Research in Connect Care

Research Overview Information Session

June 15, 2020

Alberta Health Services
Connect Care

The Connect Care Research Team

Research Triad

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CMIO:

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Connect Care Research Triad Leadership

Clinical Operations: Shelley Bannister

IT: Marcus Norman

CMIO: Leahann McElveen

AHS Research & Innovation Leadership

Marc Leduc, Sr Provincial Director

Epic

Eric Jansen, Research Application Manager

Ryan Nealon, Research Technical Support

Today's Topics

Review of study intake process and workflows

Review of key research workflows in Connect Care:

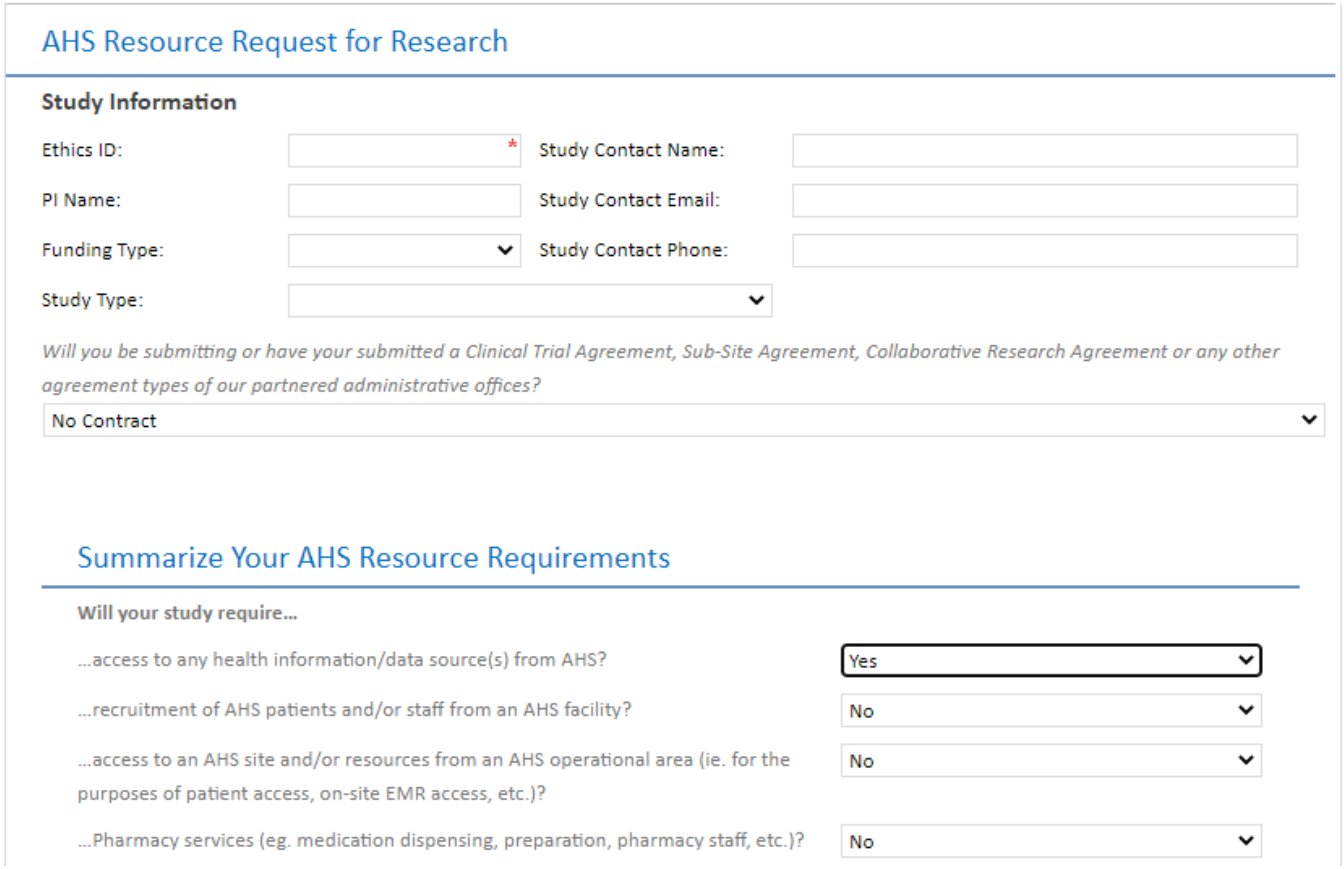
- Completing records
- Closing studies
- Charge review – reminders

Connect Care Access and Changes – How to Submit Requests

- In new or ongoing studies
- For staff who don't have research access to Connect Care
- For external Study Monitors
- To change scheduled CC training
- To change study details

