

NACTRC LEGAL

CONTRACT

THIS AGREEMENT made this _____ day of _____, 20____
by _____
and between _____
and _____

**Contract Specialists
Tracy Mudri, Beth Hunter,
November 23, 2017**

WITNESSETH: That in consideration of _____
kept and performed on the part of _____
I. Said party of _____
_____ (First Party)
_____ (Second Party),
_____ covenants and agreement
_____ hereto, respectively as _____
_____ and agrees that _____

Introduction to the NACTRC Legal Team

- Contract Administration
 - Keshena Wilson
 - Pam Runyon
 - NACTRC.CONTRACTS@AHS.CA
- Contract Specialists
 - Tracy Mudri
 - Beth Hunter
 - NACTRC.LEGAL@AHS.CA
- Legal Counsel

Contract Administration

- Responsible for:
 - Initial Review of Submission
 - TOR (Terms of Reference)
 - Account Set-up
 - RBI Forms (Request for Banking Information)
 - W8-BEN-E
 - Following in up on outstanding OA's, status of ethics, etc
 - Status of Agreement once it has gone out for signature
 - General Administration Questions
 - Provide Administrative Approval including the fully executed agreement

Administrative Approval

Contract Specialist Role

- Developed to bridge the gap between Site & Legal Counsel, and Sponsor & Legal Counsel
- Main contact for Sponsors & Legal Counsel
- Initial review of ALL agreements uploaded
- Negotiate AME's, CDA's, mirrored agreements
- Weekly status updates

