Audit of Communication, CarE Planning, and DocumenTation

A multicenter, prospective study

Implementation Manual

This study is registered at ClinicalTrials.gov
Identification #: NCT01362855

Clinical Evaluation Research Unit

Alberta Innovates Health Solutions

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Michael Smith Foundation for Health Research

Table of Contents

Introduction 4
Abbreviations used in this manual 4
Coordinating Centre Contacts 4
Study Synopsis 5
Pre-Implementation Activities 7
Ethics Committee Approval 7
Study Duration 8
Training Modules 9
Setting Stage 10
Finding the Correct Patient Population 10
Staff Education & Awareness 10
Approaching Patients and Family Members 10
Recruitment 12
Inclusion/Exclusion Criteria 12
Eligible but Not Approached for Consent 14
Obtaining Consent 15
Consent Scenarios 16
Enrollment 17
Enrolling Patients and Family Members at Different times 17
Patient/Family Member Confidentiality 18
Screening/Enrollment Algorithm 18
Overview of Data Collection and Entry 20
Central Randomization System 21
Documenting Screening Activities 21
To Enter Screening Data and/or to Enroll a Patient 21
Unique Respondent Identification Numbers 30
Respondent Identification List 31
Data Collection 32
Institution Level Data 32
Patient/Family Member Data 32
Administering the ACP Questionnaire 32
General Instructions 33
ACP Questionnaire Breakdown 34
Section 1 - Demographics 35
Section 2 - Determinants of Decision Making 37
Section 3 - Decisions About Health Care Prior to Hospitalization 38
Section 4 - Goals of Care During Current Hospitalization 39
Section 5 - CANHELP Lite 40
Section 6 - Barriers & Facilitators 41
Section 7 - Documentation of ACP/AD in the Medical Record 42
Data Entry (REDCap) 43
Basic Navigation 43
Institutional Level Data 45
Patient/Family Member Data 45
Data Conventions in REDCap 48
Saving Data 48
Editing Data 49

Query system..... 49
Finalizing Data..... 51
Case Report Forms..... 52
Chart Abstraction - Clinical Data Collection..... 52
Tips for Completing Chart Abstraction..... 53
Types of CRF Data..... 54
Documentation..... 63
Appendix (located on Carenet website)..... 64

Introduction

This Implementation Manual is provided by CERU (the coordinating centre) as a guide to study conduct and expectations. It is intended to supplement the study protocol, *Audit of Communication, CarE Planning, and DocumenTation: A multicenter, prospective study, The ACCEPT Study.* This manual is applicable to patients and family members in hospital and acute care settings.

Abbreviations used in this manual:

ACP	Advance Care Planning
AD	Advance Directive
CERU	Clinical Evaluation Research Unit (Coordinating Centre)
CRF	Case Report Form
CRS	Central Randomization System (electronic system where screening & enrolment data is entered)
DNR	Do not resuscitate
EOL	End of Life
ICF	Informed Consent Form
ICH GCP	International Conference on Harmonization Good Clinical Practices
LST	Life-sustaining treatment
REDCap	The electronic data capture system for the study

Coordinating Centre Contacts

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All questions related to study procedures should be directed to the Project Leader.

Study Synopsis

Primary Research Question: In patients at high risk of dying,

1) To what extent have the components of the ACP process already been conducted with such patients and their families?
2) What are the barriers and facilitators to an ACP conversation from their (and their family's) point of view?
3) What is their level of satisfaction with EOL communication and decision-making as measured by the CANHELP satisfaction questionnaire?

Design: This is a multicenter, prospective, design that will involve an audit of current practice, followed by several audit-feedback cycles with tailored interventions designed to improve ACP practice.

Setting: Hospitals and acute care institutions in Canada and the United States.

Study Population: We will enroll patients who are at high risk of dying and/or their families (where available). We will approach consecutive, eligible patients and their family members from participating hospital units for enrollment into this study.

Study Intervention: We will time our initial approach to be after the patient has been in the hospital for at least 48 hours up until the 120th hour (i.e. between 48 – 120 hours following hospital admission) to allow for symptoms present at the time of admission to have abated enough for the patient and family to participate in an interview. Upon enrollment, the research coordinator will conduct separate interviews with patients and family caregivers so they cannot influence each other's responses.
The research coordinator will administer the questionnaire in a face-to-face interview. From direct interview of either the patient and/or family member and chart abstraction, we propose to capture standard baseline demographics including overall pre-admission health status (Global Rating Question from SF-36), a brief frailty scale, co-morbid illnesses using the Functional Co-morbidity Index and the Charlson Co-morbidity Index. In addition, we will evaluate whether the patient and/or family member has engaged in ACP and elicit their perceived barriers and facilitators to having these kinds of ACP-related conversations; as well capture their level of satisfaction with these conversations using the CANHELP Lite satisfaction questionnaire. Upon completion of the interview, the research coordinator will review the medical record examining for the presence of 'Goals of Care" orders, 'DNR' orders and any order to withhold, limit, or withdraw life-sustaining therapies. The presence or absence of the 'Greensleeve', its contents, or any other chart documentation of a discussion with the patient and family will be documented. At the conclusion of the hospital stay (following death or discharge), the research coordinator will abstract data on hospital outcomes and resource utilization.

Outcomes: The primary outcomes of this study will be completion of ACP documentation and satisfaction with EOL care.

Significance: This will be the first large scale evaluation of ACP in Canada and abroad. The results will provide information on the current successes (and challenges) of ACP which will strengthen ACP implementation efforts across the country. Lessons learned can effectively be disseminated across the country with our partnership with CHPCA. By increasing the quality and quantity of ACP, we stand to make huge improvements in quality of EOL care in Canada and across the world and reduce overall health costs.

Pre-Implementation Activities

Ethics Committee Approval

All participating institutions must obtain local ethics committee approval in advance of study implementation at the local site. Local ethics committee policies should be followed when preparing the submission. Documents provided by the coordinating centre to the local sites to facilitate ethics committee submissions include:

- ☑ Protocol
- ☑ Informed Consent Form (ICF) template
- ☑ Patient & Family Member ACP Questionnaires
- ☑ Institutional Level Data (Assessment of Degree of System Implementation)
- ☑ Case Report Form (chart abstraction)
- ☑ Poster (optional)
- ☑ Bedside Letter (optional)

If any changes are made to the protocol or tools over the duration of the study, it is the responsibility of the participating institution to ensure ethics committee approval is obtained for any amended documents.

Since the ACCEPT Study is an observational study (non-therapeutic, non-randomized), the local ethics committee may find it permissible to submit the study on an expedited basis. Local sites should communicate with their respective ethics committee to determine the appropriate method of submission.

It is the responsibility of the participating institution to ensure they complete any annual renewals for the study. The institution's local ethics committee will have specific forms and instructions regarding completing an annual renewal.

Documentation of local ethics committee approval, including the ethics committee approved ICF, and any annual renewals must be forwarded to the Project Leader (PL) prior to the implementation of the study at the site.

Study Duration

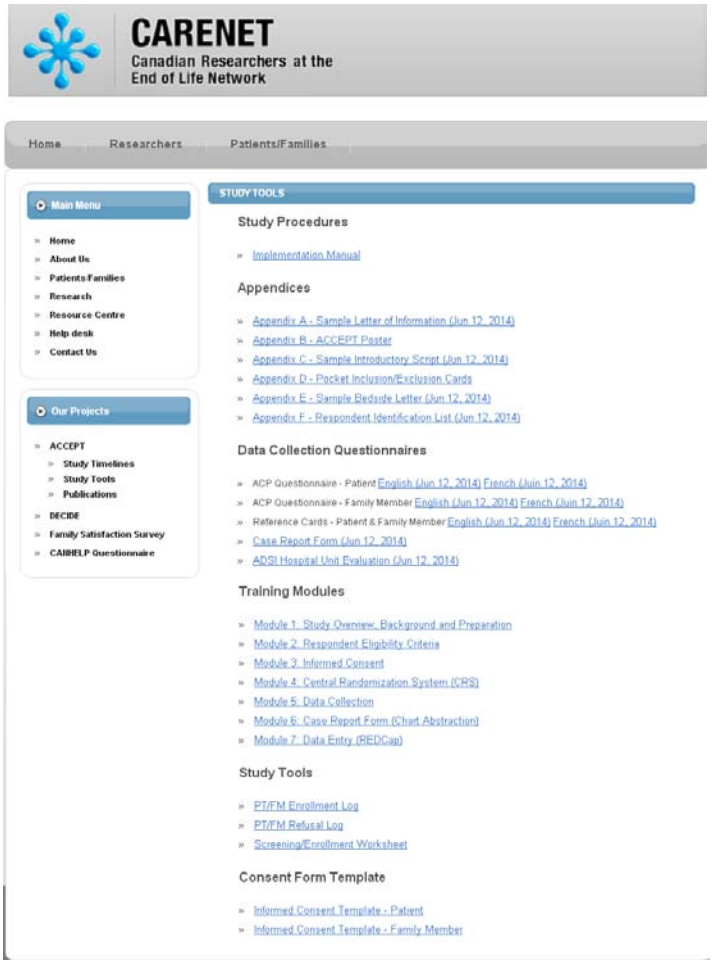
The Implementation phase of the study will include distinct audit cycles conducted annually. Each Audit Cycle consists of a data collection/entry period followed by the generation of reports and development and implementation of action plans.

Diagram 1: Audit Cycle Activities

Training Modules

Online self-training modules will be made available to participating institutions. It is the responsibility of participating institutions to self-administer the training modules to orient research staff to study procedures.

Site Training Modules are available to participating hospitals online at:
http://www.thecarenet.ca/index.php?option=com_content&view=article&id=186&Itemid=106



Training modules cover the following topics:

- Module 1: Study Overview, Background and Preparation
- Module 2: Respondent Eligibility Criteria
- Module 3: informed Consent
- Module 4: Central Randomization System (CRS)
- Module 5: Data Collection
- Module 6: Case Report Form (Chart Abstraction)
- Module 7: Data Entry (RedCap)

Any questions regarding study procedures can be directed to the Project Leader.

Setting the Stage

Finding the Correct Patient Population

In advance of commencing the audit cycle, it is advisable to determine which patient units to target for screening. The optimal ward would be where your general medical or renal patients are admitted. You may have success on oncology wards and less success on surgical wards. Focus on patients that are admitted to hospital from outside (ER, home, other hospital).
Note: We are not recruiting patients or families of patients who are in the Intensive Care Unit (ICU). We are not recruiting patients or families of patients who are under the Palliative Care Service.

Staff Education and Awareness

In-servicing and education of unit staff is an important aspect to initiating the study at the participating institution. One method of disseminating information concerning the study is to distribute a Letter of Information to clinical staff. This document could be emailed, placed in communication binders or distributed as the local team sees fit. (Refer to Carenet website for **Appendix A - Sample Letter of Information**).

Another important aspect of this process is ongoing education and promotion of the study to attending physicians, residents, nurses and other health care workers. It is helpful to begin to cultivate a relationship with health care workers on the targeted patient units by identifying the local study team (i.e. Study investigator, research coordinators, research assistants). Messages to deliver to unit staff are the study rationale and the type of patients we are recruiting.

An Information poster targeted towards health care professionals on the units is available on the Carenet website **Appendix B - ACCEPT Poster**. If you choose to use this, you must submit it to your local ethics committee for approval prior to use.

