



RESEARCHER TOOLBOX



Site initiation is a key checkpoint to ensure all approvals, documentation and procedures are in place before a study can start and participants can be enrolled.

This month's addition to the toolbox provides useful templates that may be used for a **Site Initiation Visit**, where the sponsor will meet with the principal investigator (PI) and study staff to review the protocol, trial procedures, and documentation.

New Templates include:

Site Initiation Meeting Agenda: This template lists commonly covered topics addressed in the Site Initiation Meeting, and can be customized to the needs of your study. The agenda should be sent to the site prior to the site initiation meeting.

Inclusion/Exclusion Worksheet: This worksheet can be used to go through the screening process with potential study participants.

Confidential Master Information Log: Contains the confidential list of all study participants, contact information and enrollment numbers. This is an essential document which should be securely and separately from the other study documents.

Site Screening and Enrollment Log: A place to document the screening of participants, including the outcome of screening and reasons for non-enrollment. This is an essential document and is kept in the regulatory binder.

Informed Consent Worksheet: Informed consent must be documented in accordance with Good Clinical Practice. This worksheet can be used as a training checklist to make sure all elements of the process are followed.

Adverse Event Log and Reporting: This log can be used to assist with tracking and reporting adverse events as required by Health Canada.

Serious Adverse Event Tracking and Reporting: This form assists with documentation and reporting of serious adverse events as required by Health Canada.

Visit the [ACRC toolbox](#) to access the templates.

N2 CLINICAL TRIALS EDUCATION WEBSITE LAUNCHED - [It starts with me](#)

Are you looking for a resource for patients/families that has general information on clinical trials? A new website www.itstartswithme.ca was developed by both patients and caregivers who have had experience with clinical trials. **It starts with Me** is an overview of the key components involved in participating in a clinical trial and includes questions and considerations to think about in order to make an informed decision. The website includes information on participant rights, and a glossary of terms.

Please feel free to circulate this website to anyone you feel would benefit from the information provided. The site was created by the [Network of Networks \(N2\)](#) with the intention to promote more conversation about clinical research.

To support strengthening of clinical health research in Alberta, four times a year the ACRC will feature news relevant to you. Let us know if there are any ideas you have for the next issue!

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

Glossary & Common Terminology update!

The ACRC is pleased to announce that Version 2.2 of the ACRC Glossary & Common Terminology has just been released by the Glossary working group.

The updated version can be found on ResearchAlberta.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 - CCCCR.

Email: acrc@albertainnovates.ca

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

Looking for a way to organize your studies? REDCap is a secure, web-based electronic data capture system, which is specifically geared to academic research studies. It allows researchers to quickly create databases and surveys, and is accessible across multiple sites. Data can be imported or exported in several formats, and the system can be used for scheduling, randomization, and reporting. The system also has a mobile app for data capture offline and on the go. Data is held locally, at the servers at the University of Alberta and University of Calgary.

Visit [ResearchAlberta](#) to find out more about how to gain access to or receive training on REDCap.

Health Canada (HC) and FDA News

Keeping you informed of changes in regulations.

Publication of Good Clinical Practices Inspection Information (HC): As part of Health Canada's (HC) commitment to regulatory transparency, information on all clinical trial inspections performed in Canada was published on Dec 11'15 in [Health Canada's existing Drug and Health Product Inspections Database](#). This information includes a list of all GCP inspections conducted since Jan 1'12, a preliminary overview of the inspection findings, and, Inspection Report Cards (plain language summaries) of all inspections conducted since Sep 15, 2015.

Guideline for Good Clinical Practice E6(R2) (FDA): This [draft addendum](#) amends the guidance document "E6 Good Clinical Practice: Consolidated Guidance" (E6(R1)) to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting, and also updates standards regarding electronic records and essential documents.

Electronic Study Data Submission; Data Standards; Support for Study Data Tabulation Model Implementation Guide Version 3.2 (FDA): The Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) have announced support for version 3.2 of [Clinical Data Interchange Standards Consortium \(CDISC\) Study Data Tabulation Model Implementation Guide](#) (SDTM IG 3.2), an update to the FDA Data Standards Catalog. The FDA is encouraging sponsors and applicants to use SDTM IG 3.2 in investigational study data provided in regulatory submissions to CBER and to CDER.

Clinical Research in Alberta

Alberta is host to numerous clinical trials in a wide range of fields including oncology, psychology, metabolic disorders and more. Stay on top of the latest research in the province by viewing [recently opened clinical trials](#).

If you have a clinical trial that will be opening for recruitment in the upcoming months, let us know and we will include it on our website.



Alberta in Publication

This month we are showcasing publications on the topic of **injury**.



Each issue will highlight a research area that has been recently published by Alberta researchers.

Visit our website for the [full listing](#).

- ["Oh the weather outside is frightful": Severe injury secondary to falls while installing residential Christmas lights.](#)
- [Ventilation Monitoring in Severe Pediatric Traumatic Brain Injury at Nontrauma Centers.](#)
- [The Effectiveness of Passive Physical Modalities for the Management of Soft Tissue Injuries and Neuropathies of the Wrist and Hand: A Systematic Review](#)
- [A qualitative examination of women's self-presentation and social physique anxiety during injury rehabilitation.](#)
- [Ultrasound-Guided, Percutaneous Needle Fascial Fenestration for the Treatment of Chronic Exertional Compartment Syndrome: A Case Report.](#)
- [The Epidemiology of Injuries in Football at the London 2012 Paralympic Games.](#)
- [Are psychological interventions effective for the management of neck pain and whiplash-associated disorders? A systematic review by the Ontario Protocol for Traffic Injury Management \(OPTIMA\) Collaboration.](#)