Contract Specialist Review

- Distribute agreements to others for review prior to sending to legal

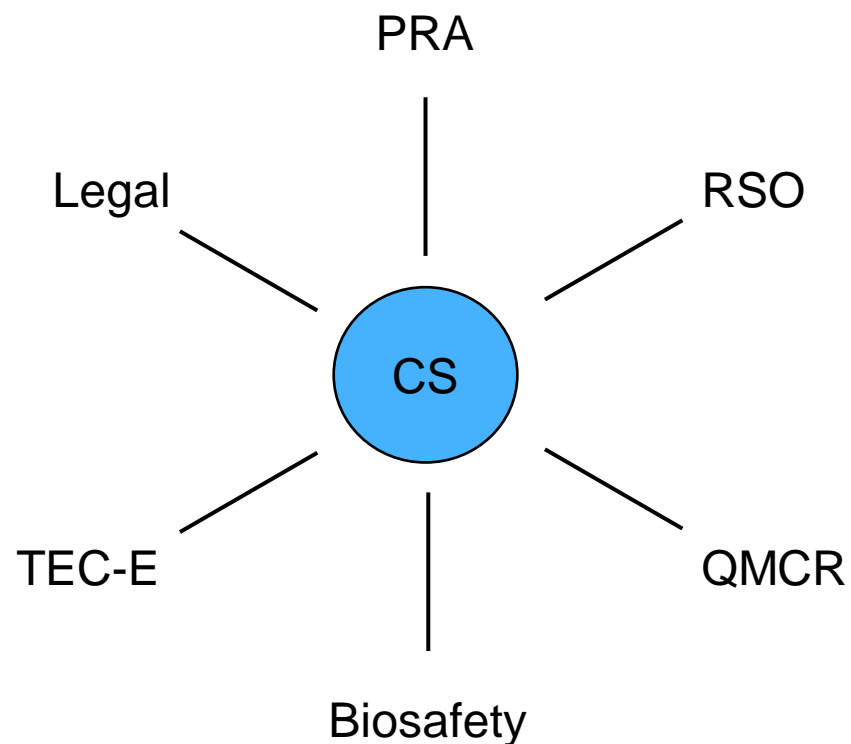
PRA – Data Elements

RSO – UA Account

QMCR – Investigator Initiated

Biosafety – Level 2 Pathogens

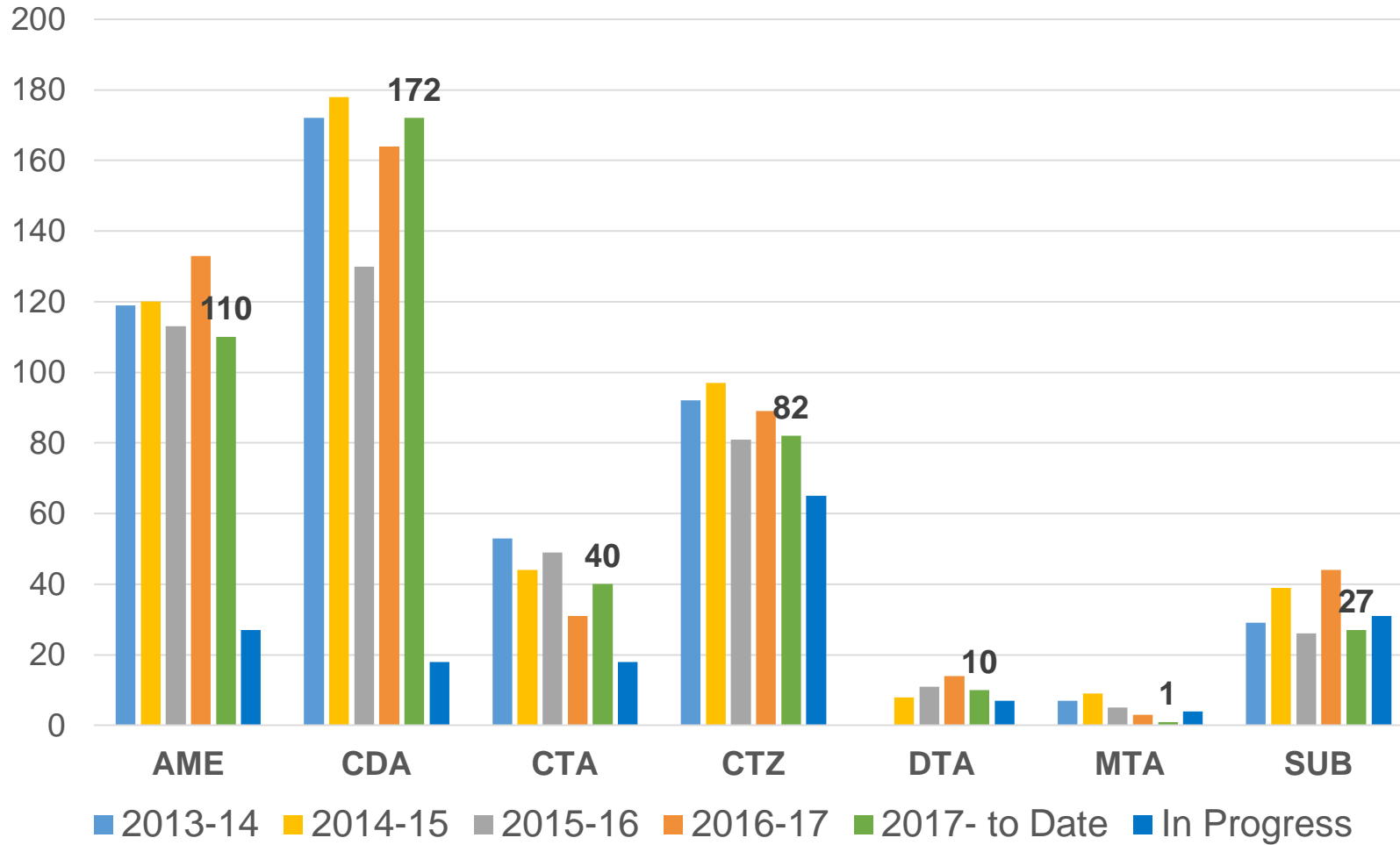
TEC-E – IP Implications



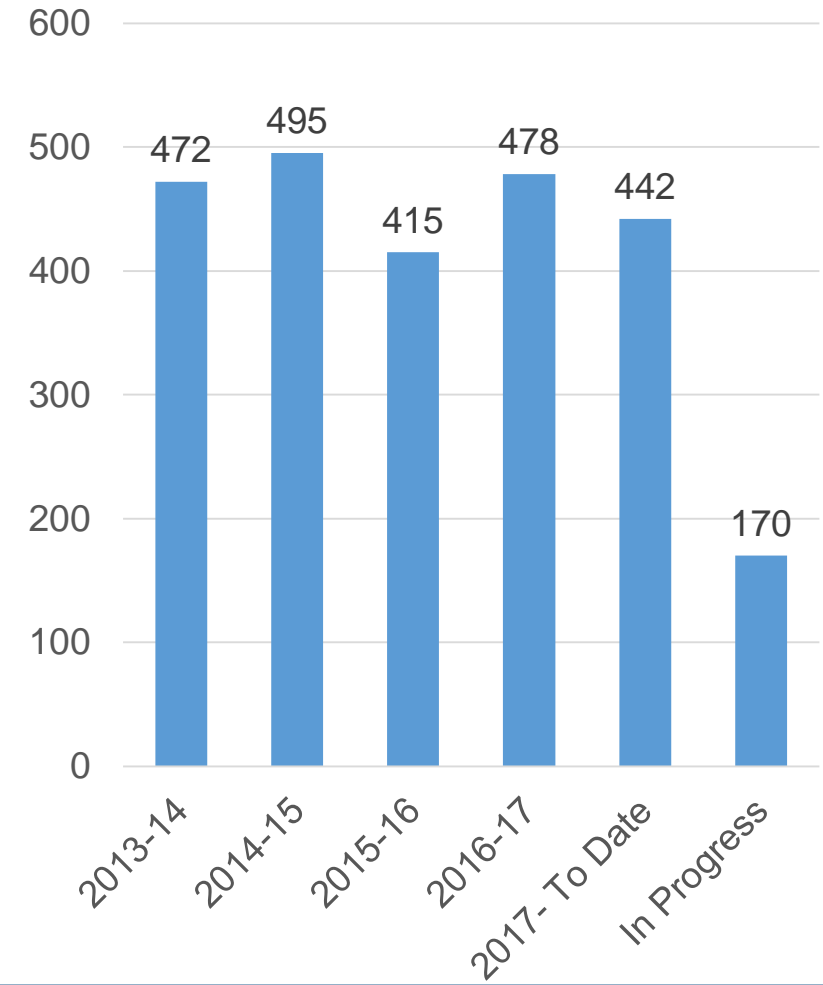
Legal Documents – What needs to be reviewed?

- CTA/Z – Clinical Trial Agreement
- CDA – Confidentiality Disclosure Agreement
- MTA/DTA – Material or Data Transfer Agreement
- SUB – Sub site or Inter-Institutional Agreement
- SUA – Start Up Agreement
- MOU – Memorandum of Understanding
- LOI – Letter of Indemnity
- AME – Amendment
- MCTA/SOW/WO – Master Agreement and Statement of Work or Work Order

