



Northern Alberta Clinical Trials and Research Centre

Research Basics
November 23, 2017

Overview

- How to use our online application
 - Creating an account
 - Uploading Protocols
 - Allowing user permissions in protocols
 - Legal Document/contract submission
 - Operational Approval submission
- Other Items:
 - e-Clinician access
 - Data Disclosure Agreements (DDA)

AA & OA

- **Edmonton-Zone Administrative Approval (AA):** NACTRC's final approval required to begin your research. You cannot conduct research on AHS property before receiving this.
- **Operational Approval (OA):** approvals required by individual sites/areas in order to conduct research at that location. Often multiple OAs are needed.
 - Examples: UAH-Posters, RAH-Health Records Chart Pull, Kaye Clinic- Family Medicine

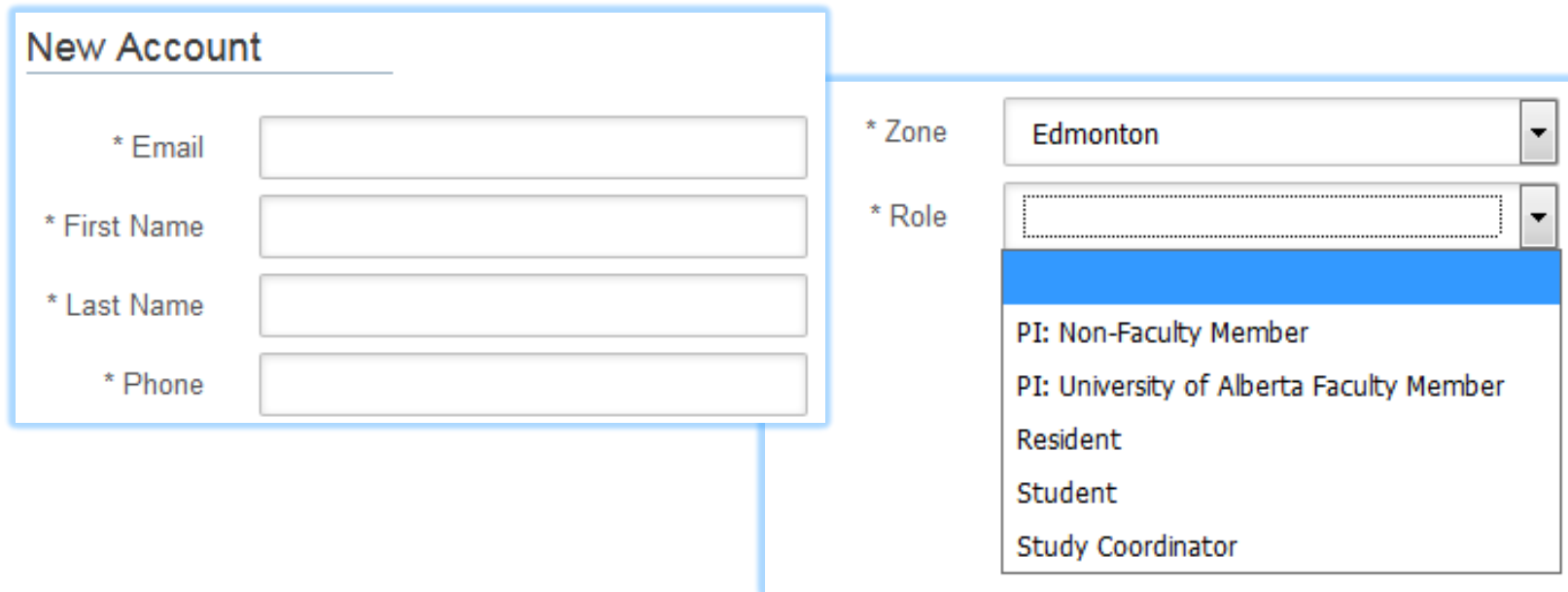
NACTRC online application

- www.NACTRC.ca



- Creating an account


- Must have @ualberta.ca, @ahs.ca, or @ucalgary.ca email account

A screenshot of the "New Account" registration form. The form is divided into two main sections. The left section, titled "New Account", contains four input fields: "* Email", "* First Name", "* Last Name", and "* Phone". The right section contains two dropdown menus: "* Zone" (with "Edmonton" selected) and "* Role". The "* Role" dropdown menu is open, showing a list of options: "PI: Non-Faculty Member", "PI: University of Alberta Faculty Member", "Resident", "Student", and "Study Coordinator". The first option, "PI: Non-Faculty Member", is highlighted in blue.

