

SASKATCHEWAN DRUG RESEARCH INSTITUTE (SDRI)

STATUS REPORT

<http://www.usask.ca/sdri/>

Mission:

- To create vital links between the pharmaceutical industry and Saskatchewan researchers.
- To increase clinical research and development by bringing together the expertise needed for sponsors, funders and investigators to meet research needs in one convenient centre.
- To promote research at basic and clinical levels that will advance our knowledge of the diagnosis, prevention and treatment of disease.
- To support the groundbreaking contributions to research conducted by busy clinicians, nurses, faculty members, graduate students, post-doctoral students, chairs and everyone else involved in clinical research.
- To maintain the integrity of clinical research by promoting adherence to the highest standards, including the three G's: Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP).
- To promote the importance of testing new treatments, drugs and devices for the benefit of medical practice and patient care in Saskatchewan and around the world.

Goals and objectives of the centre:

Established in 1993 by the University of Saskatchewan, the Saskatchewan Drug Research Institute (SDRI) provides comprehensive support services to clinical researchers. Put simply, our job is to make research easier for the faculty, students and staff we serve.

Types of activities undertaken to achieve mandate: e.g. research; graduate student training; student experience; programming; outreach

We provide advice, information and support for every kind of clinical research project, including chart reviews, registries, data collection studies, and drug, treatment and device studies.

We can help clinical researchers to:

- Work out a protocol, review and finalize it.
- Identify costs and a budget and negotiate the budget directly with the sponsor or funding agency
- Complete funding applications from government, industry and others.
- Develop case report forms, consent and/or assent forms, questionnaire and subject recruitment tools.
- Coordinate the simultaneous review, preparation of, and negotiation of essential study start-up documents, including the ethics submission, hospital approval, regulatory documents, clinical trial agreement and budget.
- Register the study in a public clinical trial registry.
- Complete the Health Canada approval application.
- Liaise among principal investigators, study staff, sponsors, clinical research organizations, research ethics boards, health regions, regulators, and other University departments.
- Prepare, review and submit protocol deviations and amendments, safety addenda or updates, internal and external adverse event reports, annual renewal forms, and administrative letters with the ethics office.
- Prepare investigators for audit, monitoring and close-out visits.
- Close out studies by preparing and submitting study closure notices to the ethics office and health region.
- Prepare invoices, track payments, pay study expenses, and reconcile study payments.

For those researchers who need study coordinator or research assistance, we have two fully licensed and registered nurses on staff with an in-depth knowledge of the research process and a diverse nursing background. Whether sites need full or partial study coordinator services, or someone to back up their existing study personnel, our research nurses can help them to:

- Manage paperwork, correspondence and data, and day to day problem solving.
- Identify potential subjects, assess inclusion/ exclusion criteria, conduct telephone and face-to- face screenings.
- Inform patients, obtain informed consent, and work directly with prospective and enrolled subjects and their families or caregivers.
- Schedule tests and appointments.
- Monitor study activities, work with pharmacy, labs and other hospital departments, and manage recruitment follow-up.

- Complete case report forms, resolve queries, and report serious adverse events.
- Collect data and biological specimens, data management, assess and coordinate clinical/ laboratory testing, phlebotomy, vital signs, pregnancy tests, blood processing, etc.
- Conduct pre-study, initiation, monitoring, and close out visits with pharmaceutical representatives.
- Handle the investigator's file, and prepare for and attend audits.

Governance:

Please note that SDRI is currently in the process of revising its governance / reporting structure.

SDRI Board of Directors

Beth Horsburgh
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(University of Saskatchewan)
Vice-President Research and Innovation
(Saskatoon Health Region)

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Clinical Research Nurse Education, TBA
Clinical Research Nurse Education, TBA