Connect Care Access for New or Ongoing Studies

Processed through completion of Health System Access Questionnaire



AHS Resource Request for Research

Study Information

Ethics ID: *

PI Name:

Funding Type:

Study Type:

Study Contact Name:

Study Contact Email:

Study Contact Phone:

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

No Contract

Summarize Your AHS Resource Requirements

Will your study require…

…access to any health information/data source(s) from AHS? — Yes

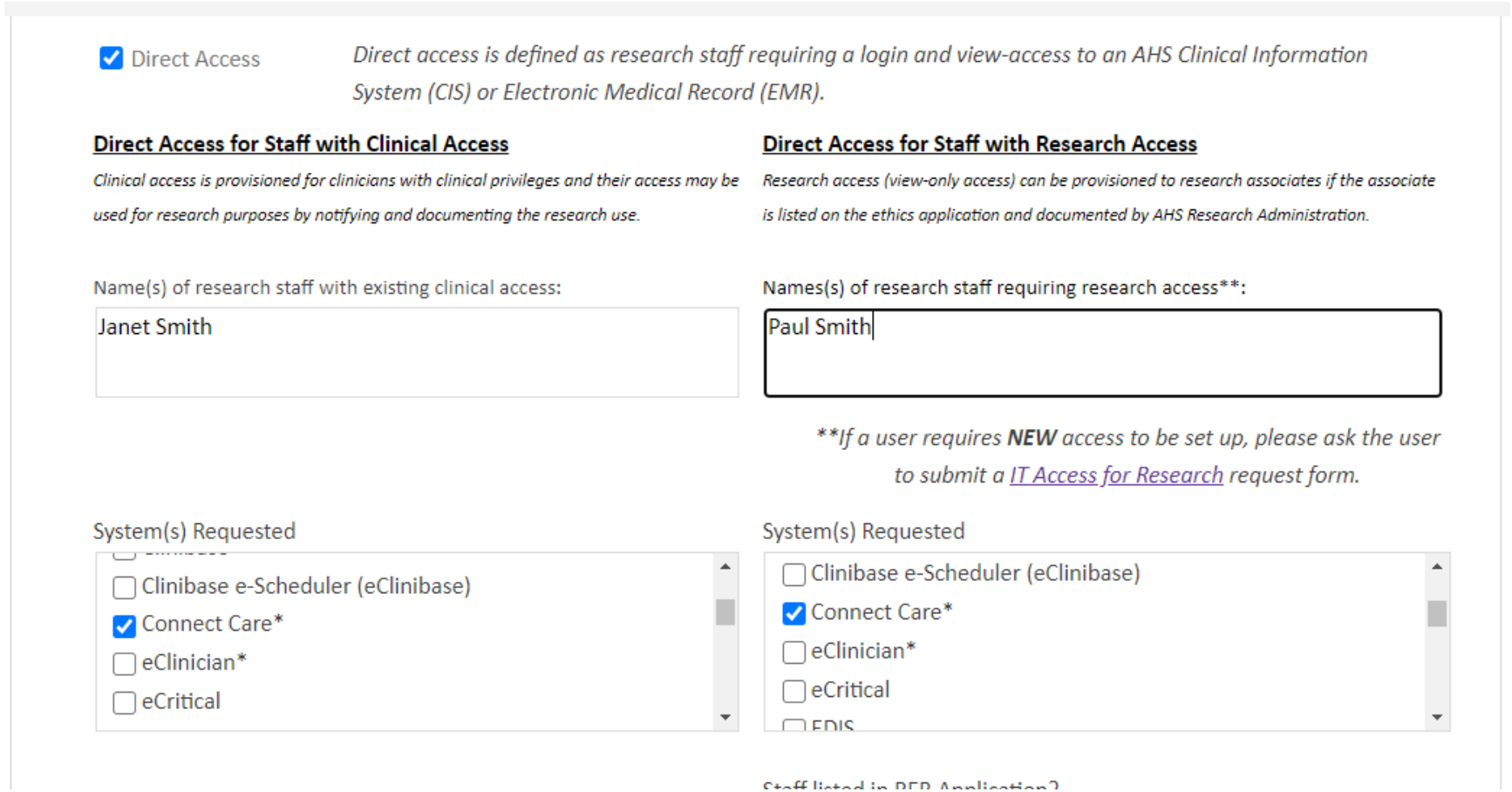
…recruitment of AHS patients and/or staff from an AHS facility? — No

…access to an AHS site and/or resources from an AHS operational area (ie. for the purposes of patient access, on-site EMR access, etc.)? — No

…Pharmacy services (eg. medication dispensing, preparation, pharmacy staff, etc.)? — No

Health System Access Questionnaire (continued)

https://extranet.ahsnet.ca/teams/AHSRA/PRA_Resources/PRA%20Pages/PRA%20Questionnaire.aspx



☑ Direct Access

Direct access is defined as research staff requiring a login and view-access to an AHS Clinical Information System (CIS) or Electronic Medical Record (EMR).