Step 1

Uploading your protocol

• Step 1: Uploading your protocol into the Protocol Bank



EDMONTON ZONE ADMINISTRATIVE APPROVAL (AA)

GET STARTED BY SELECTING ONE OF THE FOLLOWING:

INDUSTRY-INITIATED / INDUSTRY SPONSORED [View Definition >](#)

- I have a contract with a pharma company.
- The study protocol was authored by the pharma company.

[Download AA Information](#) (Industry-Initiated / Industry Sponsored)
[Download Checklist/Contact Info](#) (Industry-Initiated / Industry Sponsored)

INVESTIGATOR-INITIATED / INDUSTRY SPONSORED [View Definition >](#)

- I have a contract with a pharma company.
- The study protocol was authored by an Investigator from UA/AHS or other academic institution.

[Download AA Information](#) (Investigator-Initiated / Industry Sponsored)
[Download Checklist/Contact Info](#) (Investigator-Initiated / Industry Sponsored)

INVESTIGATOR-INITIATED / GRANT [View Definition >](#)

- I received a grant to conduct my research.
- The study protocol was authored by an Investigator from UA/AHS or other academic institution.

[Download AA Information](#) (Investigator-Initiated / Grant)
[Download Checklist/Contact Info](#) (Investigator-Initiated / Grant)

INVESTIGATOR-INITIATED / INTERNAL AND/OR CONTINGENCY FUNDING [View Definition >](#)

- I do not have a contract.
- The study protocol was authored by an Investigator from UA/AHS or other academic institution.
- I'm using internal or contingency funds to pay my expenses.

[Download AA Information](#) (Investigator-Initiated / Internal and/or Contingency Funding)
[Download Checklist/Contact Info](#) (Investigator-Initiated / Internal and/or Contingency Funding)

INVESTIGATOR-INITIATED / NO FUNDING [View Definition >](#)

- I do not have a contract.
- The study protocol was authored by an Investigator from UA/AHS or other academic institution.
- My protocol does not require any funding.

[Download AA Information](#) (Investigator-Initiated / No Funding)
[Download Checklist/Contact Info](#) (Investigator-Initiated / No Funding)

- Uploading your protocol

INDUSTRY-INITIATED / INDUSTRY SPONSORED

A clinical research study designed and funded by a pharmaceutical company, biotech or other private entities.

Subject to 30% overhead.

- [Submit the protocol](#) for this study
- If you are submitting a CDA (Confidentiality Agreement) and do NOT have a protocol, [click here](#).



- Uploading your protocol

Add Protocol

* Funding Type Industry-Initiated / Industry Sponsored

* Submitted to REB?

* Which REB are you submitting to?

* When do you expect to submit?  

* PI (must match ethics application)

Study Coordinator

* Research Protocol Title (Long Version)
Characters Remaining: 1000

Protocol Version Number

Protocol Acronym

* Research Category [Research Definitions?](#)

* Research Type

* Expected Number of Research Subjects

* eCLINICIAN is a shared Electronic Medical Record (EMR) across ambulatory and community clinic sites. All research requests require approval by the Information Stewardship Office. Will you require access to eCLINICIAN for this protocol?

* Protocol Document No file selected.

Document Password

“Protocol Dashboard”

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

[Edit PB](#) [Review PB](#)

Edmonton Zone Admin Approval (AA)

AHS Ref # 34???

Status Pending



[View AA Progress Map](#)

General Info

Protocol
Acronym
Protocol Number
Research
Category
Research Type
Funding Type

Expected
Subjects
Plan to Submit
to REB
Plan to Submit
to REB by

[Upload Approved REB Documents](#)

Legal Documents (LDs)

| ID | Type | Status | Submitted | Fully Executed |
|----|------|--------|-----------|----------------|
|----|------|--------|-----------|----------------|

[View Document Descriptions](#) [Submit New Legal Document](#)

Operational Approvals (OAs)

| ID | Site | Area | Status | Last Decision On |
|----|------|------|--------|------------------|
|----|------|------|--------|------------------|

[Download Site/Area List](#) [Submit New Operational Approval](#)

AHS Data Disclosure Agreement (DDA)

A copy of your REB approval letter is sent to AHS Provincial Research Admin. If they determine a DDA is required for this protocol, they will contact you.

eCLINICIAN

Your request to access eCLINICIAN will be submitted when your ethics has been approved.

This eCLINICIAN will support the enrollment of patients for this protocol.

Help

- [NACTRC Contracts Admin](#)
- [Provide Feedback](#)
- [Tech Support](#)

PI

Name PI Name
Email PI Email
Phone 780-407-1234
Association Department

Study Coordinator

Name Beth Hunter

Adding Permissions to your Protocol Dashboard

PB99999: PI NAME (Department Info)

PROTOCOL TITLE [Edit PB](#) [Review PB](#)

Edmonton Zone Admin Approval (AA)
AHS Ref # 34??? ✘
Status Pending
[View AA Progress Map](#)

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- [Provide Feedback](#)
- [Tech Support](#)

General Info
Protocol Acronym
Protocol Number
Research Category
Research Type
Funding Type
Expected Subjects
Plan to Submit to REB
Plan to Submit to REB by
[Upload Approved REB Documents](#)

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[View Document Descriptions](#) [Submit New Legal Document](#)

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|----|------|------|--------|------------------|

[Download Site/Area List](#) [Submit New Operational Approval](#)

PI
Name PI Name
Email PI Email
Phone 780-407-1234
Association Department

Study Coordinator
Name Beth Hunter



SCROLL DOWN

Adding Permissions to your Protocol Dashboard

Study Coordinator

Name - Beth Hunter
Email - Beth.hunter@ahs.ca
Phone - 780-407-4361

User Permissions

Name
Beth Hunter (owner)
Sheila Desarkar
PI name

[Edit Permissions](#)

Edit Protocol Permissions

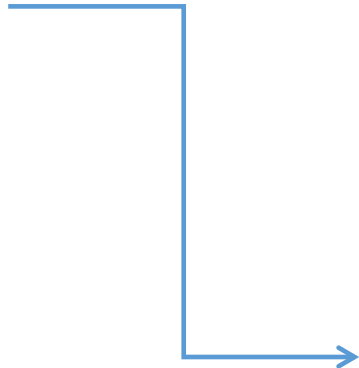
Permissions:

| User | Permission | Remove |
|------------------|---|--------|
| Hunter, Beth | Can view protocol, update ethics, and make requests | - |
| Desarkar, Sheila | Can view protocol, update ethics, and make requests | |
| PI name | Can view protocol, update ethics, and make requests | |

New Permission:

Search users by name (can only add existing users)

Add Permission **Close**



To remove

Step 2

Uploading your Contract/Legal Document

*if applicable

- Step 2: Uploading your contract/legal document (if applicable)

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

[Edit PB](#) [Review PB](#)

General Info

Protocol Acronym

Protocol Number

Research Category

Research Type

Funding Type

Expected Subjects

Plan to Submit to REB

Plan to Submit to REB by

[Upload Approved REB Documents](#)

Legal Documents (LDs)

| ID | Type | Status | Submitted | Fully Executed |
|----|------|--------|-----------|----------------|
| | | | | |

[View Document Descriptions](#) [Submit New Legal Document](#)

Edmonton Zone Admin Approval (AA)

AHS Ref # 34???