Approaching Patients and Family Members

Once the audit cycle begins, the participating institution should initiate recruitment activities. The local team should screen for eligible patients/family members on the targeted units. Potentially eligible patients may be identified by seeking input from the attending physician, medical residents, nurses, other healthcare staff, and/or by reviewing the medical chart to determine whether the patient meets the inclusion criteria.

Before approaching the patient/family member for consent, confirm eligibility by reviewing the medical chart (if not already done) and confirm 'suitability' of the patient/family member by discussing the case with a member of the health care team. By suitability, we mean that the patient/family member has the physical/emotional stamina and cognitive capacity to participate in the questionnaire. We do not have a formal capacity assessment tool that we use, just the judgment of the bedside nurse or attending physician. It is important that all patients/family members who meet the eligibility criteria are approached for consent. Regarding the patient, if

they have a test scheduled or 'is having a bad day" (i.e., symptomatic), then perhaps return at another date.

Patients unable to communicate due to language (non-English/non-French speaking) or cognitive reasons will be excluded. However, if their family member is eligible (i.e. English/French speaking) and available, we can still approach the family member.

Study patients will be asked to identify, if applicable, a family member who knows them the best (inclusive of partners, significant others, and/or close friends) who:

1) Is greater than 18 years old;
   and
2) Has visited the patient in hospital at least once
   and
3) Who provides the most care to the patient and is not paid to do so.

Family members that are 'out of province' are not eligible to participate since they do not meet criteria 2 & 3 as noted above.

If there is more than one family member available, we will allow the patient to select who participates.

If the patient is too sick to identify a family member, the researcher should approach the clinical team or medical chart to see if there is a documented Power of Attorney or substitute decision maker. In the absence of such documentation, the researcher may then approach the family.

When approaching the family, the appropriate individual will often identify themselves to the researcher as the appropriate family caregiver respondent for the study. Typically the patient's spouse or child will be the next appropriate family member respondent. Only one family member respondent can participate in the ACCEPT Study.

For the purposes of this study, the term family member refers to any caregiver that meets the definition above. A family member or caregiver does not have to be a relative, they could be a close friend or neighbour.

If there is no available family member, we will still enroll just the patient but wherever possible, we will try and enroll both patient and family members.

We will time our initial approach to be between the 48th and 120th hour, after hospital admission, to allow for symptoms present at the time of admission to have abated enough for the patient and family to participate in an interview.

A sample script is available on the Carenet website **Appendix C - Sample Introductory Script** for research coordinators who would like an example of how to introduce themselves and the study to potential participants**.**

Recruitment

Pocket Inclusion/Exclusion cards are available on the Carenet website **Appendix D - Pocket Incl/Excl Cards**.

Inclusion Criteria

#	Inclusion Criteria
1	**55 years or older with one or more of the following diagnoses:** ▪ Chronic obstructive lung disease Defined by at least **two** of the four following criteria: (a) Baseline $PaCO_2$ of ≥ 45 torr, (b) cor pulmonale; (c) Respiratory failure episode within the preceding year (d) Forced expiratory volume in 1 sec ≤0.5 L ▪ Congestive heart failure New York Heart Association class IV symptoms and left ventricular ejection fraction ≤ 25%. ▪ Cirrhosis Confirmed by imaging studies or documentation of esophageal varices and one of three conditions: a) hepatic coma, b) Child's class C liver disease c) Child's class B liver disease with gastrointestinal bleeding. ▪ Cancer Metastatic cancer or stage IV lymphoma ▪ End-stage dementia (inability to perform all ADLs, mutism or minimal verbal output secondary to dementia, bed-bound state prior to acute illness) ▪ Renal Failure Defined as chronic renal failure requiring dialysis.
	OR
2	Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition.
	OR
3	Any patient 55 to 79 years of age admitted to the hospital, who does not meet the above criteria, but in the opinion of a health care team member (Doctor, resident, nurse), he/she would not be surprised if the patient died in 6 months.

Child's Class B + C Liver Disease Classification

To determine whether a patient qualified for the study based on the Cirrhosis criteria b & c, use the following table.

Criteria	Points assigned		
	1	**2**	**3**
Total Bili Conventional SI units	< 2 mg/dl < 34 µmol/L	2.0 – 3.0 mg/dL 34 – 51 µmol/L	> 3 mg/dL > 51 µmol/L
Serum Albumin Conventional SI units	> 3.5 g/dL > 35 g/L	2.8 – 3.5 g/dL 28 – 35 g/L	< 2.8 g/dL < 28 g/L
Prothrombin time **or** **INR**	< 4 seconds < 1.7	4 – 6 seconds 1.7 – 2.3	> 6 seconds > 2.3
Ascites*	Absent	Slight	Moderate
Encephalopathy	None	Moderate	Severe
* Refer to ultrasound results. If ascites has been drained in the past, it should be considered Moderate.			

The Child-Pugh score is obtained by adding the points for all 5 criteria. Any patient having a score of 7—9 falls into Group B (significant functional compromise) and 10 – 15 falls into Group C (severe hepatic impairment). Child's Class B (with gastrointestinal bleeding), or Class C in conjunction with documented/confirmed cirrhosis is an inclusion criteria.

Correctly Documenting the Inclusion of ≥ 80 Year Olds

For patients **≥**80 years old, it is important to, whenever possible, document the specific diagnosis present.

For example: If a patient is 82 years old with COPD, they should be entered into the CRS as meeting inclusion criteria 1 "55 years or older with one or more of the following diagnoses: COPD."

For example: If a patient is 85 years old, admitted to the hospital with a UTI, since they do not meet any of the specific diagnoses in inclusion criteria #1, they should be logged as inclusion criteria #2 "Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition."

Clarification regarding qualifying a patient for the study using the COPD inclusion criteria:

It is often difficult to find forced expiratory volume (FEV1) data in the medical chart. If the medical notes document "severe" COPD and/or air flow limitation and everything else about the condition confirms that (i.e. limited functional capacity, on home 0_2, frail, etc.), AND they meet one of the other formal inclusion criteria, this patient can be included in the study. Don't exclude just because you can't find the FEV1 data and yet they are severe COPD.

Exclusion Criteria

#	Patient	Family Member
1	Non-English/Non-French speaking patient	Non-English/Non-French speaking family member
2	Cognitive impairment	

All excluded respondents should be entered into the CRS.

Patients or Family Members who are Legally Blind

Patients and/or family members who are legally blind are eligible to participate in the study. When administering the ACP Questionnaire simply omit the REALM score (Section 1, Health Literacy) and try to get through the rest of the questionnaire.

Eligible but Not Approached for Consent

There will be instances where a respondent is eligible to be included in the study based on the entry criteria however, it is not appropriate to approach them for consent to participate. Some examples of these types of situations include:

- Newly Diagnosed Patients
  Do not enroll a newly diagnosed patient (e.g. new diagnosis of metastatic cancer). These discussions would be very sensitive in a newly diagnosed patient. The intent of the study is to speak with those that have an established diagnosis.
- Actively Dying Patients
  If a patient is in the process of 'actively dying' do **not** approach them or their family members for participation in the study.

If the patient/family member was not approached for consent, document the reason why using the best response from the taxonomy below.

Patient	Family Member
Discharge soon	Discharge soon
Can't hear well/deaf	Can't hear well/deaf
Can't see well/blind	Can't see well/blind
Difficulty speaking	Difficulty speaking
At request of health care team	At request of health care team
At request of family member	At request of patient
>120 hours from hospital admission	>120 hours from hospital admission
Newly diagnosed	Newly diagnosed
Actively dying	Actively dying
Too sick	Family member cognitively impaired
Missed patient	Family member not available
Other (specify): _____	Other (specify): _____

All eligible respondents not approached for consent should be entered into the CRS.

Obtaining Consent

Following confirmation of patient/family member eligibility, the researcher should seek consent for the patient /family member to participate in the ACCEPT Study.

"Free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves."
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Procedures for Obtaining Informed Consent

The following procedures are recommended when obtaining informed consent for a potential ACCEPT Study Patient/Family Member:

1) The study team member obtaining consent is qualified to do so, and is knowledgeable in the study procedures, and rationale for the study.
2) Assess the Patient/Family Member's competence to consent to research, and document if you deem this individual incompetent.
3) Review the study details with the Patient/Family Member in a quiet, private location.
4) Do not coerce or unduly influence the Patient/Family Member to participate, or continue to participate in the study. If the Patient/Family Member is showing signs of stress, ask if they would like you to come back at another time.
5) Fully inform the Patient/Family Member of all pertinent aspects of research, in non-technical language that is easy to understand. If the Patient/Family Member does not speak English/French they should be excluded.
6) Provide a copy of the ICF and allow the Patient/Family Member ample time to read the ICF and ask questions.
7) Ask the Patient/Family Member questions to assess their comprehension of the material reviewed. Ensure he/she fully understands the information.
8) Ascertain the Patient/Family Member's willingness to participate.

It is important to document the reasons why consent was refused for the patient/family member. If the patient/family member was approached for consent and refused to participate, please indicate the reason using the list below.

Patient	Family Member
Not interested Too upsetting Too tired Too sick Discharge soon Can't hear well/deaf Can't see well/blind Other (specify): _____	Not interested Too upsetting Too tired Discharge soon Can't hear well/deaf Can't see well/blind Other (specify): _____

9) If consent is obtained, the Patient and/or Family Member and the researcher will sign and date the ICF document.
10) Document the consent process (both granted consent and refusals) in the patient medical chart.
11) Place a copy of the ICF in the patient medical chart.
12) Provide the Patient/Family Member with a copy of the signed document.
13) File the originally signed ICF in the local site study files.
14) Enter the consent 'granted' or 'refused' information in the CRS.

The research site should always adhere to ethics committee procedures when obtaining informed consent. Any questions should be forwarded to the local ethics committee at the site.

Some participating institutions are required by their ethics committee to leave a letter regarding the study at the patient's bedside before they speak to them. Refer to Carenet website for **Appendix E - Sample Bedside Letter** that may be tailored to specific institutional requirements.

The Government of Canada website for the Tri Council Policy Statement Panel on Research Ethics provides a free online training course regarding research ethics. Anyone can access this training at the following link: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/ You will be provided with a Training Certificate upon completion of the course.

Consent Scenarios

Since the ACCEPT Study involves both patient and family member participation, it is possible that different scenarios may arise concerning granting consent and refusing consent. The table below outlines these different situations along with any special procedures or considerations.

Table 1: Consent Scenarios

Patient Consent Response	Caregiver Consent Response	Procedures/Considerations
Yes	Yes	A separate ICF should be signed by the patient and the family member.
Yes	No	Consent should be signed by the patient.
No	No	None.
No	Yes	Consent should be signed by the family member.

Remember:
1) Enter all patients that meet Inclusion Criteria into the CRS, including those that are not approached for consent or those that refuse consent.
2) File the original ICF in the Patient study file.

Enrollment

A total of 60 enrollments are expected at each participating institution during each Audit Cycle. Of the 60 enrollments, at a minimum, there should be 20 patient and 20 family member respondents. For example, a site may enroll 22 patient respondents and 38 family member respondents.

The Patient/Family Member data collection package consists of the ACP Questionnaire (patient and/or family member version) and the Case Report Form (medical chart data abstraction form).

Patient/Family Member data collection can begin after consent is obtained and the Patient/Family Member is formally enrolled into the study using the CRS.

The following table illustrates data collection for patients and family members given the different consent scenarios noted in Table 1.