Direct Access for Staff with Clinical Access

Clinical access is provisioned for clinicians with clinical privileges and their access may be used for research purposes by notifying and documenting the research use.

Name(s) of research staff with existing clinical access:

Janet Smith

System(s) Requested

- ☐ Clinibase e-Scheduler (eClinibase)
- ☑ Connect Care*
- ☐ eClinician*
- ☐ eCritical

Direct Access for Staff with Research Access

Research access (view-only access) can be provisioned to research associates if the associate is listed on the ethics application and documented by AHS Research Administration.

Names(s) of research staff requiring research access**:

Paul Smith

***If a user requires **NEW** access to be set up, please ask the user to submit a IT Access for Research request form.*

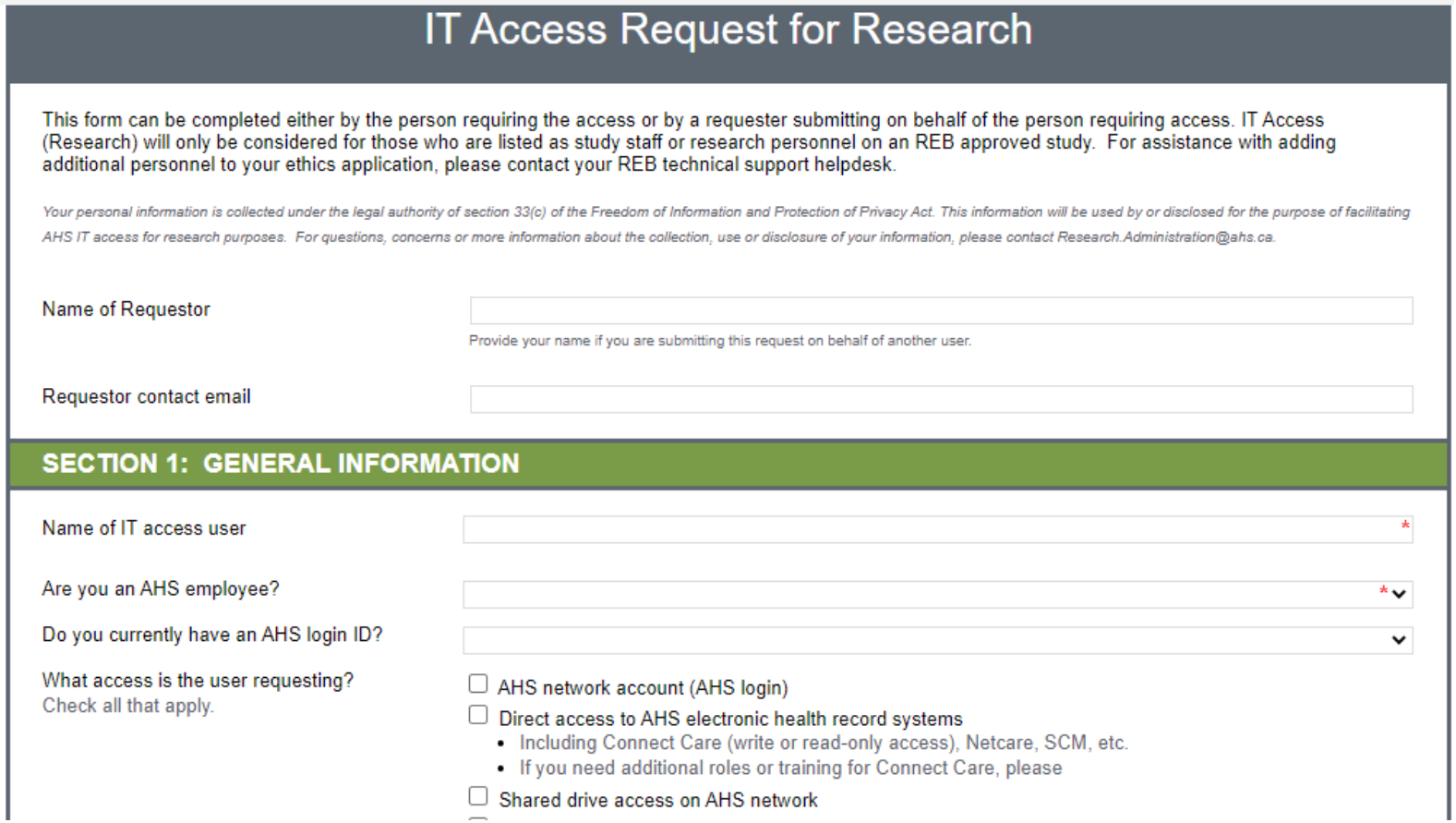
System(s) Requested

- ☐ Clinibase e-Scheduler (eClinibase)
- ☑ Connect Care*
- ☐ eClinician*
- ☐ eCritical
- ☐ EDIS

Adding Connect Care access for studies with current AHS Administrative Approval

Contact the Health System Access (HSA) Advisor who is listed on the Administrative Approval form

Connect Care Access for Research Staff



IT Access Request for Research

This form can be completed either by the person requiring the access or by a requester submitting on behalf of the person requiring access. IT Access (Research) will only be considered for those who are listed as study staff or research personnel on an REB approved study. For assistance with adding additional personnel to your ethics application, please contact your REB technical support helpdesk.

Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of facilitating AHS IT access for research purposes. For questions, concerns or more information about the collection, use or disclosure of your information, please contact Research.Administration@ahs.ca.

Name of Requestor

Provide your name if you are submitting this request on behalf of another user.

Requestor contact email

SECTION 1: GENERAL INFORMATION

Name of IT access user *

Are you an AHS employee? *

Do you currently have an AHS login ID?

What access is the user requesting?
Check all that apply.

- ☐ AHS network account (AHS login)
- ☐ Direct access to AHS electronic health record systems
  - Including Connect Care (write or read-only access), Netcare, SCM, etc.
  - If you need additional roles or training for Connect Care, please
- ☐ Shared drive access on AHS network

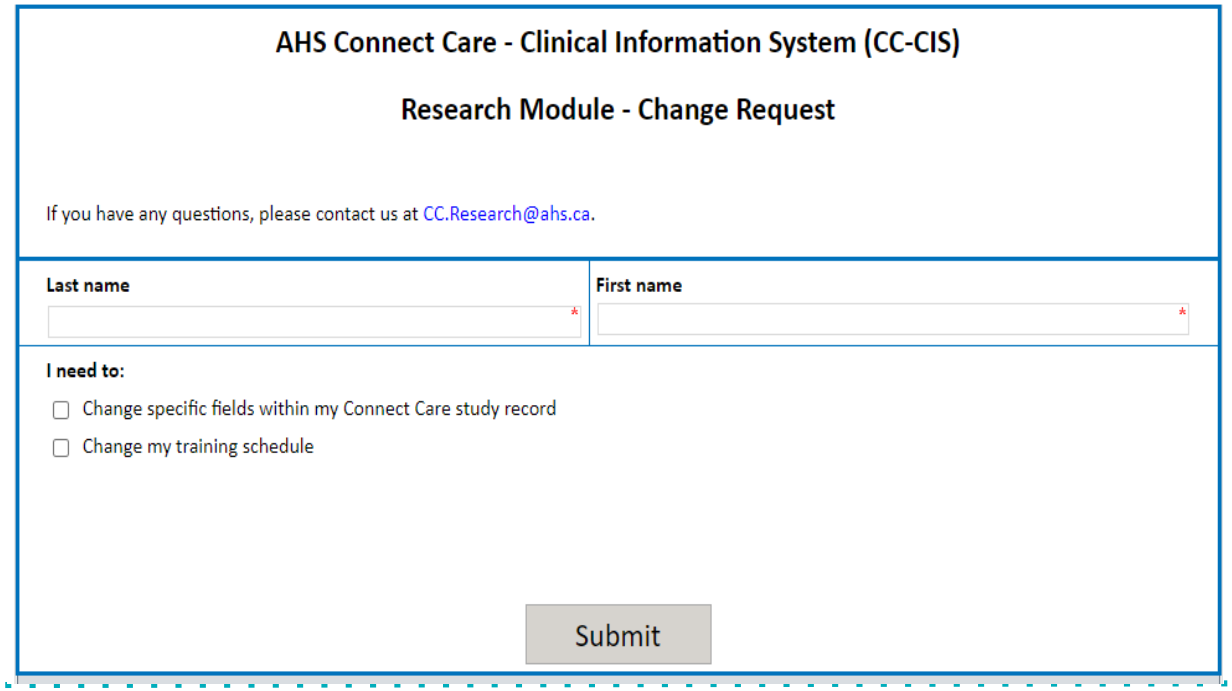
Processed through completion of Health System Access IT access for research form (http://bit.ly/1NTJabJ)

This form is also used to request access for external study monitors

Connect Care Access – to make changes to scheduled CC training or to details in the CC Record

