**Text

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**AHS MODULE**

**HSA Application - Reference Guide**

**Editable for department-specific notes**

July 18, 2023 | v.03

How to use this guide:

Please review this information carefully. It will help guide your application responses to reduce change requests and ensure approvals can be issued in a timely manner.

The current status of your application and all communication will be stored within IRISS.

You can save and access your submission directly within IRISS.

Taking notes:

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| --- | --- |
| Text boxes have been provided to add notes about selections your department would most often use to support future applications.   |  | | --- | | This space is intended for you to keep department-specific notes throughout the guide. |   For additional resources around Health System Access for Research,  visit the [**AHS Research and Innovation Tips page**](https://www.albertahealthservices.ca/research/page8579.aspx)**.** |

Access the AHS module in IRISS

As soon as you indicate you need AHS approval in your ethics application, the module will be available. You can submit at the same time as your ethics application.

**Note:** in order to complete the HSA request – **you MUST be listed** **on the ethics application.**

To access the AHS module, select the **AHS Resources Tab** when available from within your study’s workspace.



Graphical user interface, text, application

Description automatically generated

**Modifications \* Important Note \***

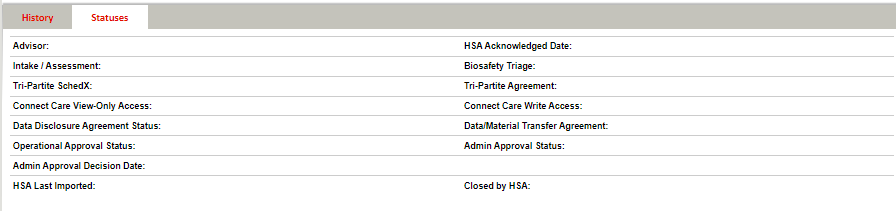
Due to current ENCAPS processes, modifications **cannot be processed** through the AHS module at this time.

To request an amendment to a submission, log a comment to AHS using the **EMAIL AHS** button in the side bar and detail the modification in your message.

Status Definitions:

A tab titled “**Statuses”** has been includedto improve visibility into the status of an application.

This dashboard will indicate the most recent date or status update for each review/approval requested in your application.



**Status Reference Table:**

|  |  |  |
| --- | --- | --- |
| **STATUS ITEM** | **ITEM DESCRIPTION** | **STATUS TYPES** |
| **Advisor** | Name and email link of the AHS advisor reviewing the application. | * Name |
| **Intake / Assessment** | Status update for ENCAPS group assignment  Status assigned by HSA to assist in the tracking and routing of the request.  Statuses with “ISCT” is assigned a designated process path for Industry-Sponsored Clinical Trials. | * Pre-Review * Ready for Review * Ready for ISCT Review * Ready for IT Access Review * Cancer ISCT * NACTRC (exclude CCI) ISCT * Info / Consult Requested * Triaged * No Further Action Required * Insufficient Info / No Response |
| **AHS DTA / MTA** | Indicates whether AHS is negotiating a data or material transfer agreement directly with the study sponsor/lead site and the university is not a signing party.  A Tripartite agreement negotiated by CSM Legal or your designated research contracting centre may still be required for the transfer of health information and/or materials. | * Required * Not Required |
| **Biosafety Triage** | Indicates if a biosafety review is required and the current processing status for biosafety review and approval. | * Not Required * Processing * Complete |
| **Tri-Partite SchedX** | Schedule X refers to the data schedule or approved data elements that’s has been negotiated and inserted as a Schedule into a contract when health information is being shared or transferred to an academic sponsor/lead site. | * Not Required * Required |
| **Tri-Partite Agreement** | Corresponds to the contact requirement at CSM Legal or your designated research contracting centre. It represents AHS’s processing status and may not correspond to CSM Legal’s status | * Not required * Processing * AHS Signatures * Completed |
| **Connect Care View-Only Access / Write Access** | Indicates if CC view or write access is *not* required or the status of the request. | * Not Required * Requested * Approved * Denied |
| **Operational / Administrative Approval Status** | Status update for current state of review.  Operational Approval refers to any request that utilizes or involves AHS property, resources, facilities, patients or staff. The researcher must obtain an operational approval from each area or department that will be impacted by the study. This approval, amongst many others, is required to launch the research study.  The individual resource approval elements combine to generate an "Administrative Approval". The Administrative Approval is a requirement to launch a research study requiring AHS resources. The HSA team provides services and advisory support to help you access the resources that your study needs. | Operational Status   * Not Required * Under Review * Information or  Consultation Required * Out to Approver(s)   Completed   * Cancelled/denied   Administrative Status   * Pending * Granted * Not Granted |
| **Data Disclosure Agreement Status** | Indicates the current status for the Data Disclosure Agreement (DDA). The DDA is a part of the Data Approval review.  The Data Approval is component of the Administration Approval and is a requirement for access to AHS data. | * Submitted * Assigned * Reviewed * Not Required * N/A (Contract in Place) * Processing * Waiting for PI Signature * Signed By PI * Fully Executed * Closed By HSA |
| **Admin Decision Date** | Date the administrative approval was either Granted or Not Granted. | * Date |
| **Closed by HSA** | Date HSA (Health Systems Access) closes the file in ENCAPS. | * Date |
| **HSA Acknowledged Date** | Date when HSA first acknowledges the application.  If this status remains unchanged for more than 2 weeks, reach out to your HSA advisor for further information. | * Date |
| **HSA Last Import:** | Date HSA last imported a status associated with your application. | * Date |