Table 2: Data Collection

Patient + Family Member	Patient Only	Family Member Only
ACP Questionnaire *Patient Version &* *Family Member Version*	ACP Questionnaire *Patient Version*	ACP Questionnaire *Family Member Version*
Case Report Form (CRF)	Case Report Form (CRF)	Case Report Form (CRF)

Enrolling Patients and Family Members at Different Times

It has been observed at some participating institutions that it is can be difficult to enroll family members since they often have other obligations that take them away from the hospital during regular business hours. If you are having difficulty enrolling family member respondents we suggest you make initial contact with family members by telephone to arrange for a mutually agreeable time to meet. We suggest you:

1) Identify yourself as a member of the patient's healthcare team.
2) Indicate the patient/family member is eligible for a study we are conducting about hospitalized elderly patients.
3) Indicate you would like to make an appointment with them to further discuss.

We are not suggesting that consent be obtained by telephone; rather we are proposing to simply make the initial contact with them in this manner. The consent process and interview would take place at an agreed upon meeting time.

**Ensure you check with your ethics committee to confirm this strategy is acceptable.

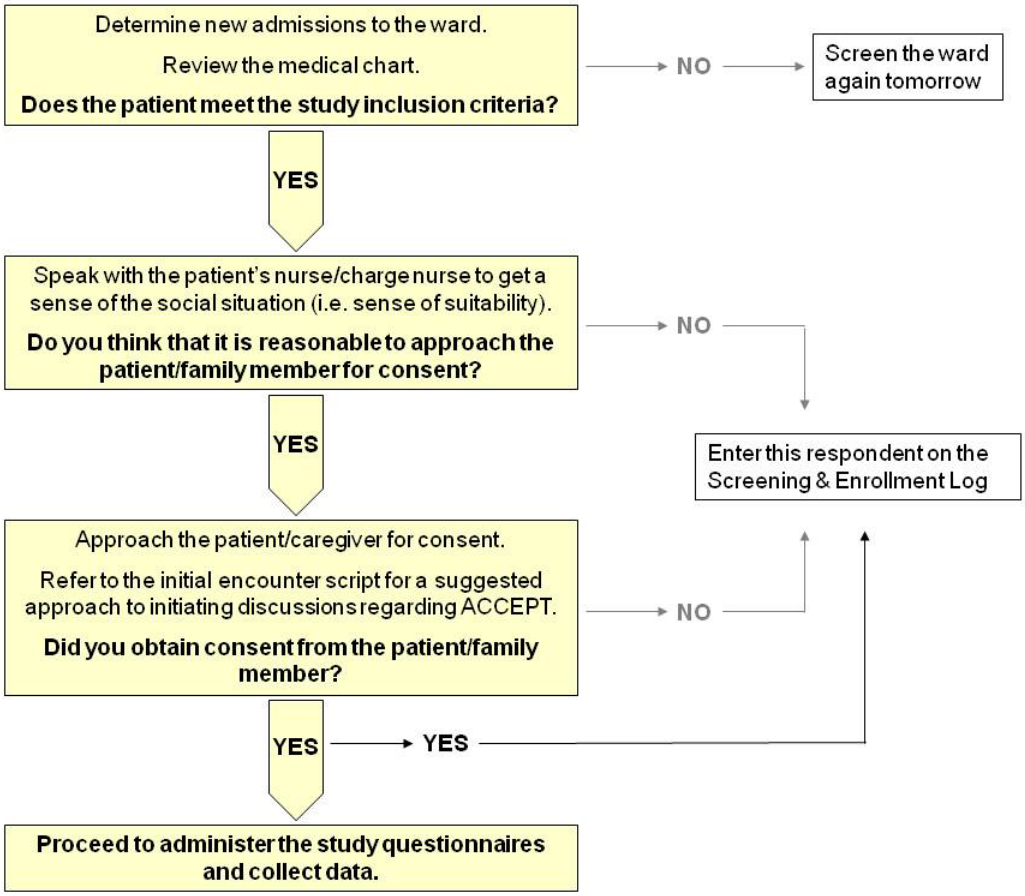
Patient/Family Member Confidentiality

By definition, and in the context of a research study, confidentiality refers to prevention of disclosure, to unauthorized individuals, of a Patient/Family Member's identity and of records that could identify a Patient/Family Member. Care and diligence in protecting confidential Patient/Family Member information must be exercised throughout the duration of the ACCEPT Study. It is advisable for sites to consult with their institutional procedures regarding privacy and confidentiality to ensuring they are adhering to local standards.

All Patient/Family Member's must be identified with a unique identifying enrollment number. (Refer to pg. 31 for assignment of enrollment numbers). Remember to document the patient's medical record number for later retrieval of the medical record for chart abstraction. Pages 52 - 63 provide further details concerning chart abstraction.

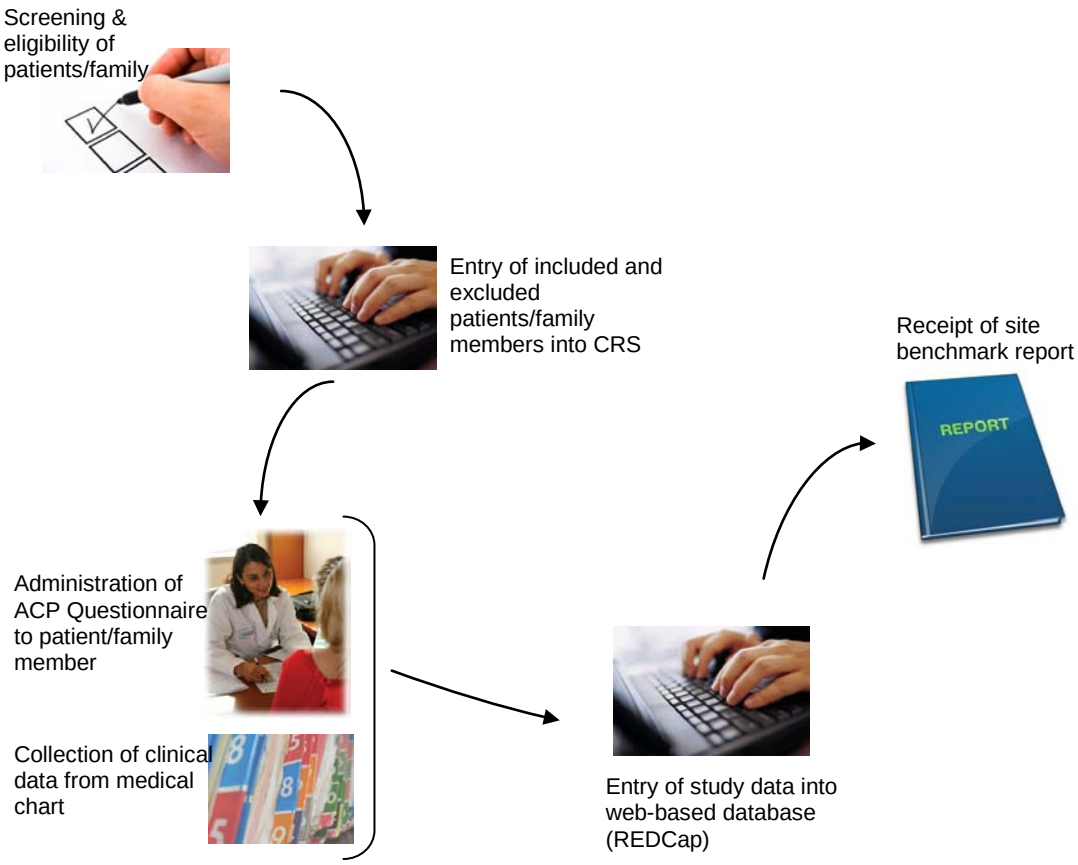
Screening/Enrollment Algorithm

We encourage sites to adapt screening practices that are efficient and optimize their valuable time. Based on experiences at Kingston General Hospital, we are offering the following screening/enrollment algorithm as a tool for sites to identify and enroll eligible patients. (Please note adoption of this strategy is not mandatory, and local ethics committee requirements concerning screening and enrollment should be followed).


Determine new admissions to the ward.
Review the medical chart.
Does the patient meet the study inclusion criteria?
NO
Screen the ward again tomorrow
YES
Speak with the patient's nurse/charge nurse to get a sense of the social situation (i.e. sense of suitability).
Do you think that it is reasonable to approach the patient/family member for consent?
NO
YES
Enter this respondent on the Screening & Enrollment Log
Approach the patient/caregiver for consent.
Refer to the initial encounter script for a suggested approach to initiating discussions regarding ACCEPT.
Did you obtain consent from the patient/family member?
NO
YES
YES
Proceed to administer the study questionnaires and collect data.

Overview of Data Collection and Entry

The following diagram illustrates the flow of data from determination of inclusion into the study through to generation of the local site benchmark report. It is important for researchers to note that there are two study databases that require data entry. The first is the Central Randomization System (CRS); this is where the research team will enter eligibility data on both included and excluded respondents. The second database called REDCap is where the ACP Questionnaire responses and chart abstraction data are entered. Together, the information entered into these databases will inform the results presented to you in your Site Report.



Documenting Screening Activities

All participating institutions screening efforts should be entered into the web-based CRS (electronic database. The CRS can be accessed at:

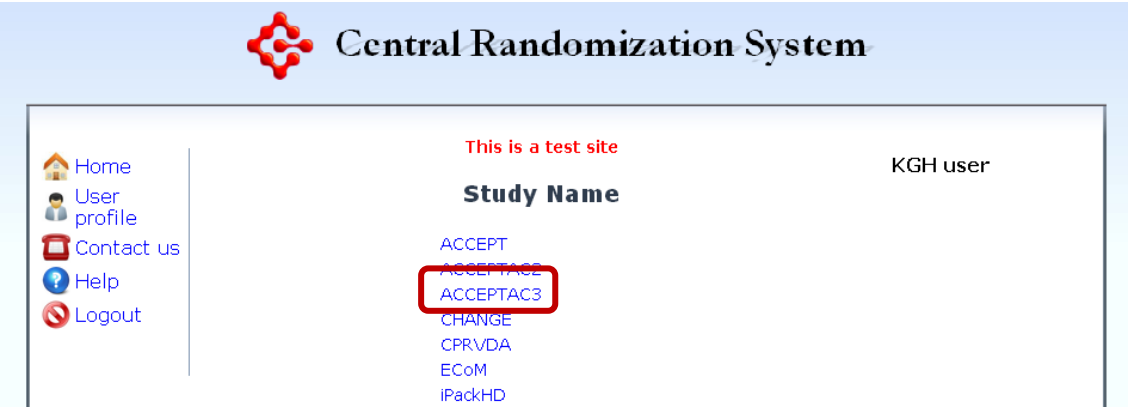
https://ceru.hpcvl.queensu.ca/randomize/

To Enter Screening Data and/or to Enroll a Patient

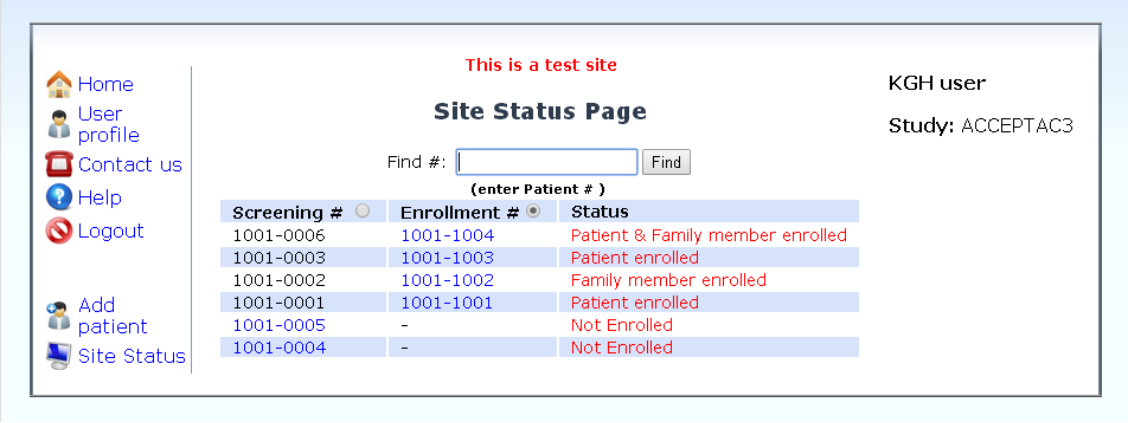
1) Log in to the CRS.

