



**A. RESEARCHER TOOLBOX – DELEGATION OF RESPONSIBILITY LOG**

*“The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties”. ICH GCP E6 (4.1.5)*



In last issue we presented the SPIRIT protocol template and publication reporting guidelines. To continue building your toolbox, the ACRC presents the [Delegation of Responsibility Log](#) that complies with applicable regulations and supports quality research.

This easy to use log helps keeps track of the study-related tasks that have been assigned to each study member. Complete the log at the beginning of your study prior to any participant-related procedures, and when there are changes to staff and roles throughout the study.

Don't forget to document the qualifications and training of all study members. The ACRC is currently developing a training log template.

**B. CITI-CANADA IS GROWING!**

Adding to the line-up of training courses, the Network of Networks (N2) has developed Health Canada [Part C, Division 5 of the Food and Drug Regulations](#). Course completion can be used as evidence of training on the regulations. Instructions on how to register are located in the [ACRC CITI-Canada Guide](#).

Interested in learning more about responsible conduct of research (RCR)? 'Writing with Integrity' is a new module available to current and future registrants. We encourage individuals who have already completed RCR to log into [CITI](#) and take this module too.

TransCelerate Biopharma Inc. has recently added CITI-Canada GCP to a [list of courses](#) that meet their [members](#) requirements for GCP training; further validating the quality of these training opportunities. Check the [ACRC website](#) for details on other CITI-Canada courses.

**C. METRICS**

The ACRC is actively promoting collaboration and provincial alignment in clinical health research by harmonizing high level metrics. Metrics are a set of measurements that quantify results. When appropriately identified and collected, metrics can:

- Tell us how we're performing by comparing against benchmarks.
- Help identify opportunities for improvement and decision making.
- Help provide a value argument for clinical research in Alberta.

Individuals from the partner organizations are identifying a library of best indicators for clinical health research in Alberta. To date, the group has identified and defined five efficiency metrics.

1. **CDA Turnaround Time** - # of calendar/business days between initial receipt of the CDA from sponsor and the date the CDA is fully executed [all signatures obtained].
2. **Contract Turnaround Time** - # calendar/business days between initial date of receipt of contract from sponsor and the date the contract is fully executed [all signatures obtained].
3. **Budget** - # calendar/business days between date of final budget and the date of contract is ready for full executed [proxy].
4. **Study Start-up Time (1)** - # calendar/business days between date of decision to participate in a trial and the date the site is ready to enroll patients.
5. **Study Start-up Time (2)** - # calendar/business days between date site receives notification of study award and the date site activation is completed [open to enrolment].

*What's next?* The group is identifying other metrics and working with AIHS to find a mechanism for collection across the province.

To support strengthening of clinical health research in Alberta, six times a year the ACRC will bring news relevant to you.

Borrowing someone else's issue or want to be one of the first to know when it comes out? [Subscribe](#) to the ACRC for updates!

Let us know if you have an idea

The ACRC Glossary and Common Terminology is being revised!

If you have any suggestions for additional acronyms, revised wording, etc. please email the [acrc@albertainnovates.ca](mailto:acrc@albertainnovates.ca)



The ACRC is a provincial initiative involving clinical researchers and administrators working together to achieve the vision of 'high quality, integrated and efficient clinical research in Alberta.'

ACRC Partner organizations:

- AHS Research, Innovation & Analytics,
- Alberta College of Physicians & Surgeons,
- Alberta Innovates - Health Solutions,
- Covenant Health - CHRC,
- AHS/University of Alberta - NACTRC
- University of Calgary - CCCRC.

Email: [acrc@albertainnovates.ca](mailto:acrc@albertainnovates.ca)

<http://www.aihealthsolutions.ca/initiatives-partnerships/acrc/>

## Health Canada (HC) and FDA News



Keeping you informed of changes in regulations - \* Are open for comments

**Inspectorate Program Annual Inspection Summary Report 2012-2013 (HC):** Knowing the common HC audit findings can help you prepare for an inspection. The HC Inspectorate Program released its [annual summary report](#) in Mar'14, outlining the latest findings for health product inspections including clinical trials, medical devices, good manufacturing practices and more.

