

## Your investigator-initiated, internally funded clinical research checklist

This checklist is a tool to help researchers navigate the various setup and close-out processes required to get an **investigator-initiated, internally funded** clinical research study up and running at the University of Alberta (U of A). *Please note that this checklist may not include each step of your study, and not every step listed may apply.* For more information about each of the items below, contact [NACTRC](#).

### 1. CONCEPT + DEVELOPMENT

- PROTOCOL DEVELOPMENT** A protocol describes your study in detail. Download interventional and observational protocol templates from the Office of Quality Management in Clinical Research ([QMCR](#)) and consult staff, if needed. Responsibility: investigator.
- DRUG DEVELOPMENT** Access services to develop pharmaceutical products and placebos through the Drug Development and Innovation Centre ([DDIC](#)).
- BIostatISTICS SUPPORT** Biostatistical support can help identify important study details such as sample size and priori analyses. Access biostatistical support through [WCHRI\\*](#), [EPICORE](#), [SPOR](#), and the [Biostatistics Consulting Group](#).
- ELECTRONIC DATA CAPTURE** REDCap is used to help build and manage research projects online. This complimentary electronic data capture system can be accessed through [WCHRI](#). The [SPOR](#) Research and Consultation Services Platform can facilitate the development of case report forms.
- DATA** The Alberta Strategy for Patient-Oriented Research (SPOR) [Data Platform](#) helps researchers determine availability and access to data. Inventory of existing data sets is available [here](#).
- PATIENT ENGAGEMENT** The Alberta SPOR [Patient Engagement Platform](#) helps researchers to facilitate meaningful and active engagement with patients/the public across all stages of health research.
- KNOWLEDGE TRANSLATION** The Alberta SPOR [Knowledge Translation Platform](#) offers consultation and support for researchers to drive knowledge into action.

### 2. REGISTRATION

- TRIAL REGISTRATION** Registration with [clinicaltrials.gov](#) is required for trials of drugs, biologics, and devices, and is encouraged for all other clinical trials. Complete registration at [clinicaltrials.gov](#). Contact the [QMCR](#) Office to obtain your username and password or to troubleshoot during registration.

### 3. ACCESS + AGREEMENTS

- PATIENT INFORMATION ACCESS + USE** Studies that access from repositories (e.g., health records) require a Data Disclosure Agreement (DDA) from AHS, unless you have an agreement negotiated through NACTRC. [Log in](#) to NACTRC and select “Get Started” to begin.
- SYSTEMS ACCESS** Studies that access electronic health records (e.g., NetCare) need to apply to the AHS Provincial Research Administration ([PRA](#)). Email the [PRA](#) to get started.
- eCLINICIAN ACCESS** Studies that access the electronic medical record eCLINICIAN require a Data Disclosure Agreement (DDA) from AHS. [Log in](#) to NACTRC and select “Get Started” to begin.

\*Priority given to members and/or those investigators conducting research aligned with their mandate.

## 4. FINANCE

- **BUDGET DEVELOPMENT** Accurate budget development helps a study achieve its objectives. [Log in](#) to NACTRC and go to PI Resources to download a budget checklist and template. Resources such as templates, guidelines, and other information are also available from the Alberta Clinical Research Consortium ([ACRC](#)).
- **ACCOUNTS** Most accounts will be set up through the Research Services Office ([RSO](#)). For information on financial conflict of interest (FCOI) contact the [QMCR](#) Office.

## 5. APPROVALS

- **ETHICS APPROVAL** Obtain ethics approval through the U of A's Health Research Ethics Board ([HREB](#)) or the Health Research Ethics Board of Alberta – Cancer Committee ([HREBA-CC](#)).
- **OPERATIONAL APPROVAL** Studies that use AHS property, resources, facilities, patients, or staff require operational approval, which can be obtained through NACTRC. [Log in](#) to NACTRC and select “Get Started” to begin.
- **HEALTH CANADA REGULATORY APPROVAL** Studies involving “off-label” uses of marketed drugs, natural health products, devices, biologics, or new products or devices require Health Canada approval in the form of a No Objection Letter (NOL) or Investigational Testing Authorization (ITA). Contact the [QMCR](#) Office for help.
- **BIOSAFETY APPROVAL** Studies that use biological pathogens on AHS property may need safety review and approval, which can be supported through [NACTRC](#). Biosafety considerations on U of A property are supported by [Environment, Health & Safety](#). Contact the [biosafety officer](#).

## 6. TRAINING

- **RESEARCH CONDUCT** The [QMCR](#) Office provides information about relevant training opportunities such as biosafety, biosecurity, CITI and Good Clinical Practice training for clinical researchers.
- **STUDY COORDINATION** [NACTRC](#) offers a two-day training program on clinical trials for study coordinators and the [QMCR](#) Office provides online clinical research coordinator training.
- **CLINICAL TRIALS** The Alberta SPOR [Pragmatic Clinical Trials](#) and [Career Development](#) Platforms offer a certificate program to train staff and investigators in patient-oriented research and the conduct of clinical trials. Learn more [here](#).
- **PRIVACY + SECURITY** The U of A [Information and Privacy Office](#) offers online privacy and security awareness training to faculty and staff. [Alberta Health Services](#) provides mandatory ‘Collect It: Protect It’ training for AHS employees and affiliates conducting research.

## 7. STUDY CONDUCT + CLOSE-OUT

- **ETHICS** The [Research Ethics Office](#) requires you to submit a closing report with your respective ethics board.
- **ADMINISTRATION** The [QMCR](#) Office will help you close out your study at Health Canada and [clinicaltrials.gov](#). A study close-out checklist is available from the [QMCR](#) Office.
- **RECORD ARCHIVING** Studies approved by Health Canada require archiving for 25 years. Archiving requirements for other studies are determined by institutional requirements. To share your data with others, the Library offers [Research Data Management](#). [NACTRC](#) supports archiving through local account setup.