A username and password will be granted to each user after training has been completed.

2) Select the ACCEPT Study (ACCEPTAC3) from the list of studies.

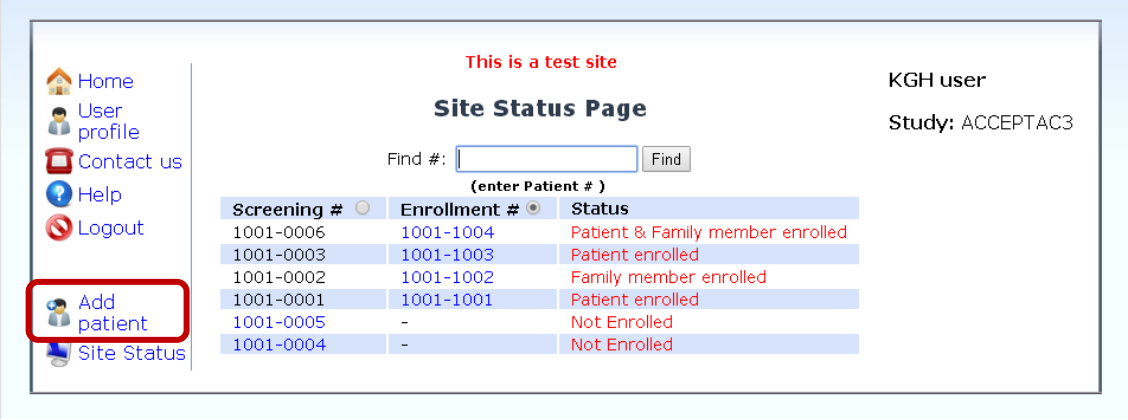


3) You will be brought to your Site Status page. This page will list all of the patient/family members you have screened and/or enrolled to date.

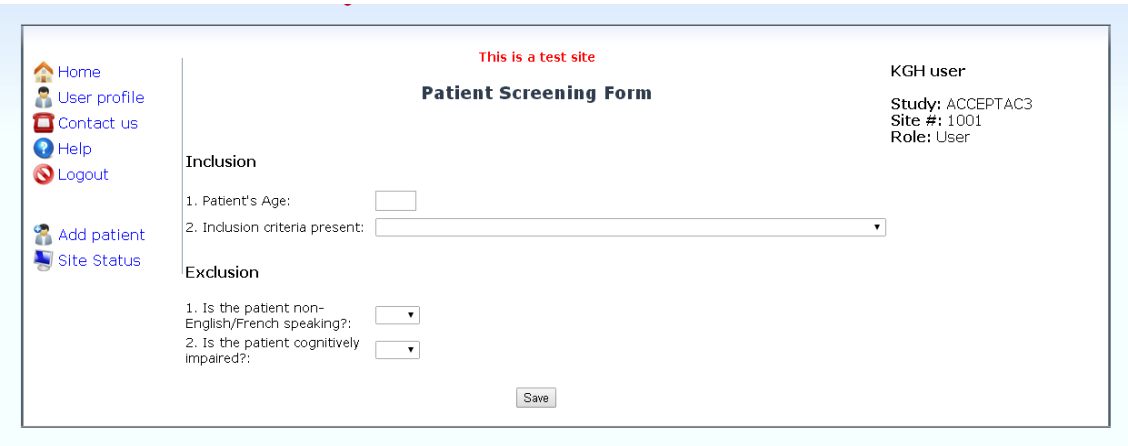


4) To view existing data simply click on the screening or enrollment number of interest. The Screening Form for that particular patient/family member will open.

5) To enter data on a new Patient/Family Member, click on the "Add Patient" link on the left menu bar.

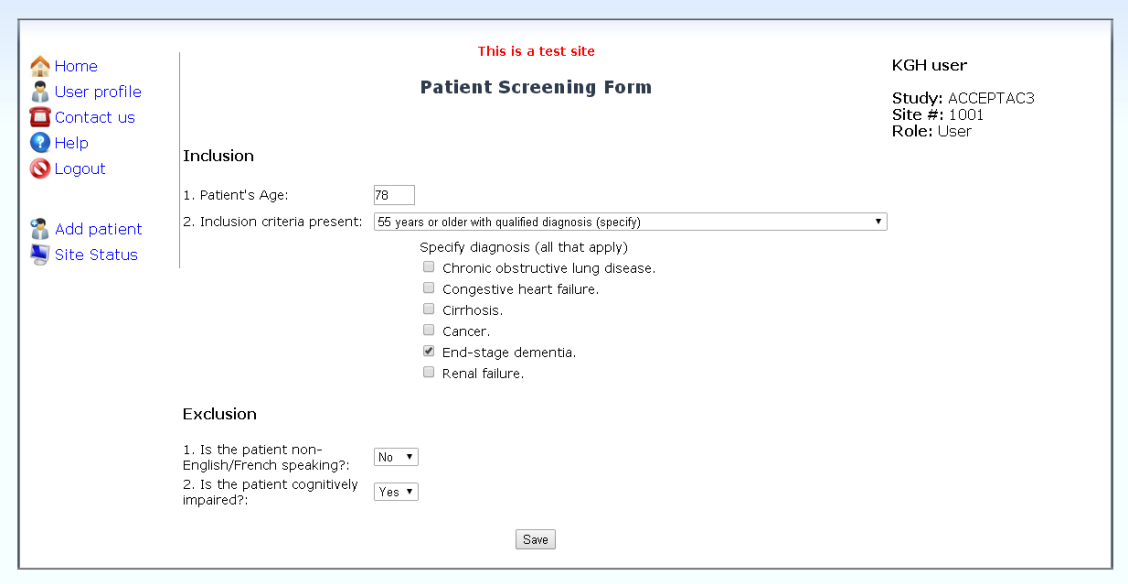


6) You will next be taken to the Screening Form. Patient eligibility criteria will always be the first data entry screen.



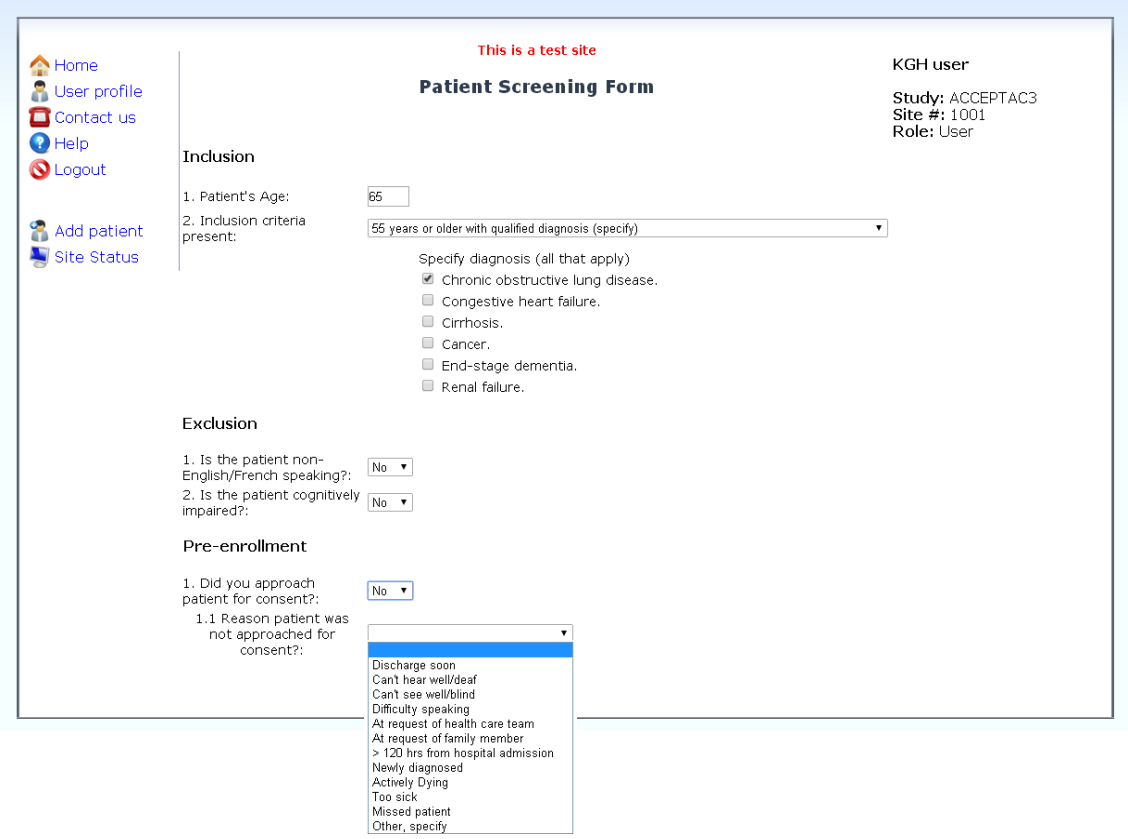
7) Enter the inclusion and exclusion criteria for the patient. Select SAVE.

a) In this case the patient is excluded.

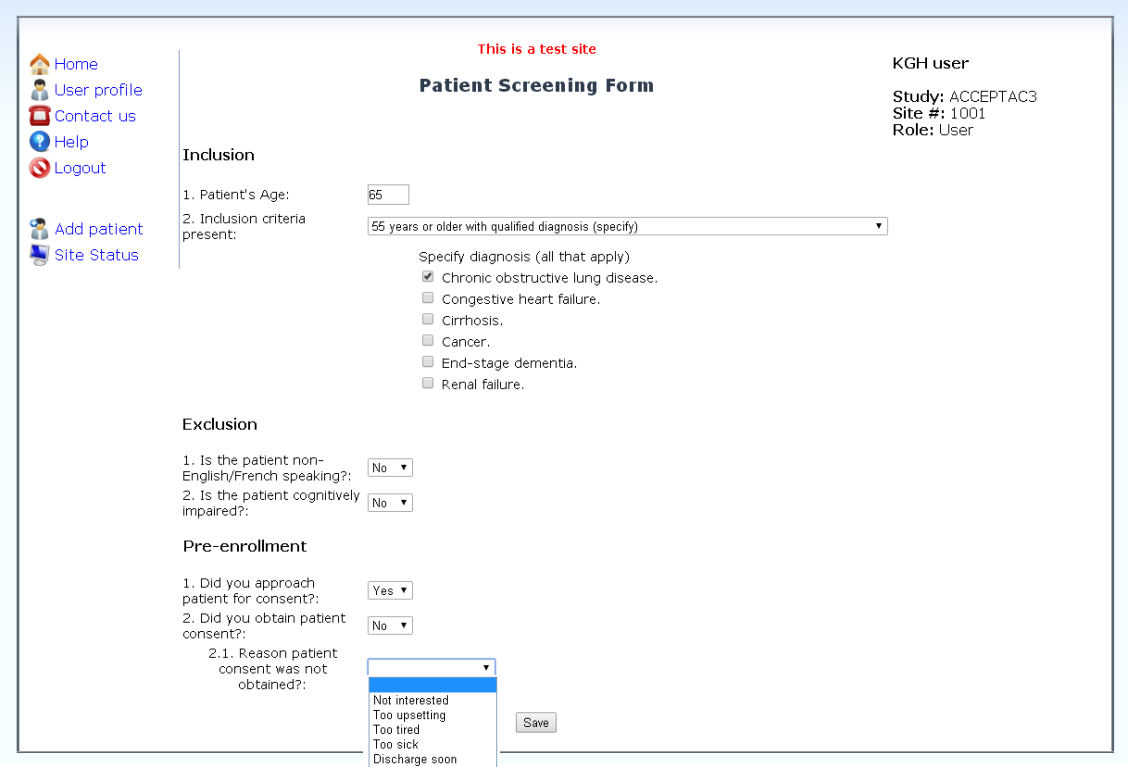


b) In the following cases the patient is eligible.