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# 1. Important Information – Getting Started

## AHS Resource Request for Research

(Data or IT systems, Operational Approval, Patient Recruitment, Purchased Services)  
Alberta Health Services' (AHS) Health System Access (HSA) team works with Alberta's academic institutions, affiliated research institutes and centers to support health research.

The necessary approvals for each resource requirement must be obtained if your research requires access to AHS:

* areas or facilities,
* data or IT systems,
* patients or staff from AHS facilities.

## Administrative approval

The individual resource approvals described below combine to generate an "Administrative Approval". The Administrative Approval is a requirement to launch a research study requiring AHS resources. The HSA team provides services and advisory support to help you access the resources that your study needs.

## Operational approval

If a research study utilizes or involves AHS property, resources, facilities, patients or staff, the researcher must obtain an operational approval from each area or department that will be impacted by the study. This approval, amongst many others, is required to launch the research study.

AHS operational approval requests are facilitated by the AHS Health System Access team. Providing thorough study and operational impact details in this submission will allow operational approvers to respond more efficiently.

## Obtaining AHS data

The data within AHS can be made available for research purposes under certain terms and conditions and can be accessed either by data extraction (done by an AHS data analyst) or by direct access to an AHS IT system.

Prior to the data access, the research study must be approved by a Research Ethics Board (REB) designated under Alberta's Health Information Act (HIA) and the researcher is required to enter into an agreement with AHS for the data disclosure. This agreement could be in the form of a Clinical Trial Agreement (CTA), Sub-Site Agreement or Data Disclosure Agreement (DDA).

To ensure the privacy and protection of AHS health information, the sharing or transfer of AHS data to any external entity must be reviewed and approved by HSA. A Data Transfer Agreement may be required with the recipient site.

## Submission process

To initiate the submission process to AHS – you must complete and submit the AHS request within IRISS. The information required for AHS will depend on your study, but general information may include:

1. CSM legal project code
2. Primary site location
3. AHS clinical department areas
4. Start and end date of research activities in each department
5. Specific system access information (e.g. Endo Pro, Sunrise Clinical Manager, Connect Care etc.)

You can submit this request to AHS according to your ethics submission status.

>> Please note, industry sponsored clinical trials and participating sites utilizing the REBX can submit this request to AHS when the ethics application has been submitted. All other studies can submit this request to AHS when the ethics application is approved.

## Review and approval

Once your submission is received, your request will be reviewed to ensure data can be obtained from the data sources you have indicated and any additional applicable approval requests will be submitted (ie. operational approval, IT access requests).

Once the request details are verified and relevant approvals obtained, an AHS Administrative Approval will be issued to indicate that all necessary AHS approvals are in place to initiate your study.

# 2. Operational Approval

## 1.0 Research Methods & Procedures

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Data for this section is populated from the ethics application and advises the need for biosafety assessment.

### 1.1 Is the investigational product a biologic based drug or vaccine?

Yes  No

**Preparation/manipulation or special handling refers to:**

Any procedure that requires staff to prepare or handle substances (bodily or products) above and beyond standard of care. This is used for biosafety assessment.

### 1.2 Is this study collecting human clinical specimens (tissue, cells, blood, bodily fluids, etc.) for analysis or monitoring?