Status Pending

X

[View AA Progress Map](#)

PI

Name PI Name

Email PI Email

Phone 780-407-1234

Association Department

Operational Approvals (OAs)

| ID | Site | Area | Status | Last Decision On |
|----|------|------|--------|------------------|
| | | | | |

[Download Site/Area List](#) [Submit New Operational Approval](#)

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Study Coordinator

Name Beth Hunter

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Help

- [NACTRC Contracts Admin](#)
- [Provide Feedback](#)
- [Tech Support](#)

Uploading your contract

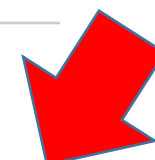
New Legal Document

| | | | |
|----------------|--|----------------|--------------------------|
| Start | | General | External Contract |
| ID | | | |
| Document Type | | | |
| PI | | | |
| Protocol Title | | | |

- Confidentiality Agreement
- Contract Amendment
- Data Transfer Agreement
- Final Protocol Budget
- Industry Contract Including Final Protocol Budget
- Industry Contract NOT Including Final Protocol Budget
- Materials Transfer Agreement
- Sponsor Supplier / Vendor Form
- Study Start-Up Agreement
- Sub-Site Contract
- W8BEN

Document Type

[View Definitions](#)



- Uploading your contract

- Sponsor (and CRO) contact information
- NIH funding?
- Financial Account selection (AHS? UofA? Other/none)
- Attaching the document
 - MUST be a Word document
 - MUST be editable

SAVE

I'm not done, but please save

SUBMIT

I'm done, please submit my information

CANCEL

I decided not to submit

- Uploading your contract

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

[Edit PB](#) [Review PB](#)

General Info

Protocol Acronym

Protocol Number

Research Category

Research Type

Funding Type

Expected Subjects

Plan to Submit to REB

Plan to Submit to REB by

[Upload Approved REB Documents](#)

Legal Documents (LDs)

| ID | Type | Status | Submitted | Fully Executed |
|---------|------|-----------|-------------|----------------|
| ID55555 | CTZ | Submitted | 15-Nov-2017 | |

[View Document Descriptions](#) [Submit New Legal Document](#)

PI

Name **PI Name**

Email **PI Email**

Phone **780-407-1234**

Association **Department**

Edmonton Zone Admin Approval (AA)

AHS Ref # **34???** X

Status Pending

[View AA Progress Map](#)

AHS Data Disclosure Agreement (DDA)

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Help

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- [Provide Feedback](#)
- [Tech Support](#)

Operational Approvals (OAs)

| ID | Site | Area | Status | Last Decision On |
|----|------|------|--------|------------------|
| | | | | |

[Download Site/Area List](#) [Submit New Operational Approval](#)

Study Coordinator

Name **Beth Hunter**

Legal document Dashboard

- Dates and turnaround times for legal documents:
 - submitted, sent to legal, sent to sponsor, finalized by legal, fully-executed
- Signatures (with dates)
- Related legal documents
- Sponsor/CRO contact information

Step 3

Submitting for Operational Approval(s)

• Step 3: Submitting Operational Approval(s)

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

[Edit PB](#) [Review PB](#)

General Info

Protocol
Acronym
Protocol Number
Research Category
Research Type
Funding Type

Expected Subjects
Plan to Submit to REB
Plan to Submit to REB by

[Upload Approved REB Documents](#)

Legal Documents (LDs)

| ID | Type | Status | Submitted | Fully Executed |
|----------------|------|-----------------------------|-------------|----------------|
| ID55555 | CTZ | Sent to Contract Specialist | 15-Nov-2017 | |

[View Document Descriptions](#) [Submit New Legal Document](#)

Edmonton Zone Admin Approval (AA)

AHS Ref # **34???** X
Status Pending

[View AA Progress Map](#)

PI

Name **PI Name**
Email **PI Email**
Phone **780-407-1234**
Association **Department**

Operational Approvals (OAs)

| ID | Site | Area | Status | Last Decision On |
|----|------|------|--------|------------------|
| | | | | |

[Download Site/Area List](#) [Submit New Operational Approval](#)

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Help

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- [Provide Feedback](#)
- [Tech Support](#)

Study Coordinator


Name **Beth Hunter**


Submitting Operational Approval(s)

You must submit individual requests to each site/area that you require.

* Site

* Area

* Date you expect to start your research in this area: 

* Date you expect to end your research in this area: 

* Will AHS staff from this area be expected to participate and/or carry out any duties related to this study?

* Will AHS staff from this area require any training or education?

* Are you expecting this AHS area to provide you with supplies and/or equipment?

Next

* Who needs to receive email notifications for this request?

Additional Comments

Characters Remaining: 2000

* Accuracy Agreement I attest that the information provided on this request for operational approval is true and accurate.

SAVE
I'm not done, but please save my information

SUBMIT
I'm done, please submit my information

CANCEL
I decided not to submit

Submitting Operational Approval(s)

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

[Edit PB](#) [Review PB](#)

Edmonton Zone Admin Approval (AA)

AHS Ref # 34???
Status Pending



[View AA Progress Map](#)

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- [NACTRC Contracts Admin](#)
- [Provide Feedback](#)
- [Tech Support](#)

General Info

Protocol
Acronym
Protocol Number
Research Category
Research Type
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Expected Subjects
Plan to Submit to REB
Plan to Submit to REB by

[Upload Approved REB Documents](#)

PI

Name PI Name
Email PI Email
Phone 780-407-1234
Association Department

Study Coordinator

Name Beth Hunter

Legal Documents (LDs)

| ID | Type | Status | Submitted | Fully Executed |
|-------------------------|------|-----------------------------|-------------|----------------|
| ID55555 | CTZ | Sent to Contract Specialist | 15-Nov-2017 | |

[View Document Descriptions](#) [Submit New Legal Document](#)


Operational Approvals (OAs)

| ID | Site | Area | Status | Last Decision On |
|-------------------------|------|----------------------|---------|------------------|
| QA33158 | UAH | Activity and Costing | Pending | |

[Download Site/Area List](#) [Submit New Operational Approval](#)


Submitting Operational Approval(s)

Status **OP APP #30773 is Approved**

Admin Approval 

OA PDF [Download](#)

Protocol Document [Download](#)

Password for Protocol File - 

Submission Comments -

Comments

This comments section can be used by researchers and approvers to communicate with each other. When you submit your comment, an email is sent to the other party so they can respond

[Add Comment](#)

| Role | Review By | Decision | Response On | Details | Contact Information |
|----------|------------------|----------|-------------|---------|--|
| ASSESSOR | Stewart Hamilton | Approved | 03-Nov-2015 | | stewart.hamilton@albertahealthservices.ca 780-407-7455 |
| APPROVER | Cathy Osborne | Approved | 18-Nov-2015 | | Cathy.Osborne@albertahealthservices.ca 780-407-3721 |

Decision required from 1 assessor(s) and 1 approver(s).

Location

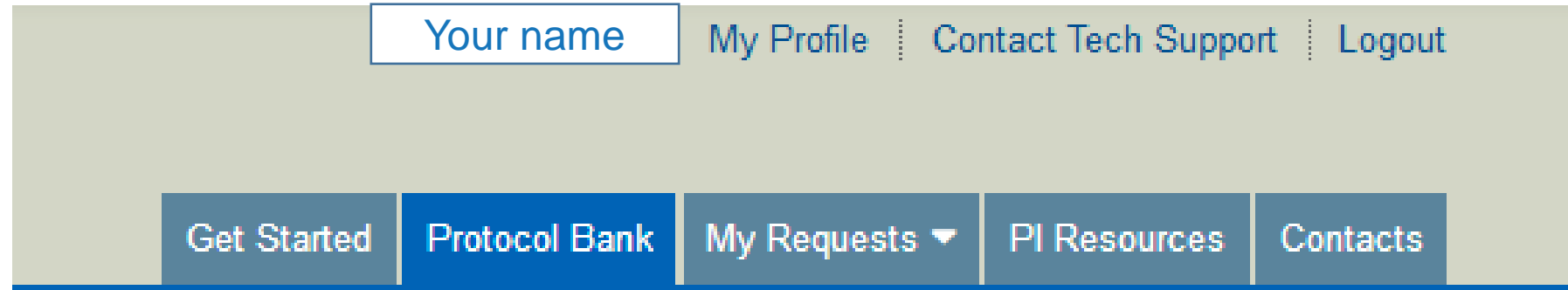
Site Name University of Alberta Hospital
 Area Name Site Approval