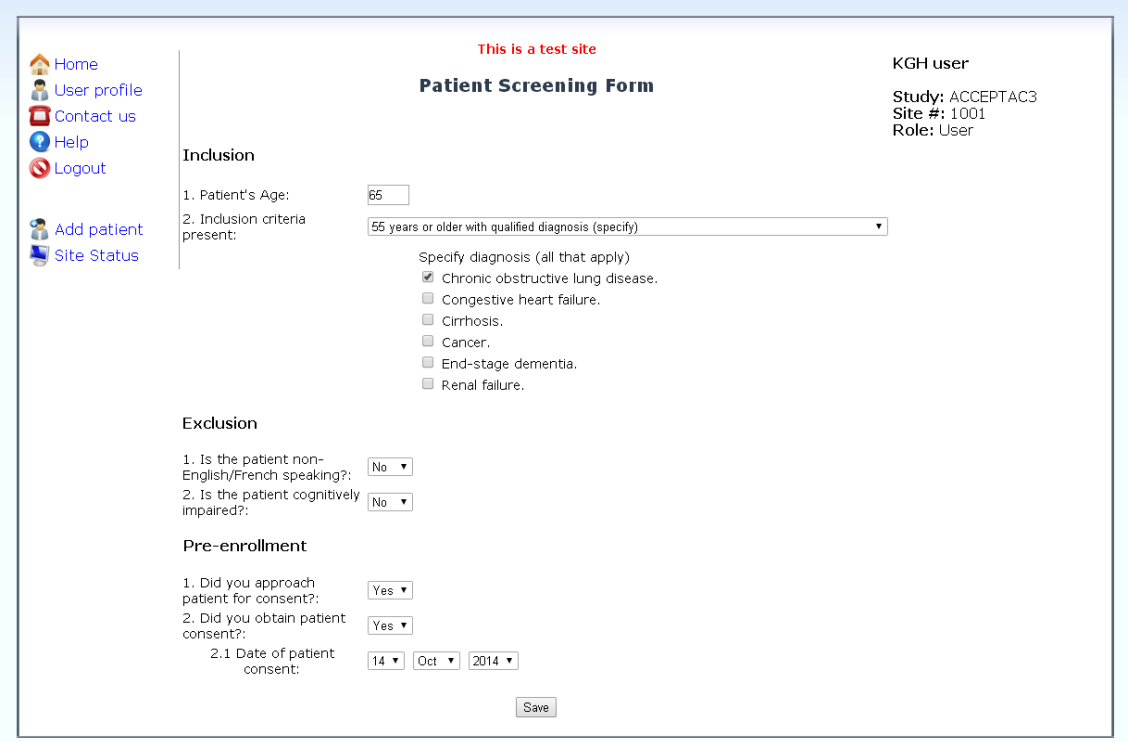
i) The patient is NOT approached for consent, indicate the reason why using the drop down menu, then SAVE the form.



ii) If the patient is approached for consent, but declines to participate, indicate the reason why using the drop-down menu, then SAVE the form.

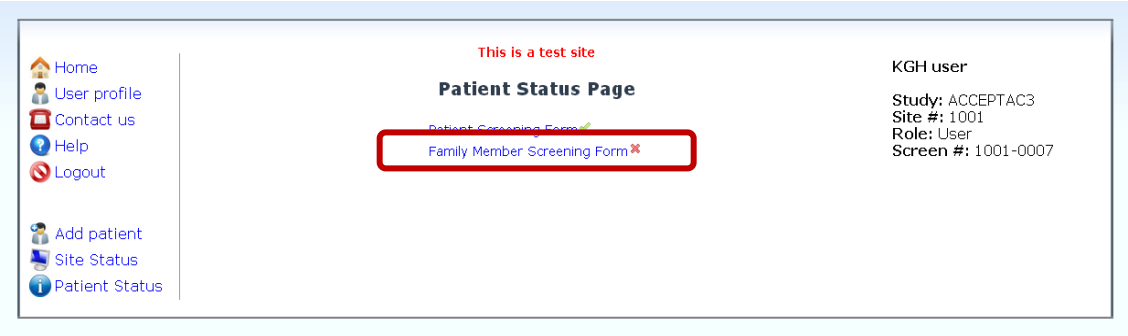


iii) If the patient is approached for consent, and consent is granted, record the date consent is obtained and then SAVE the form.



8) When a patient is enrolled you will see an enrollment confirmation form. Print this form for your study file. Click the link to proceed to the family member screening form.

9) Alternately, if the patient is not enrolled you will be taken to the Patient Status Page. Next you will enter data regarding the family member by selecting Family Member Screening Form.

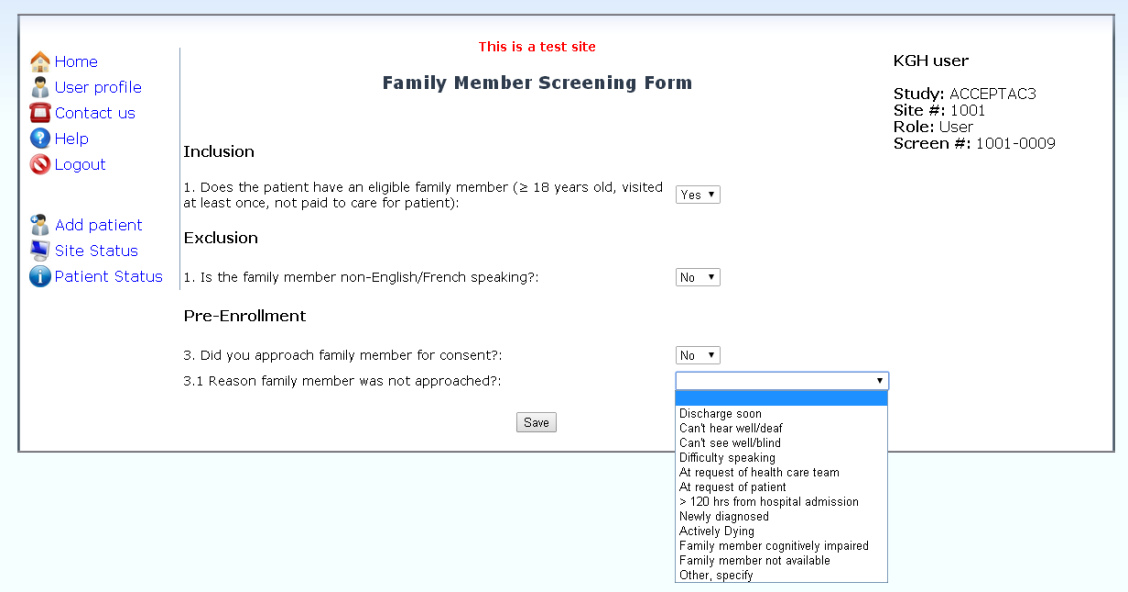


10) Enter the data for the family member.

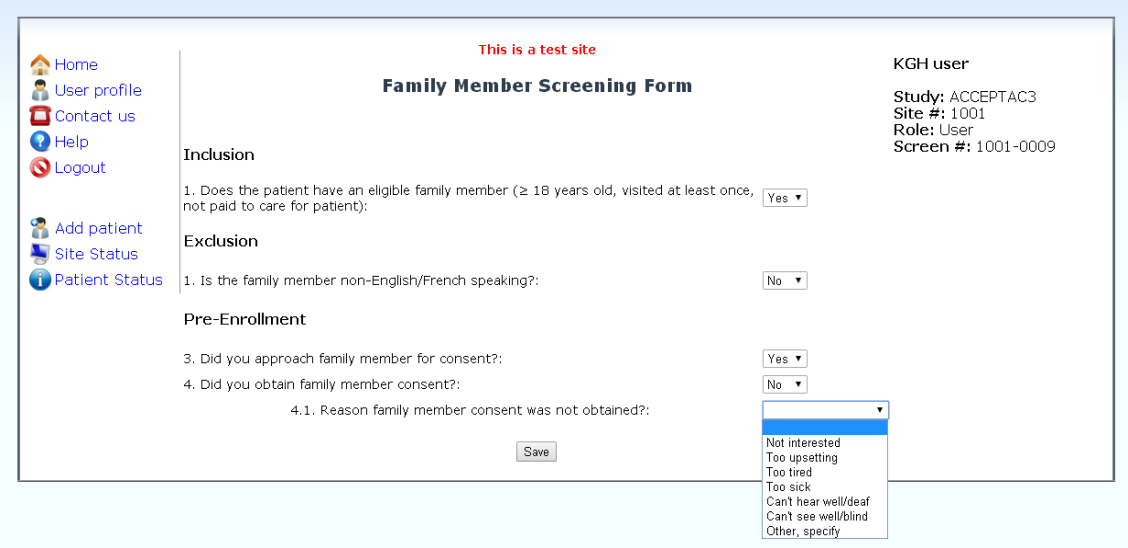
a) In this case the family member is excluded.

b) In the following cases the family member is eligible.

i) If the family member is NOT approached for consent, indicate the reason why using the drop-down menu, then SAVE the form.

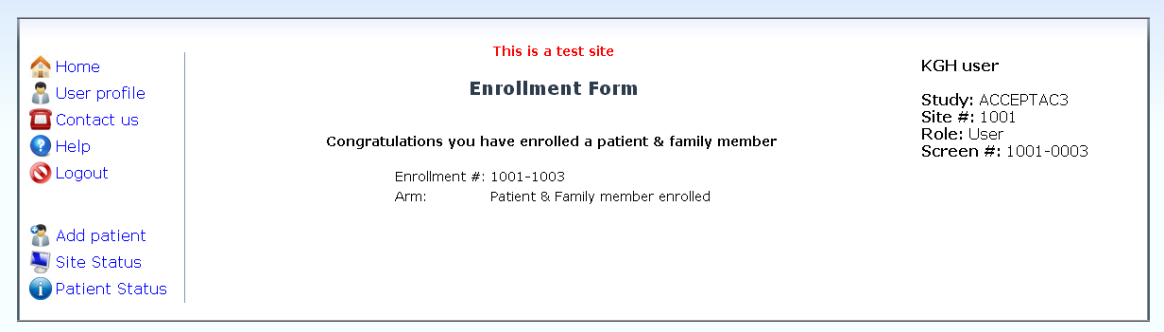


ii) If the family member is approached for consent, but declines to participate, indicate the reason why using the drop-down menu, then SAVE the form.



