



Keeping Essential Study Documents Organized

Introduction

A regulatory binder contains the study-specific information and regulatory documentation pertaining to a single study and is recommended for all intervention trials regardless of funding.

To help you organize your essential documents, the [ACRC](#) and [QMCR](#) (UofA) have provided possible options on how to organize your regulatory binder. These and other formats are acceptable though the binder setup needs to be easily understood by someone who is not familiar with the study.

Having a regulatory binder helps organize the essential documents; provides easy access to essential documents by the study monitors, auditors, REB and regulatory authorities for audit/review purposes; and enables the research team to reference information.

In maintaining the binder: ensure patient confidentiality, keep the binder in a secure location, file documents in reverse chronological order, and file notes to self in a separate location.

The regulatory binder is also referred to as the Study Binder, Investigator Binder, Administrative Binder, Regulatory Files, or Investigator's study files.

This set of tabs is part of the ACRC strategic priority #3 to '**develop provincial standards and opportunities for clinical research training**'. It contributes to a set of simple tools and training opportunities which incorporate best practice and applicable guidelines, created by the ACRC. Through these efforts, the quality of clinical research and research staff in the province is enhanced.

Alberta Clinical Research Consortium (ACRC)

The ACRC is a provincial initiative that involves academic and community-based researchers and administrators working together to achieve the vision of 'high quality, integrated and efficient clinical research in Alberta'.

From study start-up to close in all phases and disease areas, the ACRC is simplifying and harmonizing administrative processes across the province. High quality clinical research standards are upheld through the incorporation of best practices and applicable guidelines. The goal is to enhance the quality clinical research that will improve patient outcomes in the province.

ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

College of Physicians &
Surgeons of Alberta

Covenant Health

University of Alberta

University of Calgary

ACRC REGULATORY BINDER TABS

To customize the tabs for your study, download the following from the ACRC website under the [Research Toolbox](#):

- Regulatory Binder Information Sheet
- Regulatory Binder Tabs – can be printed on Avery printable 5-tabs
- Regulatory Binder Sub_Dividers

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ACRC RELATED TITLES & WEBSITES

[The Inaugural Strategic Plan Consultation \(2011\)](#)

[The ACRC Inaugural Strategic Plan \(2012\)](#)

[Strategic Plan At-A-Glance 2012-2013](#)

Tools and Templates

[ACRC Research Toolbox](#)

[CITI-Canada Training](#) and [CITI-Training ACRC Instruction Manual](#)