Processed through completion of Connect Care User Change Request Form

https://extranet.ahsnet.ca/teams/AHSRA/ITAccess/SitePages/CC_User_Change_Request.aspx



IT Access for Research Information Page

https://extranet.ahsnet.ca/teams/AHSRA/ITAccess/SitePages/CC%20Research%20Resources.aspx

Completing your Study Record Information in Connect Care

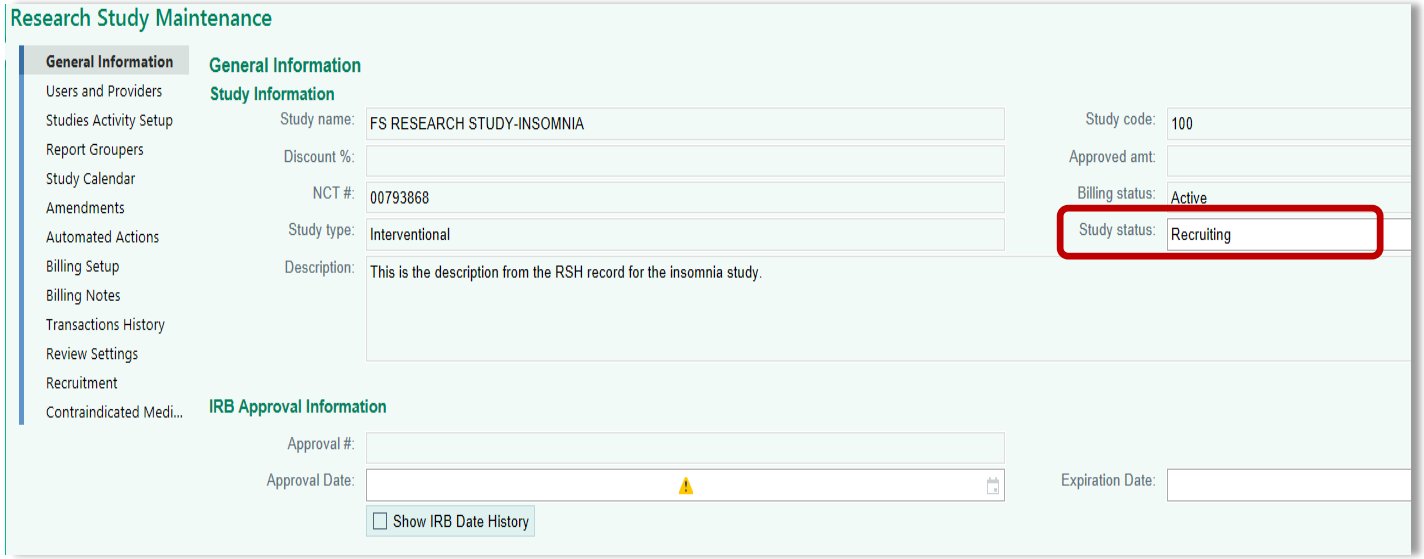
What: Applicable information related to the research study is properly entered and maintained in the CIS.

Why:

- ❑ Enables the Research in-system workflows
- ❑ Patient Safety
- ❑ Visibility
- ❑ Integration between research and clinical teams

Who:

- ❑ Health System Access (HSA)
- ❑ Study teams



What information am I responsible for maintaining?

What if I can't edit the information myself?
Submit a change request to HSA!

Following administrative approval and access provisioning to the research record in CIS, the research team is responsible for entering and maintaining (updating) all the applicable study information in the CIS.