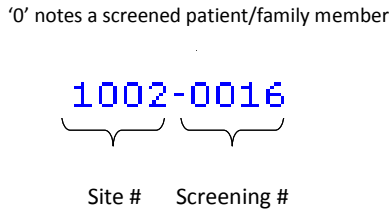
iii) If the family member is approached for consent, and consent is granted, record the date consent is obtained and then SAVE the form.

11) When a family member is enrolled you will see an enrollment confirmation form. Print this form for your study file. (The form will indicate whether you have both the patient and family member enrolled or just the family member.)

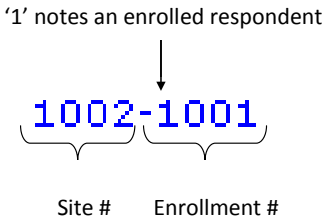


Unique Respondent Identification Numbers

All patient/family members entered into the CRS will have a screening number. The screening numbers are assigned sequentially in an 8-digit format:



Those patient/family members that proceed to be enrolled will also be issued an enrollment number. The enrollment numbers are assigned sequentially in an 8-digit format:



When you are logged into the CRS, at a glance you will be able to tell what type of respondent is associated with each enrollment number:

Site Status Page

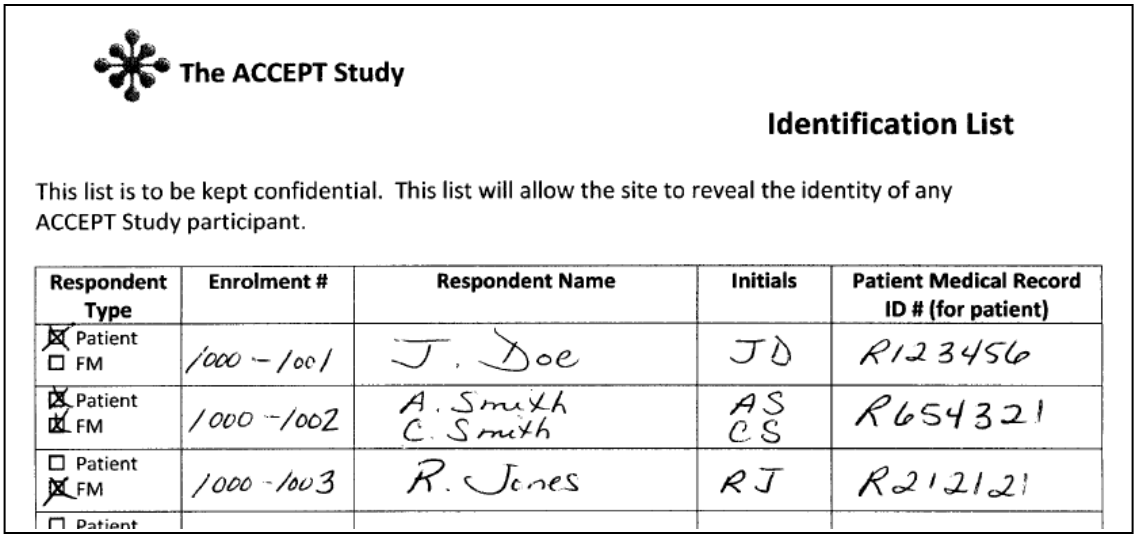
Find #: Find

(enter Patient #)

Screening #	Enrollment #	Status
1002-0012	1002-1007	Patient enrolled
1002-0011	1002-1006	Family member enrolled
1002-0008	1002-1005	Patient & Family member enrolled
1002-0006	1002-1004	Patient & Family member enrolled
1002-0005	1002-1003	Family member enrolled
1002-0004	1002-1002	Family member enrolled
1002-0003	1002-1001	Patient enrolled
1002-0010	-	Not Enrolled
1002-0009	-	Not Enrolled

Respondent Identification List

In order for the site to be able to access the relevant medical record, you will need to know the unique, hospital assigned, medical record number. It is good practice to maintain a respondent Identification List (refer to Carnet website **Appendix F - Respondent Identification List**). Below is a sample of the type of information that should be noted on an Identification List.



The ACCEPT Study

Identification List

This list is to be kept confidential. This list will allow the site to reveal the identity of any ACCEPT Study participant.

Respondent Type	Enrolment #	Respondent Name	Initials	Patient Medical Record ID # (for patient)
☒ Patient ☐ FM	1000 – 1001	J. Doe	JD	R123456
☒ Patient ☒ FM	1000 – 1002	A. Smith C. Smith	AS CS	R654321
☐ Patient ☒ FM	1000 – 1003	R. Jones	RJ	R212121
☐ Patient				

Data Collection

The coordinating centre will communicate the Audit Cycle start date. Participating institutions may begin to recruit patients/family members and conduct the study before or after the target start date, as long as they have REB approval, the necessary resources and training to begin.

There are 2 types of data collection to be conducted during each Audit Cycle:

1. Institution Level Data (Assessment of Degree of System Implementation)
2. Patient/Family Member Level Data
    a. Patient/Family Member ACP Questionnaires
    b. Case Report Form (Chart abstraction)

Institution Level Data

Collection of institutional data will allow for a comparison between those institutions with low and high degrees of system level implementation to determine if there is a higher prevalence of ACP and greater satisfaction of EOL communication and decision-making in institutions with higher degrees of system level implementation.

Institution Level Data: Assessment of Degree of System Implementation

At the beginning of the audit cycle, each participating institution should complete the Assessment of Degree of System Implementation – Hospital Unit Evaluation form. Refer to the Carenet website for the questionnaire.

The questionnaire is self administered and should be completed by the hospital staff member (Patient Care Coordinator, Manager) with responsibility for overall unit or specific involved program(s) from which the patients are recruited. Following the completion of the questionnaire, the data should be entered into REDCap. Refer to page 45 for data entry instructions.

Patient /Family Member Data

Administering the ACP Questionnaires

Each interviewer will develop their own style concerning the administration of the questionnaire. Some useful tips include:

- Use the respondent's name
- Introduce yourself and your specific role
- Ensure the respondent is ready and you have a private location to conduct the interview.
- Remove barriers to communication
- Ensure comfort and put the respondent at ease

General Instructions

1. Determine which ACP Questionnaire should be administered to the Respondent (i.e. Patient or Family Member version).
2. The questionnaires should be administered in-person with the respondent. Do **not** give the questionnaires to the respondent to fill out at their leisure.
3. Read each question to the respondent, if the respondent does not understand, repeat the question. The researcher administering the questionnaire should not interpret the questions for the respondent.
4. When the question is open-ended, do not paraphrase or change the respondent's answer. Record the answer verbatim.
5. If the respondent 'declines' to respond to a particular question, make a note in the margin. You will be able to note this when entering the data into the database (see REDCap training module).
6. Some questions have several response options. For these questions we have developed reference cards that can be handed to the respondent to aid with their responses. If applicable, the interviewer will note a statement after the question *"give CARD # to respondent."*
7. If both the patient and family member are enrolled, conduct the interviews as close to each other as possible. They can be conducted up to 1 week apart however, every effort should be made to conduct them as close to each other as possible.
8. If the interview is started, then part way through the respondent withdraws their consent to continue do not discard the questionnaire.
    a. Questionnaires that are $\geq$ 50% complete should be included.
    b. Questionnaires that are < 50% complete cannot be included. Another patient will need to be enrolled to replace this respondent. Contact the Project Leader for guidance on how to document this occurrence.

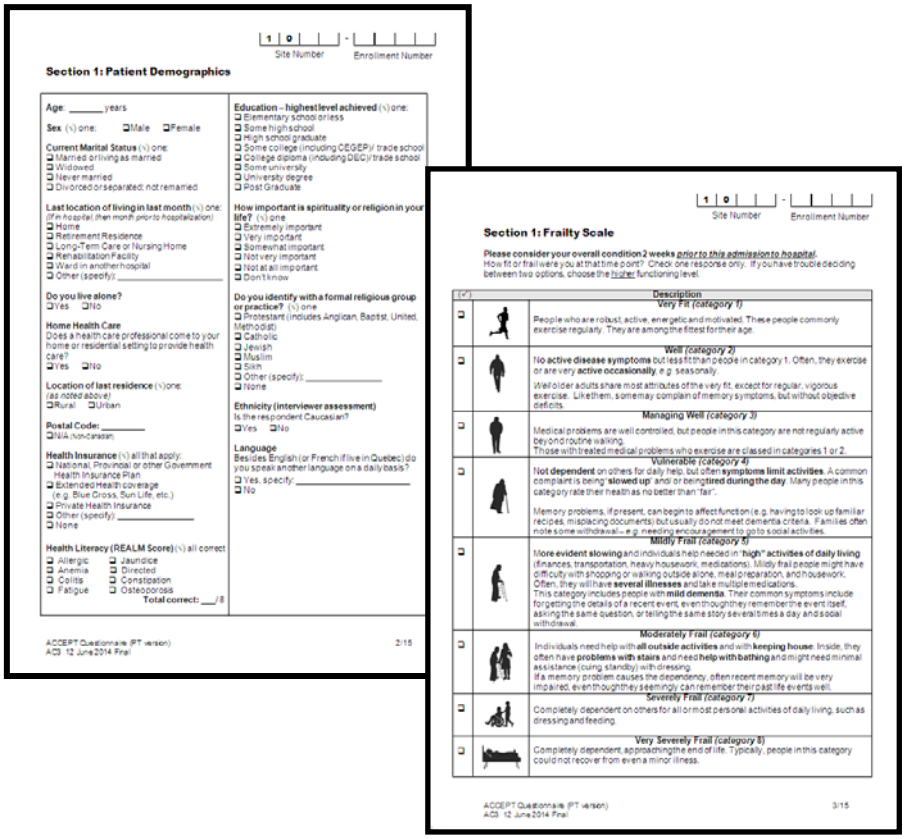
ACP Questionnaire Breakdown

The table below outlines the different sections of the ACP questionnaire, both patient and family member versions.

Patient Version	Family Member Version
Section 1 ▪ Patient Demographics ▪ Frailty Scale	Section 1 ▪ Family Member Demographics ▪ Patient Demographics, if applicable ▪ Patient Frailty Scale, if applicable
Section 2 ▪ Determinants of Decision Making	Section 2 ▪ Determinants of Decision Making
Section 3 ▪ Decisions About Your Health care Prior to Hospitalization	Section 3 ▪ Decisions About Your Relative's Health care Prior to Hospitalization
Section 4 ▪ Goals of Care During Current Hospitalization	Section 4 ▪ Your Relative's Goals of Care During Current Hospitalization
Section 5 ▪ CANHELP Lite	Section 5 ▪ CANHELP Lite
Section 6 ▪ Barriers & Facilitators	Section 6 ▪ Barriers & Facilitators
Section 7 ▪ Documentation of ACP/AD in the Medical Record at the End of the Interview	Section 7 ▪ Documentation of ACP/AD in the Medical Record at the End of the Interview

Section 1: Baseline Demographics

We have developed a comprehensive list of demographics that will enable us to adequately describe the patients involved in this study. These data may help us explain if certain types of patients are or are not involved in ACP. Most of these demographic questions are self evident. A few of them warrant further explanation as to why we are collecting them or how to collect them, these details are found below.