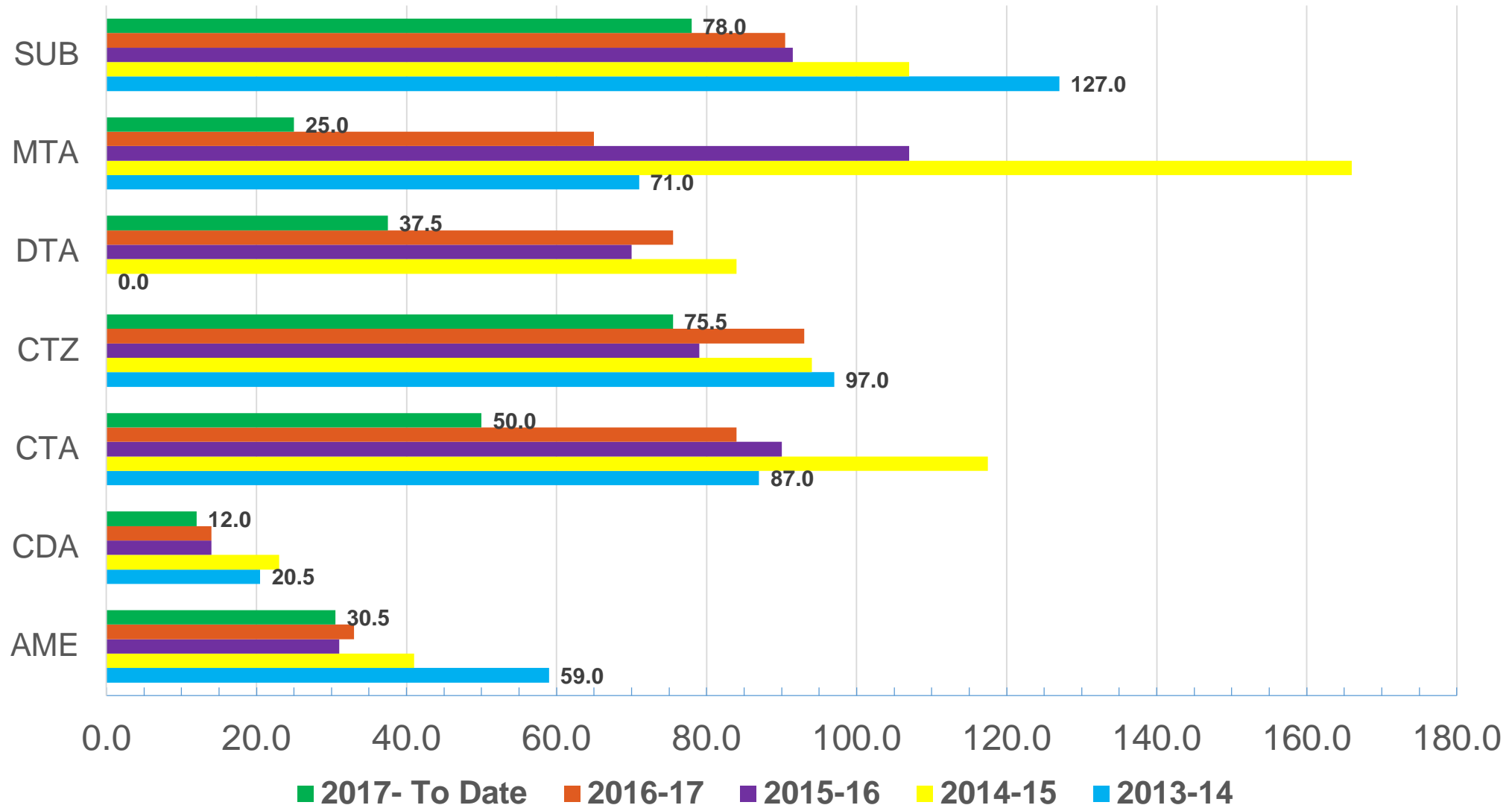
Number of Fully Executed Agreements



TOTAL # of FE Agreements Per Year



Turn Around Time (TAT) in days



How does the legal review process work?

- Documents are reviewed in the order that they are uploaded to the NACTRC online system
- Agreements **WILL NOT** be prioritized by planned SIV
(Study Initiation Visit)
- Upload the agreement as early as possible to ensure a timely review
 - Many factors can cause delays in review times including:
 - Increased submission rates
 - Sponsor response time
 - Site response times
 - Factors unique to the study



Requirements - General

- Protocol needs to be uploaded to the system first
- Agreement MUST be a editable word document (.doc, .docx)
- Sponsor/CRO Contact information
 - who is the AGREEMENT contact?

New Legal Document

Start	General	External Contacts	Finance Info	Save/Submit/Cancel	
ID	-			Study Coordinator	-
Document Type	Industry Contract NOT Including Final Protocol Budget			Protocol Number	-
PI	Michael Kolber			Protocol Acronym	-
Protocol Title	Medical Cannabinoids: An Overview of Physician Prescribing in Alberta				

* Sponsor Company Name

* Contact Name

* Contact Email

* Contact Phone

* Is there a CRO?



Who is the agreement/legal contact?
- This may be different than the study contact.

Previous

Next

Last Saved: -

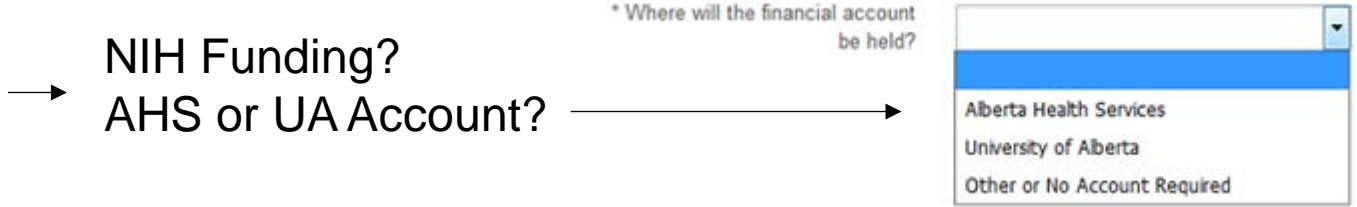
Requirements - Finance

- Finance information
 - Do you need an account? Will you be receiving funds?
 - Each study needs its own account
 - EFT (direct deposit/wire transfer) or Cheque
 - Does this information match what's in the agreement?
 - Ensure the contact information is accurate in this section

