Requesting AHS Resources for Research Purposes

Health System Access, Health Evidence & Innovation

September 21, 2020
Guiding principles in accordance with the Health Information Act

- AHS complies with s57 and s58 of the HIA. For research, additional considerations may be imposed on the researcher in addition to those imposed by the Research Ethics Board.

- Highest degree of anonymity for the persons who are the subject of the information;

- Least amount of information disclosed that will meet the needs of the stated purpose;

- Need to know – the disclosure of only necessary information to carry out research or responsibilities.
Guiding principles in accordance with Clinical Information Sharing Compact

<table>
<thead>
<tr>
<th>Principle</th>
<th>AHS Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Improvement</td>
<td>Support clinical and health system improvement initiatives, including clinical research, quality improvement and educational advancement.</td>
</tr>
<tr>
<td>Provider Access</td>
<td>Facilitate timely, reliable and secure access for all Clinical Information System (CIS) users wherever and whenever CIS information sharing is required; including access for legal or professional needs</td>
</tr>
<tr>
<td>Disclosure</td>
<td>Receive and coordinate requests for the disclosure of health information to third parties, respecting clinicians’ interests.</td>
</tr>
<tr>
<td>Protection of Information</td>
<td>Develop, implement and support technical, physical and administrative safeguards to protect health information while providing appropriate user training.</td>
</tr>
<tr>
<td>Use</td>
<td>Be transparent and accountable to clinicians, staff, government and the public with respect to the use of health, clinician or organizational information stored in or extracted from the CIS.</td>
</tr>
</tbody>
</table>
AHS' Health System Access Access – Overview

- Ethics Approval
- Legal/Contracting
- Research Finance
- Biosafety Approval (in development)
- Operational Approval
- Data & Systems Approval

Administrative Approval → Study Initiation
Legal / Contracting Approval

Purpose: to negotiate legal agreements where financial, privacy, performance or other required terms and conditions need to be formalized

- University of Alberta affiliated PIs submit to NACTRC
- University of Calgary affiliated PIs submit to CMS Legal
- AHS employees and non-affiliated PIs submit to Health System Access
Purpose: to create and manage financial accounts associated with research funding (typically associated with research contracts)

- University of Alberta affiliated PIs may hold their accounts either at NACTRC (AHS) or UofA RSO
- University of Calgary affiliated PIs hold their accounts at UofC Research Accounting
- AHS employees and non-affiliated PIs may hold their account at AHS
Operational Approval

Purpose: to request approval for researchers to access clinical operational areas and/or support from AHS staff for research activities beyond SOC

- Access to Edmonton Zone sites are submitted via NACTRC
- Access to all sites outside of Edmonton Zone are submitted via HSA Intake

*** OA tips and resources available at: HSA Resource Page ***
Biosafety Approval (in development)

Biosafety Approval

Purpose: to review for and create a plan to mitigate any biosafety-related risks for the handling, storage and use of therapies with biohazardous risks at AHS facilities

- Biosafety risks are identified and triaged via HSA Intake
Data & Systems Approval

Purpose: to document the data systems or repositories access for research purposes and enter into an appropriate data disclosure agreement (and possibly data transfer agreement).

- ALL data access requests are submitted via HSA Intake

*** Data access tips and resources available at: HSA Resource Page ***
AHS’ Health System Access Access – Summarized

- Ethics Approval
- Legal/Contracting
- Research Finance
- Biosafety Approval *(in development)*
- Operational Approval
- Data & Systems Approval

Administrative Approval

Study Initiation
Researchers submit request for data and system access

- Request is submitted via online form coordinated with the research ethics process

Health System Access (previously PRA) review

- Includes:
  - Comparing data request against ethics approval
  - Comparing proposed data use against repository operational requirements and PIA
  - If required, data negotiations are facilitated between research teams and repository owners

Data Disclosure Agreement

- Approved systems and mode of access are documented on Schedule A of a templated Data Disclosure Agreement
- Approved users are entered into the HSA Admin Database and linked to the study record
- Approved users are sent for training and CUAs are collected

Data / Systems Approval

- Data & Systems approval is incorporated into the overall Administrative Approval to indicate full approval of the research study for initiation
- Repository owners have assurance to provide data for research use

User Annual Review Process
Data and Systems Use Determination Process

User Access Review

- Aggregate/non-identifiable or extractable elements
- Identifiable data or access based on patient consent
- Direct access to EMR or paper charts
- *NEW* research documentation or orders; following consented patients
- CC-CIS Research Module (write-access)
Data and Systems Approval Summarized
# Processing Volume

<table>
<thead>
<tr>
<th></th>
<th>FY2016-17</th>
<th>FY2017-18</th>
<th>FY2018-19</th>
<th>FY2019-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intake</td>
<td>1903</td>
<td>1650</td>
<td>1619</td>
<td>1352</td>
</tr>
<tr>
<td>Assessments</td>
<td>992</td>
<td>1304</td>
<td>1267</td>
<td>1349</td>
</tr>
<tr>
<td>DDA and AMEs</td>
<td>612</td>
<td>848</td>
<td>876</td>
<td>939</td>
</tr>
<tr>
<td>Operational Approvals</td>
<td>207</td>
<td>341</td>
<td>429</td>
<td>478</td>
</tr>
<tr>
<td>(outside of Edmonton Zone)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
How do I submit my data request?

- via HSA Questionnaire
How do I submit a user direct access request?

- via IT Access Request for Research from
Processing Timelines (FY19-20)

To help shorten your processing timelines:

• Submit your HSA questionnaire as soon as possible
• Fill in the questionnaire completely
• Connect with the operational approvers early
Tips for getting and sharing your data

Do your homework – plan ahead

- Where will your data come from?
- How will you get the data (direct access or analyst extract)?
- Do your team members have the access they need?

Does your data include identifiable health information?

- Sharing health data requires data transfer provisions in a contract or data transfer agreement
- Think about how you will de-identify the data before you share it
Health System Access Summary

Bookmark the HSA Research Resource Page:
https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx