



Bottom Line

Connect Care provides a powerful clinical information system (CIS) for all who work with Alberta Health Services (AHS) to care for Albertans. Together, CIS users can leverage advanced documentation, communication and care management tools to decrease information burdens while increasing the impact of health information. The new CIS brings many research functionalities that enables a more informed and seamless process for both research and clinical operations teams when performing research related tasks by providing integrated workflows. *Charting etiquette is about the digital manners that help information creators and consumers help one another.*

This document describes the minimal use and charting etiquette expected from research teams when conducting **REB approved in-system research studies*** in AHS facilities and /or using AHS resources.

These are the key topics that enable good charting etiquette.

Study Information Management	Documentation of the research study information in the appropriate degree of detail and location to optimize the ability of other members of the research and care teams to access study related information that is relevant to the patient care.
Study Status Management	Documentation and maintenance the current status of all research studies entered in the CIS.
Patient Association & Recruitment Management	Documentation and maintenance of patient recruitment status for research studies entered in the CIS.
Scheduling Management	Documentation and tracking of study related visits in the CIS.
Documentation, Safety Reporting (AEs &SAEs) & Ordering Management	Documentation of study-related orders and the clinically relevant information in the appropriate degree of detail and location to optimize the ability of other members of the care team to provide best possible care.
Service Charge Management	Documentation and review of all charges incurred through the use of AHS services.

Individuals can self-monitor compliance with all of the above norms. Anonymized information about group compliance will be provided to user groups, area councils, specialty workgroups and quality councils.

***In-system research studies:** These are clinical research projects that meet at least one of the following criteria:

- Is an interventional trial or device study
- Includes research-specific visits that will be scheduled in the CIS
- Requires the use of recruitment tools, or research study-specific order entry or documentation
- Requires release of information to outside study monitors
- Requires notifications to study coordinators regarding Emergency Department (ED) arrivals or admissions
- Incorporates billable items (i.e. observational studies with labs or other testing)



CIS Charting Etiquette Norms

Norms

The Connect Care clinical information system (CIS) serves all who provide care where Connect Care is the record of care. Charting etiquette is about how Connect Care users help one another to increase the impact and decrease the burden of documentation.

Charting etiquette relates to professionalism and accountability. Our expectations of one another, and the digital norms that express those expectations, habituate us to good documentation practices.

Norms evolve as we adapt to Connect Care and learn how to use the CIS to best advantage. Accordingly, this charting etiquette norm will evolve in response to new opportunities, needs and challenges.

Principles

Charting norms resonates with [Connect Care Charting Principles](#), which highlight the importance of collaborative, care-centric, comprehensive, current, credible, credited, curated and chronicled clinical charting.

The principles, in turn, inform a [Clinical Documentation Framework](#) which categorizes charting functions, explains documentation processes, defines best practices and defines attributes that can be measured.

Objectives

This document intends to guide research teams on the use and maintenance of patient record in the CIS by providing practical recommendations regarding 'who' should document 'what' and 'where'.

Compacts

The [Connect Care Clinical Information Sharing Approach](#) (CISA) grounds minimum use and charting norms. CISA offers a principled approach to information stewardship that is patient and family-centric, improvement oriented, regulation-compliant, pragmatic and safe. CISA includes a [User Compact](#) affirming expectations and accountabilities between AHS and clinicians, including responsibility for the completeness and quality of Connect Care documentation.

Policy

AHS has organizational accountability for standards-compliant clinical documentation. Relevant policies and procedures include [Documentation Principles](#) and a [Documentation Process](#) that must be followed by all health care providers. These policies resonate with charting norms.

Applicability

Connect Care charting etiquette guidelines apply to all in-system research teams that are conducting research studies in AHS facilities and/or using AHS resources.

Charting etiquette guidelines will evolve as more research functionalities in Connect Care become available, the use increases and opportunities associated with shared and exception documentation become known.

Accountability

The provincial Clinical Documentation Committee, and its workgroups, oversee development, monitoring and optimization of Connect Care Charting Etiquette norms.



