

Memorandum

Date: January 2016

To: All AHS Managers

From: AHS Research, Innovation & Analytics

RE: Streamlined AHS Provincial Research Administration Processes

As Alberta's largest provider of care, AHS partners with Alberta's universities, funders and others to enable front-line teams to test ideas and adopt them. By integrating research and innovation into the delivery of care, AHS can nurture health research breakthroughs, innovations and new knowledge to the point where they generate tangible, real world clinical value. A critical component of this work is to initiate research studies led by our academic partners.

To help manage the growing number of requests and demand on AHS operations to support clinical research, AHS Provincial Research Administration is working with AHS operational areas and our partners at the Universities, the Research Ethics Boards (REBs), NACTRC and Cumming School of Medicine Legal Services to implement a streamlined pathway for requesting access to AHS resources and services.

This pathway will result in enhanced compliance with Alberta legislation, ethics requirements, system access protocols and AHS policy for conducting clinical research within AHS facilities.

Commencing early 2016, AHS Provincial Research Administration team will be notified of all studies and/or amendments approved by a REB. With the researcher's consent, the REB submission documents will be reviewed by AHS Provincial Research Administration for clinical operational impact and AHS data requirements. Our team will then initiate the following processes on behalf of the researchers:

HIA Research Agreements

To ensure compliance with the *Health Information Act* (HIA), all clinical health research studies without an AHS-negotiated Clinical Trial Agreement that request AHS "owned" data or health information must complete an HIA Research Agreement.

Upon ethics approval, a Research Administration Advisor ("Advisor") will confirm data requirements with study personnel and assist in connecting with relevant AHS repository holders to organize data extraction and execute a <u>single research agreement per study</u> regardless of the number of AHS repositories accessed across the province. If material or data transfer are anticipated, the transfer agreement(s) will be prepared at the same time.

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Access to Information Technology (IT) Systems for Research Purposes

To manage compliance with AHS information security and IT <u>policies</u>, all requests for use of AHS IT systems will be managed through the *IT Access for Research* process, which is separate from the Identity & Access Management (IAM) portal recently deployed for clinical access. *AHS clinical staff will not use the IAM portal to assist researchers in completing requests for AHS network or IT systems*

If direct access to AHS systems or Netcare is requested to support the research study, the AHS Provincial Research Administration team will organize the IT access for all personnel working on the study. The provisioned access for the personnel will remain in place for the duration of the study or until the personnel is no longer associated with the study.

New personnel joining a study must complete an online *Request for IT Access (Research)* form if the AHS network, shared drives or any proprietary IT system are required for the study. Please <u>click here</u> or visit http://bit.ly/1NTJabJ for a copy of the form.

Operational Approval for Investigators Affiliated with the University of Calgary

Effective February 1, 2016, Operational Approvers are <u>no longer required</u> to provide written authorization to investigators prior to their submitting their ethics application to the University of Calgary's Conjoint Health Research Ethics Board (CHREB). Instead, CHREB will alert the AHS Provincial Research Administration team of the request for AHS support and the Research Advisor will summarize the operational requirements based on the submission to the ethics board. The Advisor will contact the designated AHS manager(s) to request approval. When all approvals are obtained, the researcher and operational area(s) will be notified that the study can be initiated.

Investigators are strongly encouraged to consult with AHS operational areas prior to submission to confirm the resources and services they need are available.

- Researchers using NACTRC to initiate studies will continue using the NACTRC system for Operational Approvals. There are no changes in this process.
- Researchers in adult oncology continue to work with the existing trial initiation processes at the Cross Cancer Institute or Tom Baker Cancer Centre's Clinical Trial Unit.

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