Site Number | Enrollment Number

Section 1: Patient Demographics

Age: _____ years

Sex (√) one: ❑Male ❑Female

Current Marital Status (√) one:
❑ Married or living as married
❑ Widowed
❑ Never married
❑ Divorced or separated; not remarried

Last location of living in last month (√) one:
(If in hospital, then month prior to hospitalization)
❑ Home
❑ Retirement Residence
❑ Long-Term Care or Nursing Home
❑ Rehabilitation Facility
❑ Ward in another hospital
❑ Other (specify): _____

Do you live alone?
❑Yes ❑No

Home Health Care
Does a health care professional come to your home or residential setting to provide health care?
❑Yes ❑No

Location of last residence (√) one:
(as noted above)
❑Rural ❑Urban

Postal Code: _____
❑N/A (non-Canadian)

Health Insurance (√) all that apply:
❑ National, Provincial or other Government Health Insurance Plan
❑ Extended Health coverage (e.g. Blue Cross, Sun Life, etc.)
❑ Private Health Insurance
❑ Other (specify): _____
❑ None

Health Literacy (REALM Score) (√) all correct
❑ Allergic ❑ Jaundice
❑ Anemia ❑ Directed
❑ Colitis ❑ Constipation
❑ Fatigue ❑ Osteoporosis
Total correct: ___/8

Education – highest level achieved (√) one:
❑ Elementary school or less
❑ Some high school
❑ High school graduate
❑ Some college (including CEGEP)/ trade school
❑ College diploma (including DEC)/ trade school
❑ Some university
❑ University degree
❑ Post Graduate

How important is spirituality or religion in your life? (√) one
❑ Extremely important
❑ Very important
❑ Somewhat important
❑ Not very important
❑ Not at all important
❑ Don't know

Do you identify with a formal religious group or practice? (√) one
❑ Protestant (includes Anglican, Baptist, United, Methodist)
❑ Catholic
❑ Jewish
❑ Muslim
❑ Sikh
❑ Other (specify): _____
❑ None

Ethnicity (interviewer assessment)
Is the respondent Caucasian?
❑Yes ❑No

Language
Besides English (or French if live in Quebec) do you speak another language on a daily basis?
❑ Yes, specify: _____
❑ No

ACCEPT Questionnaire (PT version)
ACS 12 June2014 Final
2/15

Site Number | Enrollment Number

Section 1: Frailty Scale

Please consider your overall condition 2 weeks *prior to this admission to hospital*.
How fit or frail were you at that time point? Check one response only. If you have trouble deciding between two options, choose the higher functioning level.

(✓)		Description
❑		**Very Fit *(category 1)*** People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
❑		**Well *(category 2)*** No **active disease symptoms** but less fit than people in category 1. Often, they exercise or are very **active occasionally**, *e.g.* seasonally. *Well* older adults share most attributes of the very fit, except for regular, vigorous exercise. Like them, some may complain of memory symptoms, but without objective deficits.
❑		**Managing Well *(category 3)*** Medical problems are well controlled, but people in this category are not regularly active beyond routine walking. Those with treated medical problems who exercise are classed in categories 1 or 2.
❑		**Vulnerable *(category 4)*** Not **dependent** on others for daily help, but often **symptoms limit activities**. A common complaint is being "**slowed up**" and/or being **tired during the day**. Many people in this category rate their health as no better than "fair". Memory problems, if present, can begin to affect function (e.g. having to look up familiar recipes, misplacing documents) but usually do not meet dementia criteria. Families often note some withdrawal – *e.g.* needing encouragement to go to social activities.
❑		**Mildly Frail *(category 5)*** More **evident slowing** and individuals help needed in "**high" activities of daily living** (finances, transportation, heavy housework, medications). Mildly frail people might have difficulty with shopping or walking outside alone, meal preparation, and housework. Often, they will have **several illnesses** and take multiple medications. This category includes people with **mild dementia**. Their common symptoms include forgetting the details of a recent event, even though they remember the event itself, asking the same question, or telling the same story several times a day and social withdrawal.
❑		**Moderately Frail *(category 6)*** Individuals need help with **all outside activities** and with **keeping house**. Inside, they often have **problems with stairs** and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing. If a memory problem causes the dependency, often recent memory will be very impaired, even though they seemingly can remember their past life events well.
❑		**Severely Frail *(category 7)*** Completely dependent on others for all or most personal activities of daily living, such as dressing and feeding.
❑		**Very Severely Frail *(category 8)*** Completely dependent, approaching the end of life. Typically, people in this category could not recover from even a minor illness.

ACCEPT Questionnaire (PT version)
ACS 12 June2014 Final
3/15

Health Literacy (REALM)

Health Literacy is a key determinant to preferences for EOL treatment. We are using a validated short item questionnaire to measure health literacy, the REALM tool. REALM is a medical-word recognition and pronunciation test comprising of medical terms arranged in order of complexity by the number of syllables and pronunciation difficulty.

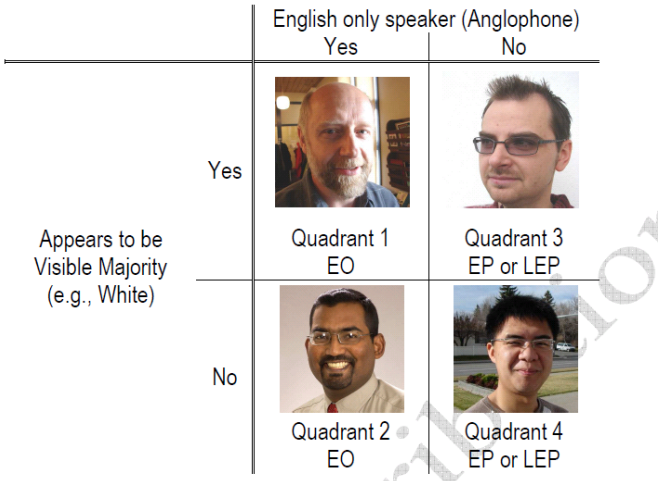
1) Provide the respondent with the reference card (CARD 1).
2) Ask the respondent to read down the list, pronouncing aloud as many words as they can.
3) As the respondent reads the list, the interviewer scores the number of words pronounced correctly. (It is not important to know which words are correct, rather it is important to capture the number of correctly pronounced words.)

Note: if a respondent is legally blind, omit this section from the administration of the questionnaire.

Ethnicity and Language

Recording ethnicity is quite problematic and providing long lists of various ethnic groups, like we have in past survey data, has not yielded valid results. We are trying a novel method for determining the impact of 'ethnicity' on access to health care resources. It turns out that disparities are most related to whether you appear as a visible minority and speak another language, other than the 2 official languages of Canada.

Figure 1: The multicultural population



English only: EO; English proficient: EP; Limited English proficient: LEP

We will categorize patients as to whether they appear to be Caucasian (this should be discerned by appearance) and by asking the patient if they are proficient in another language other than English (or French if in Quebec). In the end, we will want to be able to categorize patients (Or family members) in one of the 4 quadrants below (See Figure 1).

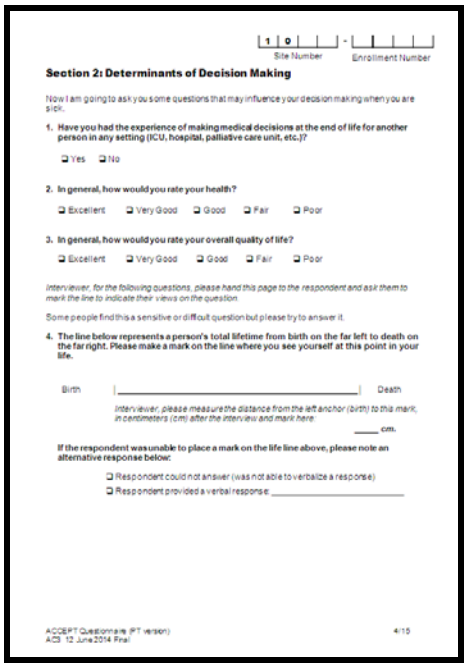
Frailty Estimation

Complete the frailty estimation by considering the patient's overall condition <u>two (2) weeks</u> prior to this admission to the hospital. The respondent can be provided with the applicable reference card (CARD 2).

In instances when an interview is conducted with both the patient and their family member, there may be a discrepancy between what is reported by the respondents. In these cases, always use the patient's (i.e. self-report) response.

Section 2: Determinants of Decision Making

Section 2 contains a number of questions that may relate to the respondent's preferences for EOL care. We will want to capture these data points and analyze them afterwards to see if we can better understand what the key determinants are to preferred care at the end of life.



1 0 | | | - | | | | |
Site Number Enrollment Number

Section 2: Determinants of Decision Making

Now I am going to ask you some questions that may influence your decision making when you are sick.

1. **Have you had the experience of making medical decisions at the end of life for another person in any setting (ICU, hospital, palliative care unit, etc.)?**

❑ Yes ❑ No

2. **In general, how would you rate your health?**

❑ Excellent ❑ Very Good ❑ Good ❑ Fair ❑ Poor

3. **In general, how would you rate your overall quality of life?**

❑ Excellent ❑ Very Good ❑ Good ❑ Fair ❑ Poor

Interviewer, for the following questions, please hand this page to the respondent and ask them to mark the line to indicate their views on the question.

Some people find this a sensitive or difficult question but please try to answer it.

4. **The line below represents a person's total lifetime from birth on the far left to death on the far right. Please make a mark on the line where you see yourself at this point in your life.**

Birth _____ Death

Interviewer, please measure the distance from the left anchor (birth) to this mark, in centimeters (cm) after the interview and mark here:

____ cm.

If the respondent was unable to place a mark on the life line above, please note an alternative response below:

❑ Respondent could not answer (was not able to verbalize a response)
❑ Respondent provided a verbal response: _____

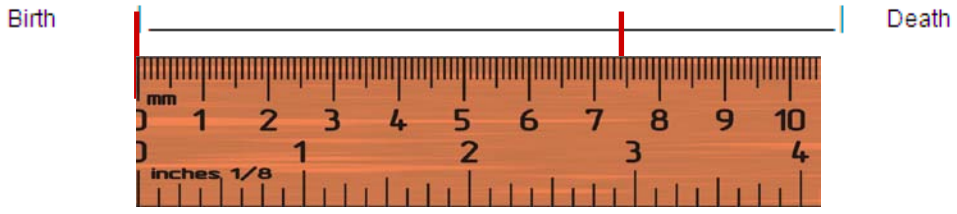
ACCEPT Questionnaire (PT version)
ACS 12 June 2014 Final 4/15

Lifetime Line (Question #4)

When administering question #4, read the question to the respondent, then:

1) Pass the questionnaire over to the respondent and ask them to place a mark (i.e. a line not an 'x') on the life line indicating where they feel they are at this point in their life.
2) After the interview, measure the distance from the 'Birth' anchor to the respondent's mark.
3) Record the distance to the nearest millimeter. See below for an example.

4. The line below represents a person's total lifetime from birth on the far left to death on the far right. Please make a mark on the line where you see yourself at this point in your life.



