NACTRC

Your investigator-initiated, non-funded (or in-kind support) 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, non-funded (or in-kind support)** 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. 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.

5. 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.

6. 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.