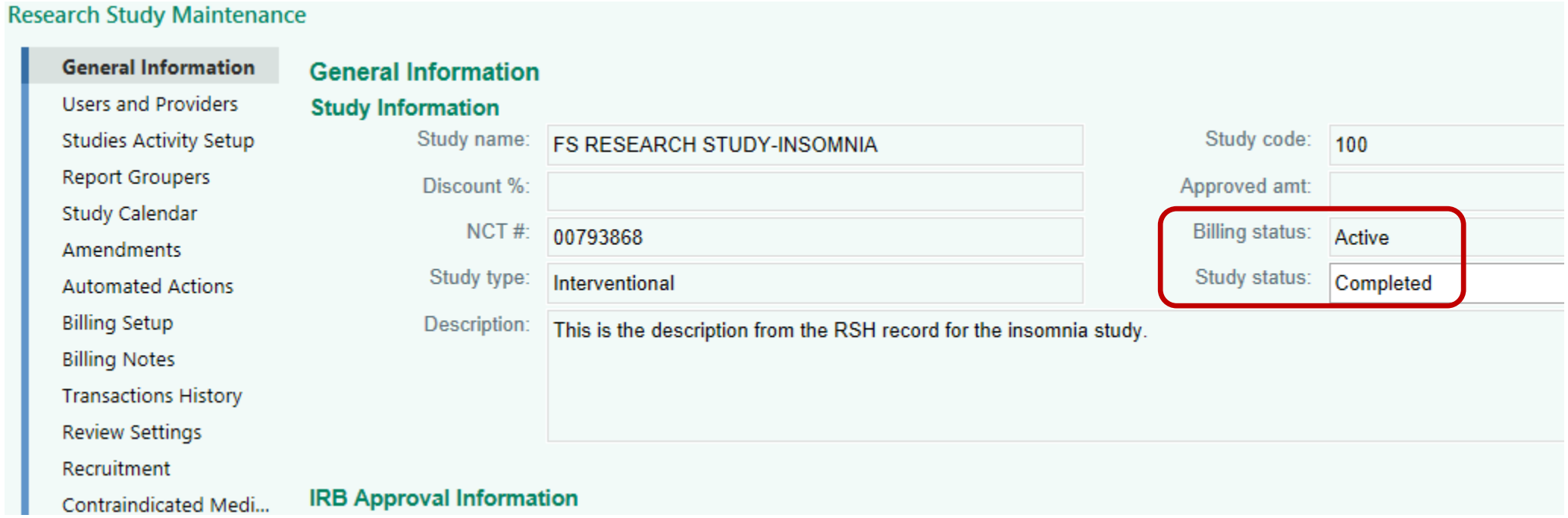
Examples of information included in the research record that study teams will have view-only access to:

- Study Name & Code
- Study Type & Phase
- Study & Billing Status
- NCT #
- Study Team Info
- Disease Area
- Study Description
- Billing Information

Examples of information that will require entry by research teams:

- Protocol Association
- Update Study Status
- IRB (REB) Approval
- Study Branches/Arms
- AE Term Setting
- IRB (REB) Expiration
- Contra-Indicated Meds
- Protocol Amendments

Closing your Study Record Information in Connect Care



Completing Patient Study Record Information in Connect Care

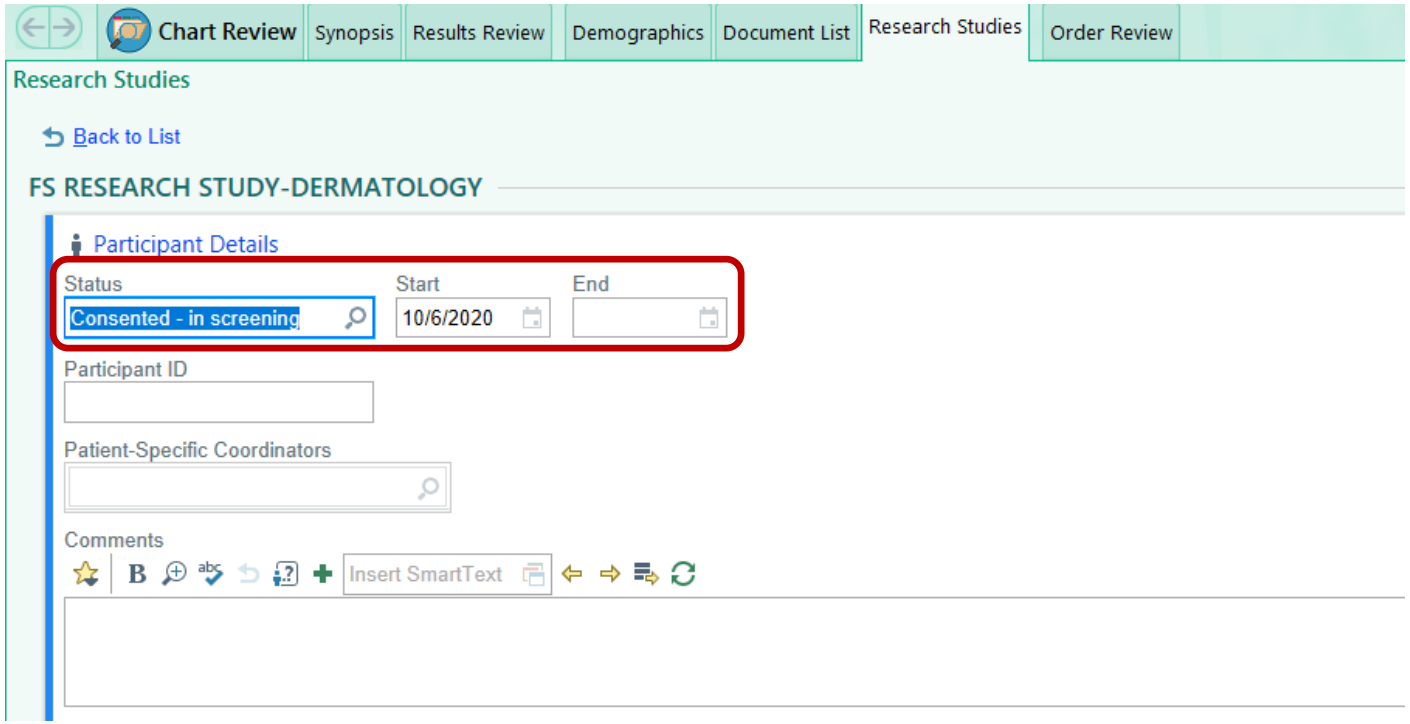
What: Study patients are linked to the respective research study, their recruitment status is up to date and ICFs are scanned into their chart.