Yes  No

### 1.2.1 Are the samples collected coming from a population known or reasonably expected to be infected with or carriers of a pathogen?

Yes  No

### 1.3 Does the project involve any of the following for the investigational product or during processing of samples collected?

**Sample collection activity definitions:**

**Culturing Activities**  
An attempt to culture/propagate/amplify a biological organism from an investigational product and/or collected samples.

**Aerosol generation (delivery system or material processing)**  
Are any of the study activates involving an investigational product and/or collection and processing of samples aerosol generating. For example, a drug is administered through aerosol delivery vs. oral or intravenous delivery.

**Purposeful isolation or manipulation of >= risk group 2 pathogen(s)**  
Will the study involve isolating or manipulating (e.g. genetic recombination, cell culturing) a risk group 2 or greater pathogen. A pathogen’s risk group is determined by searching for the pathogen on the government of Canada’s ePATHogen database.

## 2.0 Which Strategic Clinical Network(s) would your study be most closely associated with?

Addiction and Mental Health

Bone and Joint Health

Cancer

Cardiovascular Health and Stroke

Critical Care

Diabetes, Obesity and Nutrition

Digestive Health

Emergency

Indigenous Wellness Core

Maternal Newborn Child & Youth

Medicine (Hospital Medicine, Kidney Health, Respiratory Health)

Neurosciences, Rehabilitation & Vision

Population & Public Health

Primary Health Care

Seniors Health and Continuing Care

Surgery

Not Applicable

## 3.0 Select the clinical disease area primarily associated with your study:

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Selected clinical disease areas will be directly linked with available primary site locations. Only sites with applicable facilities will later be listed as options for the primary site location.

(eg. If your clinical disease area includes stroke, only sites with stroke departments will be available to choose for your primary site.)

## 4.0 Will your study be recruiting AHS patients and/or staff from an AHS facility or, require access to an AHS site and/or resources for the purpose of patient access, equipment/space, on-site chart access, virtual program support or other study activities?

Yes  No

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### 4.1 My study will be primarily run out of this site:

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Site selections are based on selected clinical disease areas from question 3.0. Only sites with associated clinical disease departments will be available. If your primary site is not shown, go back to question 3.0 and review your selected clinical disease area.

## 4.2 Select the required AHS departments for this research:

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If you are unsure of the department, please ask your team clinician what unit or department they select when logging into Connect Care.

**IMPORTANT SEARCH TIPS**

**Use the filter options** in the following hierarchical order to find associated departments:

1. City, 2. Location, 3. Epic Specialty

Click “Advanced” to open additional filter options.

**Use % before any word** (or partial word) to filter keywords in **any** order. (eg. %child will bring up all locations with the word “children” or “childrens” anywhere in the title.

### 4.3 In addition to the primary site, will your study need access to other sites?

Yes  No

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In addition to sites where the study will be primarily run, you must indicate any additional sites the study will need access to, including for recruitment purposes. Note: for multi-site studies, official participating sites (pSites) will apply for their own AHS approvals so only include additional sites your specific team will need access to.

## 5.0 Will your study use AHS patient health information or AHS data sources?

Yes  No

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Refers to both extracts and direct access. By indicating YES, additional information will be required.

The research study must be approved by a Research Ethics Board (REB) designated under Alberta's Health Information Act (HIA) and the researcher is required to enter into an agreement with AHS for the data disclosure. This agreement could be in the form of a Clinical Trial Agreement (CTA), Sub-Site Agreement or Data Disclosure Agreement (DDA). Be sure to have this information in place prior to continuing this application.

Types of agreements requiring legal review can be found on the [CSM Legal site](https://cumming.ucalgary.ca/research/csm-legal/getting-agreements-signed/types-agreements-our-office-handles).

## 6.0 Will your study require the services from an AHS purchased services department?

Yes  No

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Additional information about AHS purchased Services and contact information if you are unsure can be found on the [AHS Research site](https://www.albertahealthservices.ca/research/Page16075.aspx).

### 6.1 Select AHS Purchased Services:

Pharmacy department

Laboratory Services department

Diagnostic Imaging department

Health Information Management (HIM) department

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## 7.0 Will you be submitting, or have you submitted, a Clinical Trial Agreement, Sub-Site Agreement, Collaborative Research Agreement or any other agreement types of our partnered administrative offices?

