

## Your investigator-initiated, grant-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, grant-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

- RESEARCH QUESTION DEVELOPMENT** A Research Question Development Guide is available from the [Alberta Clinical Research Consortium](#). Also, the AbSPORU Consultation and Research Services (CRS) Platform can support building and fine-tuning the research question.
- 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 follow the Standard Protocol Items: Recommendations for Interventional Trials ([SPIRIT Checklist](#)). Support is available from QMCR, WHCRI or [AbSPORU CRS](#).
- 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](#), [AbSPORU](#), the [Biostatistics Consulting Group](#), the [Training and Consulting Centre](#), and Clinical Research Unit Edmonton ([CRUE](#))
- 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](#). Support for development of case report forms can be accessed through WCHRI, QMCR or AbSPORU CRS.
- DATA** The Alberta SPOR SUPPORT Unit ([AbSPORU](#)) [Data Platform](#) helps researchers determine availability and access to data. Inventory of existing data sets is available [here](#). The U of A Research Records Stewardship Guidance Procedure is available [here](#).
- PATIENT ENGAGEMENT** The AbSPORU [Patient Engagement Platform](#) helps researchers to facilitate meaningful and active engagement with patients/the public across all stages of health research.
- KNOWLEDGE TRANSLATION** The AbSPORU [Knowledge Translation Platform](#) offers consultation and support for researchers to drive knowledge into action (knowledge synthesis, knowledge translation and implementation science).

### 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.

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

### 3. ACCESS + AGREEMENTS

- **STUDY AGREEMENTS** Depending on your research, you may need a Clinical Trial Agreement (CTA), a Sub-Site Agreement (SUB) with another institution, a Confidential Disclosure Agreement (CDA), a Material Transfer Agreement (MTA), or a Data Transfer Agreement (DTA). RSO reviews and provides agreements for all grant-funded studies and any sub-out contracts of those. NACTRC is responsible for industry or pharmaceutical agreements and in-coming clinical trial agreements. [NACTRC's legal team](#) can review or provide these 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 AHS health information, data systems, or purchased services departments need to apply to the AHS Health System Access (HAS). Email the [HSA](#) to get started.

### 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](#)). For in-kind UofA research support budget considerations contact QMCR.
- **ACCOUNTS** Most accounts will be set up through the Research Services Office ([RSO](#)). Proposals need to be approved by RSO before applying for funding. Contact your RSO [research facilitator](#) to help you throughout proposal development. 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, Good Clinical Practice (GCP) and Division 5 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 AbSPORU [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 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.