Charting Principles

The following principles inform Connect Care Charting Etiquette Norms.

Connect Care clinical documentation will be:

1. **Collaborative**
with all health care providers sharing responsibility for the quality, credibility and usefulness of the Connect Care health record while respecting the contributions of one another.
2. **Care-Centric**
enabling best possible health care and outcomes while minimizing negative impacts of secondary purposes, such as administrative, analytic and investigative.
3. **Comprehensive**
through capture, to the right chart area using the right tools, of all information supporting decision-making where Connect Care is the record of care.
4. **Current**
with timely entries that allow the entire health care team to align with current plans.
5. **Credible**
drawing from primary sources, validating accuracy with patients, and correcting erroneous information.
6. **Credited**
appropriately attributing external and internal sources, noting when others' documentation is updated, modified or copied.
7. **Curated**
balancing recording of new observations with refining of enduring observations.
8. **Chronicled**
telling the patient's story in a way that preserves the narrative while exposing important developments.

Organizational Drivers for Research

1. **Enhance Patient Safety** by flagging patient records with their participation in research studies.
1. **Integrate Inquiry & Research into Operations** by creating processes and workflows to perform, track, and report on inquiry and research [using AHS resources]. In supporting this function, the CIS will:
 - Enable inquiry by training AHS staff and researchers to use tools and workflows that allow them to 'ask questions of what we do'
 - Enhance recruitment with tools and functionalities that will increase opportunities for Albertans to know about and participate in research
 - Provide reporting templates that will help research teams, research-associated managers and monitors to manage and oversee research studies
 - Incorporate Financial Services that facilitate cost recovery for services (i.e. Lab, DI, Pharmacy, Medical Records)
 - Enable study administration and research record creation



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Study Information Management

Minimum Use

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
- Billing Status
- NCT #
- Study Team Info
- Disease Area
- Study Description
- Billing Information

Examples of information that will require entry by research teams:

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

What is it?

Ensuring that all the applicable and/or relevant information related to the research study is properly entered and maintained in the CIS.

What is applicable and/or relevant study related information for Connect Care?

Information is study related if it:

- Impacts the patient care and safety inside and outside the study
- Impacts the workflows of other AHS and University teams using the CIS
- Brings visibility and transparency related to the patient's health journey in the AHS healthcare system

Why does it matter?

Creating a research record with the above information enables research specific Connect Care functionality. It will also increase visibility to research and enable for better integration between research and clinical workflows.

Documentation of the research related information will allow other teams in AHS (research and clinical) to access important information that could impact the patient care, the continued participation of the patient in the study, and/or study integrity.

Clinical care teams will be able to contact appropriate research personnel, if and when they need to discuss the research study itself or the patient's participation in it.

Who is responsible?

For information entered *prior* to CIS access being granted to the research team:

The Health System Access (HSA) team will be responsible for the completion and oversight of this step for all research studies.

For information entered *after* CIS access has been granted to the research team:

The research teams will be responsible for entering and maintaining (updating) the information related to their own research studies.

How is it done?

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in you Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care.



Study Status Management

Minimum Use

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

Examples of study statuses:

- Recruiting
- Active not recruiting
- Suspended
- Terminated
- Completed
- Closed recruitment

What is it?

Ensuring that the study status in the CIS accurately reflects the current study recruitment stage.

Why does it matter?

This information will allow members of the care and research teams to be up to date regarding which studies are actively recruiting. Having this information available may enhance study recruitment, as enrolling research studies and other pertinent information will be more visible to CIS users.

Study teams will only have research-access to the study record in the CIS and other required data repositories for as long as the study is active (not completed, closed or terminated). The maintenance of the study status will serve as check point for the HSA team and ensure proper access continuance.

Who is responsible?

Each research team will be responsible for maintaining the status information for its own research studies.

How is it done?

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in you Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care.



Patient Association & Recruitment Management

Minimum Use

Following the study and status set up into the CIS, the research team must link all the patients who are participating in the research study to the respective research record.