Document Type	Industry Contract NOT Including Final Protocol Budget	Protocol Number	-
PI	PI NAME	Protocol Acronym	-
Protocol Title	Protocol Title will be seen here		

* Will you be receiving any funding directly or indirectly from NIH (National Institutes of Health)?

* Where will the financial account be held?



Full mailing address where payments from sponsor / CRO are to be sent:

* PI Name

* Care of

* Address (line 1)

Address (line 2)

Address (line 3)

Address (line 4)

Address (line 5)

* Country

* Province/State

* Town/City

* Postal Code/Zip

* Will funds be paid by EFT (Electronic File Transfer) or Cheque? (Cheque is preferred)



Full mailing address where payments are to be sent

This information will be used in your agreement.
Please ensure accuracy.

Previous

Next

Requirements – Finance continued

- UA account?
 - Must provide a draft budget/payment terms for initial review
- Finalized Budgets – Must upload to the system
 - If no copy of the finalized budget is uploaded to the system, there will be a delay in sending the agreement out for signature collection
 - Budget provided by Site is compared to the one provided by Sponsor
 - Any discrepancies must be resolved before signature collection
 - Excel Spreadsheet – provide if possible
 - Used for AHS Finance review
 - Saves time in following up with Sponsor

PB99999: PI NAME (Department Info)

PROTOCOL TITLE

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

Edmonton Zone Admin Approval (AA)

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

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
ID55555	CTZ	Sent to Contract Specialist	15-Nov-2017	



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

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.

Operational Approvals (OAs)

ID	Site	Area	Status	Last Decision On
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[Download Site/Area List](#) [Submit New Operational Approval](#)

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**

New Legal Document

[Start](#)
[General](#)
[External Contacts](#)
[Finance Info](#)
[Save/Submit/Cancel](#)

ID	-	Study Coordinator	-
Document Type	-	Protocol Number	-
PI	PI Name	Protocol Acronym	-
Protocol Title	Protocol Title		

Document Type

▼

-
- Confidentiality Agreement
- Contract Amendment
- 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

[View Definitions](#)

[Next](#)

Last Saved: -

Requirements - Data Elements

SCHEDULE "X"

DATA ELEMENTS

Data Set	Description of Personal Health Information to be Disclosed for Research Purposes by AHS.
	Data elements as listed in the: [identify sources of data elements]

The data elements collected as a part of the clinical study and documented in any applicable case report forms or data capture tools to the extent that they exist on the records of patients who have been consented to participate in the study, may be disclosed to the local Alberta researcher under Section 54 of the Health Information Act of Alberta after the protocol has been approved by the local Research Ethics Board.

In the transfer of study data to the Coordinating Centre, reasonable efforts should be made, where possible, to de-identify any potentially identifying health information/data elements of study participants in accordance with [Alberta Health Services' Non-Identifying Health Information Standard](http://www.albertahealthservices.ca/about/Page210.aspx) (<http://www.albertahealthservices.ca/about/Page210.aspx>).



Requirements - Data Elements

- DTA/MTA/SUB
 - in order to avoid having to do a Data Disclosure Agreement (DDA) in addition to the DTA/MTA/SUB we incorporate a Data Elements Schedule
 - Helen Shannon – Provincial Research Administration (PRA)
 - Research.Administration@ahs.ca
 - PRA requires **eCRF's** in order to provide data schedule
- Data Elements must be received BEFORE an agreement can be finalized

Contact

- NACTRC.legal@ahs.ca
 - Tracy and Beth

- NACTRC.contract@ahs.ca
 - Keshena and Pam

THANK YOU – QUESTIONS?