods**
  - For UBC employees: <http://riskmanagement.ubc.ca/health-safety>
  - For non-UBC employees:
    - Kel-Ex Agencies Ltd <http://www.kel-ex.com/>
    - SaftPak <http://www.saftpak.com/Training/training.aspx>
- **Population Health Data Training**
  - PopData BC provides various workshops and best practice documents <http://www.popdata.bc.ca/etu>
- **CIHR Knowledge Translation Tutorials**
  - Knowledge translation learning modules: *A Guide to Research and Knowledge-user Collaboration in Health Research*; *Introduction to Evidence-Informed Decision Making*; and *Critical Appraisal of Intervention Studies*  
<http://www.learning.cihr-irsc.gc.ca/course/category.php?id=2>
- **Health Services Research – Tutorials and Online Textbooks**
  - This website has a number of links related to health services research including links to statistics and research methodology and epidemiology tutorials  
<http://www.hsrmethods.org/Links.aspx?mode=type&name=Tutorials%20and%20Online%20Textbooks>

## Reference Books

### **Good Clinical Practice: Standard Operating Procedures for Clinical Researchers**

*Josef Kolman, Paul Meng, and Graeme Scott (editors)*

This text provides the materials necessary to develop a useful set of investigator Standard Operating Procedures.

### **Principles and Practice of Clinical Research**

*John I. Gallin and Frederick P Ognibene (Elsevier, 2002)*

This book provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research.

### **Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance**

*Fay A. Rozovsky and Rodney K. Adams (John Wiley & Sons, 2003)*

Provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Review Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability.

### **Responsible Research: A Guide for Coordinators**

*Carol A. Fedor, Phillip A. Cola and Christine Pierre (Remedica Publishing, 2006)*

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.

### **Clinical Research Coordinator Handbook**

*Deborah Norris (Plexus Publishing, 2009)*

This text provides coverage of Clinical Research Coordinator duties and regulatory requirements, including sections on investigator responsibilities, data clarification, and adverse event reporting. The book's five appendices include a directory of CRC resources, updated forms and checklists, state regulatory requirements and contact information, conversion charts and tables, and a glossary

### **The Manager's Role as Coach**

*William Handricks (National Press Publications, 1994)*

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 how to increase your effectiveness as a manager.



## **Essentials of Qualitative Inquiry**

*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.

## **PRISM – Program for Readability in Science & Medicine**

*JR Ridpath, SM Greene & CJ Wiese (Group Health Research Institute, 2009)*

[www.grouphealthresearch.org/capabilities/readability/ghchs\\_readability\\_toolkit.pdf](http://www.grouphealthresearch.org/capabilities/readability/ghchs_readability_toolkit.pdf)

This is an online toolkit to assist in the development of readable and participant-centered material used with research participants. A 1-hour free online workshop is also available at

<https://www.iths.org/events/prism-plain-language-training-researchers>.

## **The CRC's Guide to Coordinating Clinical Research**

*Karen E. Wood (Thomson Center Watch, 2004)*

The CRC's Guide to Coordinating Clinical Research is a comprehensive training guide offering step-by-step information on how to successfully coordinate a clinical trial.

## **Protecting Study Volunteers in Research**

*Cynthia McGuire Dunn and Gary L Chadwick (Thomson CenterWatch, 2004)*

Protecting Study Volunteers in Research is a suggested educational resource by NIH and FDA and was designed to help organizations provide the highest standards of safe and ethical treatment of study volunteers.

# AGENCIES, GROUPS AND NETWORKS

## Canadian

### Health Canada

- **Clinical Trials Manual**  
[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clin/cta\\_intro-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clin/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/eng/acts/F-27/>

### Network of Networks (N2) <http://www.n2canada.ca>

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://www.pre.ethics.gc.ca/eng/index/>

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-accor.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 of the Information and Privacy Commissioner <http://www.oipc.bc.ca/>

The Office of the Information and Privacy Commissioner is independent from government and monitors and enforces BC's Freedom of Information and Protection of Privacy Act (FIPPA) and Personal Information Protection Act (PIPA). FIPPA allows access to information held by public bodies (such as ministries, universities and hospitals) and determines how public bodies may collect, use and disclose personal information.

## Other

### 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

### Support Programs to Advance Research Capacity (SPARC)

SPARC provides expert strategic support to UBC researchers who seek funding for innovative research initiatives. They help to develop research partnerships and build interdisciplinary, inter-institutional teams that may involve government, the private sector and the community. Their services include Internal Review, strategic workshops, and brokering team development and partnerships with government, industry and consumer groups.

<http://research.ubc.ca/sparc>

### Office of Research Service (ORS)

ORS 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](http://www.ors.ubc.ca)

### Office of Research Ethics (ORE)

ORE supports the highest ethical and regulatory standards for research involving human subjects at the University of British Columbia, its affiliated hospitals and research institutes. The ORE supports researchers through the entire ethics review process, from the preparation of a protocol submission to continuing review of ongoing research. The ORE also serves to facilitate the review process conducted by UBC affiliated Research Ethics Boards (REBs), develop and enforce policies and procedures at the University in compliance with national and international guidelines, and educate researchers as to the importance of research ethics and ethics review.