Why:

- ❑ Patient Safety
- ❑ Visibility
- ❑ Integration between research and clinical teams
- ❑ Study integrity

Who:

- ❑ Study teams



How are Charges and Activities tracked in system?

- Once the orders for tests and medications (Lab, DI and Pharmacy) have been properly entered, charges (costs associated with the activity) will submitted in the system (dropped charges).

- The research teams must review all the charges/activities associated with the respective study.

- All charges/activities must be marked as either standard of care (SOC) or research. Please note that all research related charges/activities must be associated with the respective research study in the CIS

Why is Charge Review important and how do I complete it?

What happens to my patients' billing when I do not complete the charge review, and why is this so important to complete?

Every patient that is linked to a study MUST undergo charge review, and each charge related to a service performed on your study patient must be associated with one of three groups:

- Study-Related – Bill to Study
- Non-Study Charges (standard of care)
- Study-Related – Bill to Patient/Insurance (i.e. services offered "in kind" or free of charge).

- **When a patient is linked to a research study ALL CHARGES including standard of care are held for review** until the research coordinator has marked the research charge review as "Mark Account as Reviewed".

- **Charges quickly build up and any studies holding up large sums in charge accounts will be flagged as not up to date, especially if your patient is admitted.**

- **Review the "Research Charge Review" guide on your Research Coordinator Learning Home Dashboard** for more information and steps to performing charge review.

Take away messages

- Ensure to review and learn the HSA IT access webpage, and to complete the correct HSA form according to your request. If you have any questions, please email research.administration@ahs.ca

- Maintain your study record information and keep it current in CC (especially the study status) and notify HSA of your study completion by emailing research.administration@ahs.ca

- Enter and maintain the recruitment status of each study patient including the start and end dates. And upload the ICF to the patient's chart.

- Complete the charge review workflow for your studies.

Support and Resources

Support Available

- Training Manuals, User Guides, FAQs

Additional Resources

- Clinical Inquiry Newsletter
- Connect Care updates (email)
- CIS Procedure and Quick Start Guide
- Recorded and upcoming webinars
- HSA website https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx

Questions?

We are here to answer your questions.

Contact Connect Care:

CC.Research@ahs.ca

Alberta Health Services
Connect Care

Questions & Answers Summary

Question 1: If we have a research assistant who may not be an AHS employee, but coming in as a contractor for a few months, can we request permission for Connect Care access?

A: Yes, it may be possible to provide temporary access to contractors, but the request would require an assessment. Please submit the IT access request form (http://bit.ly/1NTJabJ) to have the request reviewed.

Question 2: Can we build cohort specific surveys into Connect Care?

A: This may be possible on a project-by-project basis. Functionality within system could allow for custom questionnaire generation and is currently under consideration as a future optimization feature and service. It is not currently available.

Question 3: If a patient has completed the study, however the study data was not verified by a CRA due to current COVID-19 precautions, will the data still be available for monitor remote access review?

A: Patient data will still be available until the study itself is closed. The CRA will still be able to view the data in the patient chart if this chart is released to the monitor. A study end date should be recorded for the patient in system, based on the date when the patient completed their participation in the study, not based on the date the study was completed as a whole.

Questions & Answers (cont'd)

Question 4: If there is a study drug that needs to be added into Connect Care, or needs to be corrected, do I submit a ticket to IT or should I contact the Connect Care research team?

A: For new study and INV drug builds, there is a form available from HSA to submit a request for a new study drug ERX. You will be provided this information during your study approvals performed by HSA. For corrections to an existing drug build, open an IT ticket using the Connect Care IT ticketing system, and choose "X" as the application team. STUDY MEDICATION SUBMISSION FORM (complete one for each medication): http://wspharmapp01/NSD/Default.aspx

Request to change/update/delete an INV Medication Record in Connect Care

To make any changes to or delete an existing INV Medication Record, please open an IT Ticket (vFire ticket) to AHS Pharmacy at https://insite.albertahealthservices.ca/cis/Page23730.aspx .