Yes  No

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Types of agreements requiring legal review can be found on the [CSM Legal site](https://cumming.ucalgary.ca/research/csm-legal/getting-agreements-signed/types-agreements-our-office-handles).

### 7.1 Select One:

CSM Legal  NACTRC

### 7.1.1 CSM Legal Contract ID:

# 3. Data Access

This section only appears if you have indicated YES for question 5.0 in Operational Approvals.

## 1.0 Will any data collected from AHS sources be transferred to another collaborating academic institution or private company?

Yes  No

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Legal consultation and processes are required for all multi-site studies and those associated with an industry sponsor.

## 2.0 Are you reusing data collected from a previously approved REB study:

Yes  No

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**IMPORTANT**

Previously issued approvals are one-time use. All reuse of data must be disclosed and approved for every use-case.

The data within AHS can be made available for research purposes under certain terms and conditions, and can be accessed either by data extraction (done by an AHS data analyst) or by direct access to an AHS IT system.

Additional information about systems access can be found on the [AHS website.](https://www.albertahealthservices.ca/research/Page16074.aspx)

### 2.1 Provide the ethics IDs

## 3.0 Would you like to request a 'Data Extract' from any AHS database?

Yes  No

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Data sources from which the extraction was obtained must be documented by HSA.

A full list of AHS databases can be found through the [Enterprise Data Catalogue](https://extranet.ahsnet.ca/teams/EIM/EMDMS/EnterpriseDataCatalogue/SitePages/Home.aspx) (AHS network account is required to access.) Choose OTHER if your database is not listed here.

**NOTE**

By selecting “Connect Care”, an additional question section will load upon save to collect information specific to Connect Care access.

## 4.0 Does your study require direct access to any AHS database?

Yes  No

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For each database request, **you must indicate** which team members require access as the bottom.

**NOTE**

By selecting “Connect Care”, an additional question section will load upon save to collect information specific to Connect Care access.

## 5.0 Do you need assistance identifying any additional AHS data sources?

Yes  No

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## 6.0 You have indicated that this study requires access to AHS 'Paper Charts' - specify the study team members that need access to the paper charts:

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# 4. Connect Care

This section appears only if you have requested either an extract or direct access to ConnectCare in the Data Access section.

## 1.0 You have indicated that you require direct access to Connect Care, you must specify which type of direct access. For assistance determining the level of Connect Care access required for the study, visit HSA Team Resources CC Access Tips.

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## 2.0 Does the study sponsor have monitors that require access to Connect Care?

Yes  No

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## 3.0 Does your study require you to submit research-specific orders for APL (Alberta Precision Labs)?

Yes  No

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| --- |
|  |

## 4.0 Does your study require you to submit research-specific orders for Diagnostic Imaging?

Yes  No

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## 5.0 Does your study require you to submit research specific orders for Pharmacy?

Yes  No

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## 6.0 Does your study require an ERX build?

Yes  No

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In Connect Care, ALL medications (investigational or SOC) or products given to AHS patients as part of a research study must be recorded in the patient record. Please refer to the [ERX decision tree](https://extranet.ahsnet.ca/teams/AHSRA/News%20%20Annoucements/Medication%20Decision%20Tree.pdf) to help you decide if the medications involved in your study require an ERX build. Please complete and submit the [ERX Submission Form](http://wspharmapp01/NSD/Default.aspx).

*(Note: You must be on an AHS network to access the ERX submission form which requires you to login under an AHS user name and password)*

## 7.0 For hematology or oncology studies, will a treatment protocol be built?

Yes  No  Not Applicable

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A treatment protocol/plan is used to manage orders related to schedule dependent treatments such as a patient’s chemotherapy regimen, hemodialysis or infusion-based medications.

Treatment protocol builds are currently available for hematology or oncology studies only. To indicate a request for build, submit a [Service Now Ticket](https://insite.albertahealthservices.ca/cis/Page23730.aspx).

# 5. Department Information and Purchased Services

This section will be pre-populated based on your responses from Operational Approvals.

You can use the **ADD button** if a department you require access to is not yet listed.

Use the **UPDATE buttons** for **EACH DEPARTMENT** and **PURCHASE SERVICES** to complete your access application.

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# 6. Documentation

**IMPORTANT**

**DO NOT** add documents that are already found in the ethics application.

Only upload documents that are needed for AHS review *(examples include CRF - Case Report Form - / data elements, information letters or AHS issued email/letters of support*).

Disregard the Advanced Option section.

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