The research team must maintain the recruitment status of each of the research study patients. Examples of patient recruitment statuses:

- Screened
- Disqualified
- Consented-in Screening
- Enrolled
- Declined
- On Follow-up
- On Treatment
- Withdrawn
- Completed

The research team is expected to scan a copy of the initial and any updated versions of the signed Informed Consent Forms (ICFs) into the patients' chart, including sub-studies ICFs for all in-scope studies. Assent forms should be compiled with the main ICF and uploaded as one document. The sub-study or other related ICFs should be scanned and uploaded separately.

What is it?

Ensuring the study patients are accurately flagged as being part of the respective research study and that their recruitment status is maintained up to date.

Why does it matter?

Properly linking the patient to the respective study and scanning the ICF into the patient record will allow clinical care teams to know when a patient is participating in a study and all the information related to their participation including, but not limited to, the type of study, disease area, possible side effects and investigation medication/device as applicable. This knowledge will impact the treatment provided to that patient whenever they are being seen for a non-study visit in an AHS facility. The care team will know who they contact should they have questions related to, for example, contra-indicated treatments, medication interaction or any action that would lead to patient disqualification in the research study.

Following the above instructions for ICF scanning will ensure protection to patient privacy, consistent and proper in-system filing, and easy access to the desired document.

Research teams will know if a patient is already enrolled in a research study, which will decrease the chances of having patients being inappropriately involved in more than one study at the same time.

CIS users will be able to pull reports that will include all of your study patients and become aware of anytime your patients have visited another AHS facility for a non-study related visit. You will have access to the full chart and all the information you need to properly report, for example, an adverse event (AE).

All these steps will enhance patient safety.

Who is responsible?

The research teams will be responsible for maintaining the recruitment status information for all patients participating in their study.

How is it done?



Study patient linkage and recruitment status management

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in your Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care

Informed Consent Form Scanning

Research teams may use any equipment (AHS, University or personal) to scan the ICFs as long as they follow the instructions below:

IN THE CLINIC or CLINICAL AREA device: Scan the document (using an AHS scanner available in an AHS clinical area) to the patient record using the Scanning workflow.

OUTSIDE AHS (University or personal device): Use their own scanning device, converting the document to a .pdf and uploading to the patient record using the Upload workflow. Storing of these digital records locally must be compliant with all relevant AHS Information Management Policies and confidentiality agreements (i.e. it is personal health information, keep it private, safe and secure).

HIM ASSISTANCE: Walk to your local HIM office and bring the paper copies of the consent letters in an envelope. Note on the envelope "Research consents, paper copies must be returned to research team & Research team contact info (name/phone number)"

NAMING CONVENTION:

Document Type: Research Consent

Document name: The name must include <document type (ICF)>Type of ICF (Main, Sub, Gen)> <study identifier (Ethics ID)> and <version (v1.0, v10,v2) > Max.: 39 characters

Examples:

- ICF_Main_PRO000XXXXX_V1
- ICF_Main_HREBA.CC-18-XXXX_V2
- ICF_Main_REB15-XXXX_V10

Other abbreviations (examples):

- ICF_Supp: supplementary ICFs
- ICF_Sub: sub-study ICFs
- ICF_Withdraw: Withdraw ICFs
- ICF_Add: addendum ICFs
- ICF_Gen: genetic testing ICFs



Scheduling Management

Minimum Use	All research related visits must be scheduled within the CIS.
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What is it?

Ensuring that all encounters and visits related to research are done in system and are properly associated (linked) to the respective research study.

Why does it matter?

In-system scheduling allows for both research and clinical care teams to know when the research patients are expected to have a research related visit, facilitating proper clinical space, timing and workflows.

Being aware of when the next study related visit will occur may impact the treatment provided to the patient during a non-study-related visit. It may help the clinical team to prioritize communications or interventions that could otherwise impact the patient's participation in the study. This will minimize the risk of applying medications or treatments that could interfere with the research study.

All these activities will become more visible for research and operations.

Who is responsible?

