This checklist has been developed by the Clinical Trial Support Unit (CTSU) as a resource for investigators to navigate the various steps required to start-up and close-out industry-initiated, industry-funded clinical research at the University of Saskatchewan (USask). *Please note this is intended as a guide only and may not include all steps required for your specific study, nor may every step listed apply to your specific study.*

START-UP	
☐	**Industry Role.** The industry-sponsor is typically responsible for writing the protocol, obtaining No Objection Letter or Investigational Testing Authorization from Health Canada to test the drug or device developed, coordinating data management and statistical support, and trial registration on clinicaltrials.gov.
☐	**Site Qualification.** The CTSU works to connect industry-sponsors with investigators during initial engagement and can assist interested investigators with site qualification questionnaires or site intelligence surveys.
☐	**Site Selection.** Once the site has been officially selected a Confidential Disclosure Agreement (CDA) may be required before the sponsor will share the protocol. CTSU Contracts negotiates these agreements on behalf of USask and the PI and they must be signed by the Board of Governors on behalf of the institute.
☐	**Site Regulatory Documents.** The industry-sponsor typically requests completion of regulatory forms as well as collection of documents to confirm qualification of study staff and labs. Completion and collection of regulatory documents is provided through the CTSU standard start-up package.
ACCESS & AGREEMENTS	
☐	**Study Agreements.** In addition to the CDA, you may also require other agreements, including but not limited to a Clinical Trial Agreement (CTA), Sub-Site Agreement (SSA), and/or Material Transfer Agreement (MTA), depending on your research. CTSU Contracts negotiates these agreements on behalf of USask and the PI and they must be signed by the Board of Governors on behalf of the institute.
☐	**Patient Information**. Studies that access repositories (e.g., health records) require a Data Transfer Agreement (DTA) from the Saskatchewan Health Authority (SHA), unless you have an agreement negotiated through SHA.
FINANCE	
☐	**Budget Negotiation.** Sufficient budget to cover all associated study costs at the site level, including applicable Institutional Overhead, is required. Budgets should include study staffing, administration efforts, reimbursement for SHA screening and services, and per-protocol as well as follow-up costs. Expert budget negotiation is provided through the CTSU standard start-up package.
☐	**Accounts & Invoicing.** A research fund must be set-up in UnivRS for all research at the USask. The CTSU offers management and reconciliation of the research fund, as well as invoicing of the sponsor according to the approved budget in the CTA, as part of the standard start-up package.
APPROVALS	
☐	**Ethics Approval.** Obtain ethics approval through a Research Ethics Board (REB). The CTSU obtains ethical approval through the USask REB on behalf of the investigator as part of the standard start-up package.
☐	**Operational Approval.** Research studies that use SHA property, resources, facilities, patients, or staff require operational approval. The CTSU requests operational approval on behalf of the investigator as part of the standard start-up package.
TRAINING	
☐	**Research Conduct.** Training courses through the CITI Program are available as part of USask's membership with N2 Network of Networks. It is recommended researchers complete the Responsible Conduct of Research, Canada GCP, and Health Canada Division 5 courses at

	minimum. Adoption of Standard Operating Procedures is a regulatory requirement and it is recommended sites adopt relevant SOPs available through N2. Please contact CTSU Operations for access.
☐	**Study Coordination.** The Clinical Research Coordinator course is also offered through the CITI Program. The CTSU has highly trained and experienced Clinical Research Coordinators and Clinical Research Nurses available to hire for CTSU-supported studies. All CTSU Coordinators have completed CITI training.
☐	**Patient-Oriented Research.** The Saskatchewan Centre for Patient-Oriented Research offers a variety of training for staff and investigators engaging in patient-oriented research and clinical trials.
STUDY CONDUCT & CLOSE-OUT	
☐	**On-going Trial Activities.** Once initiated, studies must be maintained (e.g., amendments, safety reporting, renewals, etc.) and closed-out upon study completion. These services can be provided after start-up by the CTSU.
☐	**Record Archiving.** Studies approved by Health Canada require archiving for 15 years (previously 25 years). Archiving studies for other studies are determined by institutional requirements. Archiving is the responsibility of the study Principal Investigator.