**Considerations when Transferring Clinical Investigation Oversight to another IRB (FDA):** As part of a joint effort between the FDA and Office for Human Research Protections (OHRP), the FDA released [final guidance](#) in May'14 outlining responsibilities of institutional review boards (IRBs), investigators and sponsors when transferring an ongoing clinical trial from one IRB to another.

**Electronic Records and Signature (FDA):** [21 CFR Part 11](#) outlines the requirements for the use of electronic records and signatures in place of paper records. In Mar'14 the FDA opened these regulations to comment. Also available is a [guidance document](#) on the FDA's current thinking on the scope and application of the regulation.

**Medical Devices: Exemption from General Requirements of Informed Consent (FDA):** In Apr'14 comment was requested on 21 CFR 50.23. In circumstances such as a public health emergency, general requirements for informed consent can be waived for the use of investigational in vitro diagnostic devices. Find out [more](#).

**\*FDA Use of Focus Groups (FDA):** The FDA is engaging the public through [focus groups](#) to get a better understanding of public attitudes, motivations and feelings on health topics. The FDA has requested comment on its use of focus groups until Jul 7'14.

---

## Newly opened trials in Alberta

Between Mar'14 and April'14, the following clinical trials have opened for participant recruitment as collated from [clinicaltrials.gov](#). The list may include trials that are recruiting\* and not yet recruiting in Alberta. Please check with the study team for the latest study status. If you have a clinical trial that will be opening for recruitment in the upcoming month, let us know and we will include it in the next issue.



- [An Exercise Trial and Economic Analysis in Men With Prostate Cancer](#)
- [Trends In Oxygen Saturation In Healthy Term Infants In The First Few Days Of Life: The "TOST" Study](#)\*
- [Prucalopride Versus Placebo in Diabetic Gastroparesis](#)\*
- [Comparison of Surveillance Colonoscopy Techniques in Patients With IBD](#)\*
- [Outcomes of Angiotensin Converting Enzyme Inhibitor Management Strategies Prior to Coronary Artery Bypass](#)\*
- [Timing of Indomethacin Administration for the Prevention of Post-ERCP Pancreatitis \(PEP\)](#)\*
- [Confirmatory Clinical Trial of the Evera MRI System for Conditionally-safe MRI Access](#)
- [HCMR - Novel Markers of Prognosis in Hypertrophic Cardiomyopathy](#)
- [Evaluating an Internet-based Program for Anxious Youth: a Pilot RCT](#)\*
- [Study of EVP-6124 \(Alpha-7 nAChR\) as an Adjunctive Pro-Cognitive Treatment in Schizophrenia Subjects on Chronic Stable Atypical Antipsychotic Therapy](#)\* Psychopharmacology Research Unit, University of Calgary, 403-210-6904

---

## Alberta in Publication – Evidence Based Medicine and Guidelines – recent publications

*This month we're showcasing Alberta's contribution to the evidence base for health care decisions and practice.*



Each issue will highlight a research area that has been recently published by Alberta researchers. Visit the ACRC website under [Clinical Research Source](#) for the [full listing](#).

- [Canadian Society of Nephrology Commentary on the 2012 KDIGO Clinical Practice Guideline for the Management of Blood Pressure in CKD.](#)
- [Improving the Evidence Base in Palliative Care to Inform Practice and Policy: Thinking Outside the Box.](#)
- [Clinical Practice Guidelines for Delirium Management: Potential Application in Palliative Care.](#)
- [Future resuscitation guidelines should contain more specific recommendations regarding simulation-based training.](#)
- [A questionnaire to assess the relevance and credibility of observational studies to inform health care decision making: an ISPOR-AMCP-NPC Good Practice Task Force report.](#)