Each study team will have their own workflow for scheduling research visits and will assign their own accountabilities. The scheduling workflow will be determined by the area or department in where the research study is being conducted. Schedulers may be members of the research teams or staff in the ambulatory programs.

How is it done?

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in your Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care. Please note 'Schejstration' is not a research specific workflow, therefore the Connect Care Support Team for Research is not responsible for the development or maintenance of these resources.



Documentation, Safety Reporting (AEs & SAEs) & Ordering Management

Minimum Use

Clinical staff working on the research teams (i.e. Investigators, Research Nurse) are responsible for entering all clinically relevant research related information in the CIS as progress notes.

It is recommended Adverse Events (AEs) to be entered in the designated AE field and follow the AE reporting procedure.

The ordering of tests and or medications must be done in-system.

What is it?

Ensuring that all test and medication ordering done during a research study visit is completed in-system and all clinically relevant information is available to the care teams.

Progress note: Clinically significant information only. This information should be made available to care teams outside the study team. E.g. patient has experienced heartburn related to study medication.

Research note: Information that is relevant only to the study and which is not clinically relevant. E.g. please note this visit is outside the study protocol visit window. Do not include any proprietary information.

Medication Administration: All medication administered inside an AHS care setting must have its administration documented in the Medication Administration Record (MAR) by user who administered the medication. E.g. INV Med administered by a Research Coordinator in clinic.

Why does it matter?

Sharing clinically relevant information including the meds (INV/SOC) provided/administered to patients and the AEs in the CIS will allow the care teams to be aware of that patient's full healthcare journey whenever they present to an AHS facility for a non-study related visit. Clinical care teams will be able to follow up on the care initiated by the study team and/or start a treatment when applicable. The information in the chart will also help future research studies as it will allow for a more complete medical history.

When orders are placed in-system, the charge related to that order is dropped in the CIS and the information related to the tests and medications ordered will become part of the patient record, therefore visible to both research and clinical care teams. The charge associated with the ordering will become visible to all pertinent groups including research teams, AHS service areas and AHS Finance.

All these steps will enhance patient safety.

Who is responsible?

The research team will be responsible for linking the visits and reporting the AEs.

The user administering the INV or SOC med must document the administration in the MAR.

The research team will also be responsible for sending the progress note information to the appropriate care team personnel who will then enter the information into the progress note field.

The research team is responsible for queue up ordering requests and the appropriate member of the care team (signatory) will sign off and complete the request.

How is it done?

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in you Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care. Please note 'Progress Notes' is not a research specific workflow, therefore the Connect Care Support Team for Research is not responsible for the development or maintenance of these resources.



Service Charge Management

Minimum Use

Once the orders for tests and medications (Lab, DI and Pharmacy) have been properly entered, charges (costs associated with the activity) will be submitted in the system (dropped charges). The research teams must review all the charges associated with the respective study.

All charges must be marked as either standard of care (SOC) or research.

Please note that all research-related charges must be associated with the respective research study in the CIS.

What is it?

Ensuring that all charges associated with the respective research study are properly reviewed and reconciled.

Charges must be marked as follows:

Non-study related: Standard of Care

Study-related (Bill to the study): research study-related orders charged to the study sponsor or study team.

Study-related (Bill to Patient/Insurance): research study-related orders that are provided in-kind.

Why does it matter?

The research team will be able to ensure the correct and service charges are linked to the correct study allowing for a more transparent and accurate cost-recovery process.

Who is responsible?

The research study team is responsible for reviewing all charges associated with the research patients that are linked to the respective team's research studies. The research team will review all charges (research and SOC) incurred during study and non-study related visits as some charges take place during a SOC visit may be a result of research study, and vice versa.

How is it done?

Please go to your Learning Home Dashboard to access the Quick Start Guides and/or to the Health System Access Resource Page in your Research Coordinator dashboard to access One Pagers with instructions on how to perform these workflows in Connect Care. Please note 'Ordering' & 'Charge Review' is not a research-specific workflow, therefore the Connect Care Support Team for Research is not responsible for the development or maintenance of these resources.