Operational Approvals

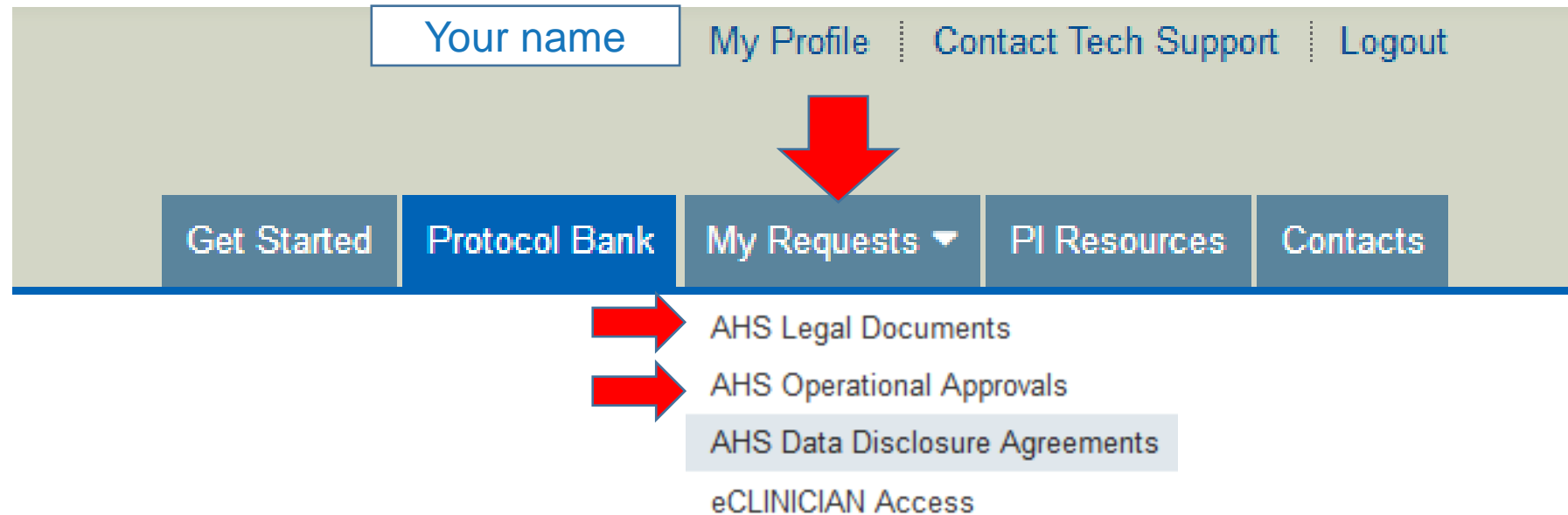
- One for each site/area
- Once submitted, cannot be amended
- Are only required for AHS property- not UofA, PCN, Covenant Health regions, etc.
- Main sites are UAH, Stollery, Kaye, Mazankowski, RAH, Glenrose, CCI

NACTRC Application – other items



To see a list of the projects in your Protocol Bank

NACTRC Application – other items



To see a list of the Legal documents or Operational Approvals for the studies in your Protocol Bank.

Other items

- Data Disclosure Agreement (DDA)
 - Formerly known as the Research Agreement (RA), or HIA Research Agreement
 - Required for studies that do not have contracts, that require AHS data access
 - Processed by the PRA (Provincial Research Administration team)
Research.administration@ahs.ca
 - When finalized, we are notified directly by the PRA
- E-Clinician Access
 - Submitted on your behalf by NACTRC. When uploading protocol, you will be asked if you need access.
 - Contact : ISOResearch@albertahealthservices.ca

One quick reminder: REMO access

1.6 Research Locations and Other Approvals

- 1.0 * List the locations of the proposed research, including recruitment activities. Provide name of institution, facility or organization, town, or province as applicable

University of Alberta Hospital (UAH) Movement Disorders Clinic,
Edmonton

Alberta Diabetes Institute (ADI), University of Alberta, Edmonton

Patients to be recruited from those already receiving medical care for Parkinson's Disease at the UAH and through the Parkinson's Disease Society, Edmonton Branch

- 2.0 * Indicate if the study will use or access facilities, programmes, resources, staff, students, specimens, patients or their records, at any of the sites affiliated with the following (select all that apply):

Alberta Health Services Institutions and Facilities

List all health care research sites/locations:

University of Alberta Hospital Movement Disorders Clinic, Edmonton

- Questions?
- Need to book a training session?
- Have additional questions?

Contact me at:

sheila.desarkar@ahs.ca

780-407-6041