<http://www.ors.ubc.ca/ethics/home>

### Research & Trust Accounting

To 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/rta/index.cfm](http://www.finance.ubc.ca/rta/index.cfm)

### University Industry Liaison Office (UILO)

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/](http://www.uilo.ubc.ca/)

## Professional Development

### Association of Administrative & Profession Staff (AAPS)

The AAPS provide annual funds to eligible UBC staff for professional development.

<http://www.hr.ubc.ca/learning-development/funding/>

### Health, Safety and Environment (HSE)

HSE offers a variety of training programs for UBC staff including lab safety, first aid, fire safety and transport of dangerous goods courses.

<http://riskmanagement.ubc.ca/>

### The MOST Program

The MOST Program offers workshops designed to develop knowledge and skills, and enhance self-understanding for UBC faculty and staff.

<http://www.hr.ubc.ca/learning-development/most-workshops/>

### UBC Life Sciences Libraries

<http://www.library.ubc.ca/life/>

- **Biomedical Branch Library** at Vancouver General Hospital  
Dean Giustini, Librarian  
*Medicine, Ophthalmology, Orthopaedics, Psychiatry, Radiology, Surgery*  
Phone: 604-875-4505 x 6-2392, Email: [dean.giustini@ubc.ca](mailto:dean.giustini@ubc.ca)
- **Eric Hamber Library** at Children's & Women's Health Centre of BC  
Tricia Yu, Librarian (Monday-Thursday)  
*Medical Genetics, Obstetrics & Gynaecology, Paediatrics*  
Phone: 604-875-2154, Email: [tricia.yu@ubc.ca](mailto:tricia.yu@ubc.ca)
- **St. Paul's Hospital Library**  
Barbara Saint, Librarian  
*Medicine*  
Phone: 604-682-2344 x62090, Email: [barbara.saint@ubc.ca](mailto:barbara.saint@ubc.ca)
- **Woodward Library** located on UBC Main Campus  
Kathryn Hornby, Librarian  
*Anatomy, Anesthesiology, Dentistry, Family Practice, Immunology, Medicine, Ophthalmology, Orthopaedics, Pathology & Laboratory Medicine, Population and Public Health, Psychiatry, Radiology, Surgery*  
Phone: 604-822-5810, Email: [kathy.hornby@ubc.ca](mailto:kathy.hornby@ubc.ca)

# RESEARCH SUPPORT

The following is a list of programs that provide work study opportunities to university and college students. Students who apply to these programs are highly motivated students to work part-time or volunteer and often are looking for opportunities in research settings. As a research coordinator, manager or supervisor consider utilizing these programs to access additional support to your research program.

**UBC Science Co-op (Life Sciences)** – access to highly qualified and motivated undergraduate science students for 4, 8, 12 or 16 month work terms.

[www.sciencecoop.ubc.ca/employers/why](http://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/faculty-staff/hire-a-student/>

**UBC School of Library, Archival and Information Sciences** – access to graduate students with expertise in archival work, records management, database design and search functionality, indexing and classification, research and analysis, web design and content development.

[www.slais.ubc.ca/](http://www.slais.ubc.ca/)

**UBC Faculty of Medicine Summer Student Research Program** – funding for several months to UBC students completing a research project with a member of the Faculty of Medicine.

<http://www.med.ubc.ca/research/dfo/students/ssrp.htm>

**SFU Co-op** – access to undergraduate and graduate students from various programs.

[www.sfu.ca/coop/employers/home](http://www.sfu.ca/coop/employers/home)

**Langara College Library & Information Technology Program** Contact: Carol Elder at 604-323-5862, email:

[celder@langara.bc.ca](mailto:celder@langara.bc.ca)

**Emily Carr University of Art + Design** – through the Career & Cooperative Education program, employers have access to art, design and media students. Contact: Shannon McKinnon at 604-844-3843.

**BCIT Biotechnology students**

[www.co-op.bcit.ca](http://www.co-op.bcit.ca)

**Humber College Clinical Research Graduate Certificate students**

<http://www.humber.ca/program/clinical-research>

**University of Western Ontario Clinical Trials Management students**

<https://www.uwo.ca/cstudies/courses/postdegreeprograms/diploma/clinical/index.html>

# 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](http://www.cfri.ca)

[www.cfri-training.ca](http://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](http://www.providencehealthcare.org/research)

<http://www.cheos.ubc.ca/> (under News & Events click on **Events**)

## Vancouver Coastal Health Research Institute

[www.vchri.ca](http://www.vchri.ca) (click on **Grants and Education** for upcoming workshops)

## Fraser Health Authority

<http://research.fraserhealth.ca> (click on **Clinical Trials** and **Education** for further information)

## Office of Research Ethics, UBC

<http://www.ors.ubc.ca/ethics/>



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