- Select the option " I Have an Issue Related to How Connect Care Supports My Documentation, Orders, Decisions or Practice Improvement";
- Enter your personal information including the best number to reach you at;
- Select the Clinical Area as "Pharmacy"
- Select the Patient Context as "Any".
- Select the Connect Care Department Name as the AHS Pharmacy closest to the AHS department where you see your research patients;

Questions & Answers (cont'd)

Request to change/update/delete an INV Medication Record in Connect Care – cont'd

- Under issue, enter "Update or Delete INV Med Record";
- Under issue description, enter the following information:
  - Your department name
  - Medication name as it appears in Connect Care (full name)
  - Medication strength and form
  - Include the medication record # (if known)
  - Study name
  - The requested change (if you need to update the name, please type it out how it should look like)
  - The order set name if applicable

- Include screenshots of the problems encountered
- If you do need to provide patient information to resolve the issue, please limit it to the Medical Record Number

You will receive an email confirming your ticket has been submitted and whenever it has been resolved.

Questions & Answers (cont'd)

Question 5a: I remember hearing at one point that Connect Care would be able to help identify potential participants. Is that functionality up and running?

A: It is possible to create and use reports to find patients in Connect Care who qualify for your study, if you have ethics approval with consent to review patient charts for this purpose. If you do have ethics approval to review patient charts prior to patient consent during enrolment, you can use these reports and create your own lists. Track boards, status boards and patient lists (handy for inpatient settings) are available tools to identify patients in inpatient settings. Watch for future webinars focused on this subject. If you have a specific use case, please submit it to cc.research@ahs.ca. In terms of research coordinators flagging patients in system as the study status 'identified' or 'interested', at this time, it is not recommended that RSCs link patients to a study (or mark their pre-enrolment status) until an informed patient consent is signed. However, the patient's clinical care team can link a patient to a study and mark them as interested after confirming with the patient through conversation.

Questions & Answers (cont'd)

Question 5b: Are ADT events for enrolled study patients still being sent to the study teams?

A: ADT event notifications will be sent as an In-Basket message to the PI, Coordinators and Nurses listed on the Users and Providers form in the Study Record, unless the notifications have been suppressed upon request by the Study Team to HSA.

Question 5c: If my only research associated non-SOC task is a research kit, will I never have research charges to review? The past 10 patients we have enrolled over the last three months, always tells me I have 0$ research charges to review.

A: We suggest that you not focus on the dollar amount; charges in system are being used as activity tracking functionality, to understand and track SOC vs research charges and activities. While there may not be a dollar amount assigned, there is still a requirement to review and release that charge. It remains very important that study teams review their billing reports so that SOC charges are not held up in system where it will affect downstream process.

Questions & Answers (cont'd)

Question 6a: Is there still work being done 'behind the scenes' to address issues with research billing review, to describe each charge and make it less difficult to figure out? This relates to the challenges that research teams are encountering when trying to figure out the research related activity and its respective charge. For example, I have never seen 'Research Kit' as a charge; sometimes we see multiple, duplicate charges and 10 of them may be called the same thing. As another example, specimen collection shouldn't always be charged when using certain areas.

A: Work is in progress to clarify the relationship between research charges and activities to enable more intuitive 'matching' with your orders. More information on charge review will be developed and shared when this work is complete and we have new information. In general, when something is ordered in system, a corresponding charge will also display in system. There may be multiple charges associated with one order, and service areas may add charges associated with a particular order, as needed. Some of these are activity charges, and some of them may reflect activities tracked by the service area or by the hospital. They will not necessarily result in a 'charge' being billed to a study.

Questions & Answers (cont'd)

Question 6b: Can each discipline input charges? For example, pharmacy may bill a study for work related to applying amendments, etc.

A: If the order is linked to the research study, and there is a corresponding charge dropped in the system, the charge will also be associated to that study. There is a difference between patient specific charges and study set-up / study applied charges. Study fees, such as start-up related activities for example, are managed differently from patient specific charges. Overall study applied charges are managed outside of the Connect Care system, and are continuing to use existing processes.

Question 7: Sometimes "clinic collect" doesn't show up when I create a research kit Why is that?

A: Orders for inpatient labs look and work differently than outpatient orders. Inpatient orders should show 'lab collect' or 'unit to collect' as options. If you continue to experience this issue, please take a screen shot and submit as an IT ticket marking "research" as the corresponding IT team to address the ticket.

Note for reference:

Health System Access IT Access for Research page:
https://extranet.ahsnet.ca/teams/AHSRA/ITAccess/SitePages/CC%20Research%20Resources.aspx