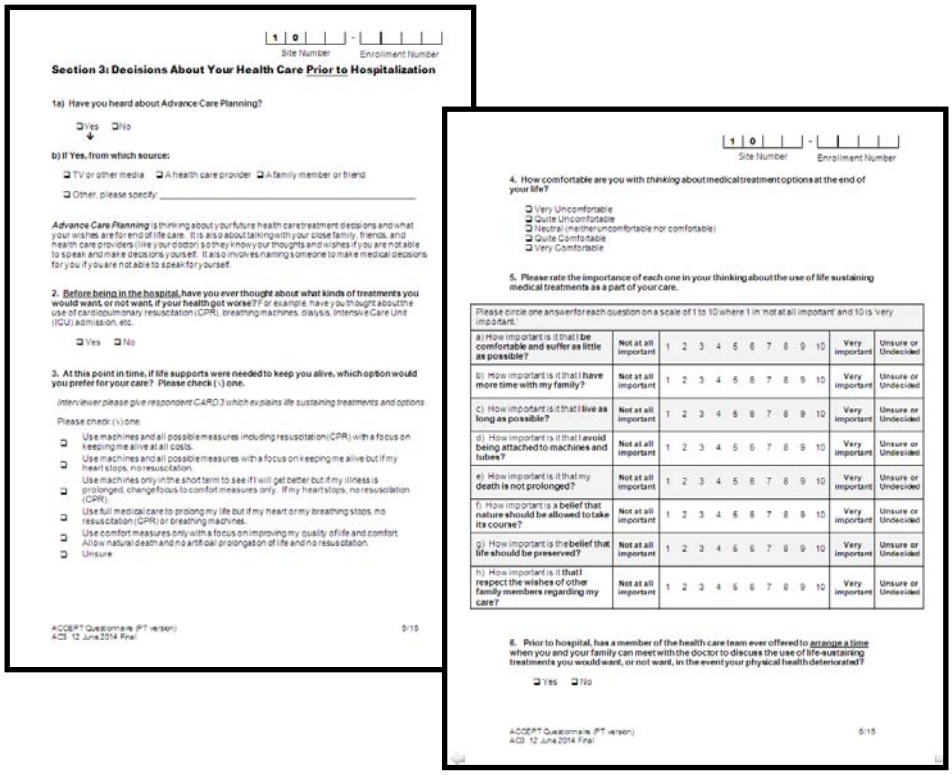
Interviewer, please measure the distance from the left anchor (birth) to this mark, in centimeters (cm) after the interview and mark here: 7.4 cm.

Some interviewers have noted that this is a particularly difficult question for respondents to answer. Some respondents do not make a mark but indicate verbally their response (e.g. 3 years left to live) or they simply cannot provide a response. If at the life-line is not used please note one of the following:

- ❑ Respondent could not answer (was not able to verbalize a response)
- ❑ Respondent provided a verbal response: _____

Section 3: Decisions About Your Health Care *Prior to* Hospitalization

In this section, we are trying to ascertain whether the respondent has engaged in ACP ***prior*** *to* hospitalization.



Site Number | Enrollment Number

Section 3: Decisions About Your Health Care Prior to Hospitalization

1a) Have you heard about Advance Care Planning?

❑Yes ❑No

b) If Yes, from which source:

❑ TV or other media ❑ A health care provider ❑ A family member or friend

❑ Other, please specify: _____

Advance Care Planning is thinking about your future health care treatment decisions and what your wishes are for end of life care. It is also about talking with your close family, friends, and health care providers (like your doctor) so they know your thoughts and wishes if you are not able to speak and make decisions yourself. It also involves naming someone to make medical decisions for you if you are not able to speak for yourself.

2. Before being in the hospital, have you ever thought about what kinds of treatments you would want, or not want, if your health got worse? For example, have you thought about the use of cardiopulmonary resuscitation (CPR), breathing machines, dialysis, Intensive Care Unit (ICU) admission, etc.

❑ Yes ❑ No

3. At this point in time, if life supports were needed to keep you alive, which option would you prefer for your care? Please check (√) one.

Interviewer please give respondent CARD 3 which explains life sustaining treatments and options

Please check (√) one.

- ❑ Use machines and all possible measures including resuscitation (CPR) with a focus on keeping me alive at all costs.
- ❑ Use machines and all possible measures with a focus on keeping me alive but if my heart stops, no resuscitation.
- ❑ Use machines only in the short term to see if I will get better but if my illness is prolonged, change focus to comfort measures only. If my heart stops, no resuscitation (CPR).
- ❑ Use full medical care to prolong my life but if my heart or my breathing stops, no resuscitation (CPR) or breathing machines.
- ❑ Use comfort measures only with a focus on improving my quality of life and comfort. Allow natural death and no artificial prolongation of life and no resuscitation.
- ❑ Unsure

ACCEPT Questionnaire (PT version) ACS 12 June 2014 Final 5/15

Site Number | Enrollment Number

4. How comfortable are you with *thinking* about medical treatment options at the end of your life?

- ❑ Very Uncomfortable
- ❑ Quite Uncomfortable
- ❑ Neutral (neither uncomfortable nor comfortable)
- ❑ Quite Comfortable
- ❑ Very Comfortable

5. Please rate the importance of each one in your thinking about the use of life sustaining medical treatments as a part of your care.

Please circle one answer for each question on a scale of 1 to 10 where 1 in 'not at all important' and 10 is 'very important.'													
a) How important is it that I **be comfortable and suffer as little as possible?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
b) How important is it that I **have more time with my family?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
c) How important is it that I **live as long as possible?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
d) How important is it that I **avoid being attached to machines and tubes?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
e) How important is it that my **death is not prolonged?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
f) How important is a **belief that nature should be allowed to take its course?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
g) How important is the **belief that life should be preserved?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided
h) How important is it **that I respect the wishes of other family members regarding my care?**	Not at all important	1	2	3	4	5	6	7	8	9	10	Very important	Unsure or Undecided

6. Prior to hospital, has a member of the health care team ever offered to arrange a time when you and your family can meet with the doctor to discuss the use of life-sustaining treatments you would want, or not want, in the event your physical health deteriorated?

❑ Yes ❑ No

ACCEPT Questionnaire (PT version) ACS 12 June 2014 Final 6/15

Question #3

It is important that the respondent understand the concept of 'life sustaining treatments' first mentioned in questions #2, 3 and in subsequent questions. Before asking question #3 give the respondent CARD 3 which explains life sustaining treatment options, so we can be sure they know what we are referring to.

Question #7

If the respondent has answered 'yes' they have discussed their preferences for using or not using life sustaining treatments with someone, proceed with asking the questions presented in the table. Each table row asks whether the respondent engaged in these with a specific individual (e.g. Family doctor, nurse, lawyer, etc…). If the response is 'yes', follow-up questions

are asked regarding some of the details surrounding the discussion (e.g. how often, when they last spoke about this matter and under what circumstances).

Individual preferences were discussed with

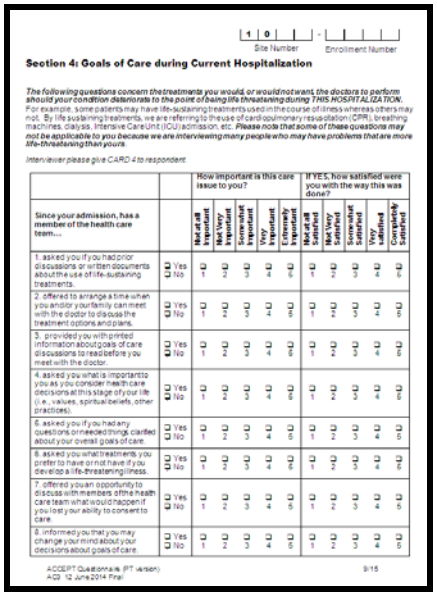
Details regarding the discussion

	Have you had a discussion?	**If Yes, how often?**	If Yes, When was the last time you discussed these preferences with your _____	Do you remember what was the trigger or what precipitated the conversation? (circle all that apply)	Location of conversation
		1. Once 2. A few times	1. More than a year ago 2. Within the last	1. Previous personal health crisis or deterioration in health 2. Previous experience with EOL	1. Home 2. Hospital 3. ER

Respondents may have had a conversation with a family member who is also their surrogate decision maker and their responses to the details of this (these) conversation(s) may be the same.

Section 4: Goals of Care During Current Hospitalization

This section is trying to determine the respondent's perspective on communication and decision making about the use of life sustaining treatments while in hospital (during **current hospitalization**, not prior to hospital or previous hospitalization). If respondents refer to previous conversations outside the current hospitalization, please keep directing them back to conversations and events during the current hospitalization.



Site Number | Enrollment Number

Section 4: Goals of Care during Current Hospitalization

The following questions concern the treatments you would, or would not want, the doctors to perform should your condition deteriorate to the point of being life threatening during THIS HOSPITALIZATION. For example, some patients may have life-sustaining treatments used in the course of illness whereas others may not. By life sustaining treatments, we are referring to the use of cardiopulmonary resuscitation (CPR), breathing machines, dialysis, Intensive Care Unit (ICU) admission, etc. *Please note that some of these questions may not be applicable to you because we are interviewing many people who may have problems that are more life-threatening than yours.*

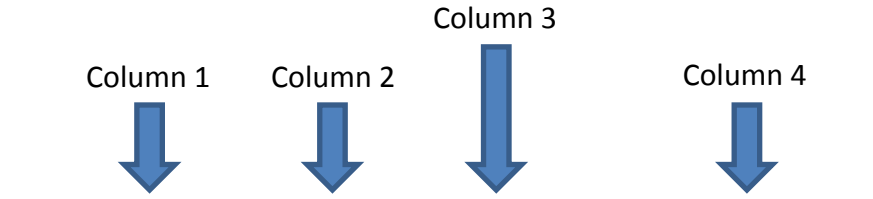
Interviewer please give CARD 4 to respondent

Since your admission, has a member of the health care team....		How important is this care issue to you?					If YES, how satisfied were you with the way this was done?				
		Not at all Important	Not Very Important	Somewhat Important	Very Important	Extremely Important	Not at all Satisfied	Not Very Satisfied	Somewhat Satisfied	Very Satisfied	Completely Satisfied
1. asked you if you had prior discussions or written documents about the use of life-sustaining treatments.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. offered to arrange a time when you and/or your family can meet with the doctor to discuss the treatment options and plans.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. provided you with printed information about goals of care discussions to read before you meet with the doctor.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. asked you what is important to you as you consider health care decisions at this stage of your life (i.e., values, spiritual beliefs, other practices).	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. asked you if you had any questions or needed things clarified about your overall goals of care.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. asked you what treatments you prefer to have or not have if you develop a life-threatening illness.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. offered you an opportunity to discuss with members of the health care team what would happen if you lost your ability to consent to care.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. informed you that you may change your mind about your decisions about goals of care.	☐ Yes ☐ No	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ACCEPT Questionnaire (PT version)
ACQ 12 June 2014 Final 9/15

Questions #1-14

Prior to starting this section, provide the respondent with CARD 4 options and explain the potential responses.

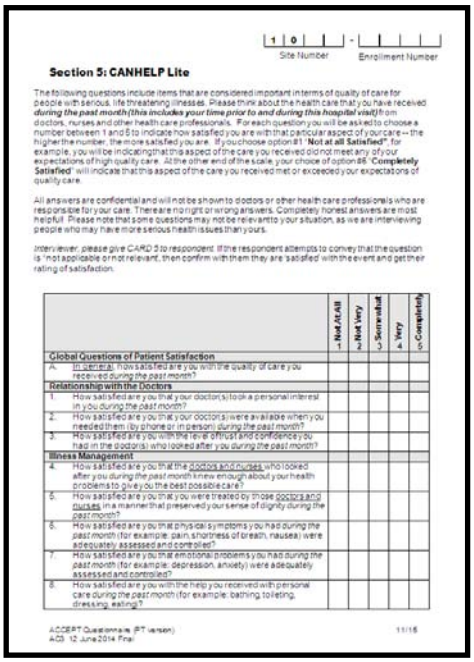


		How important is this care issue to you?					If YES, how satisfied were you with the way this was done?				
Since your admission, has a member of the health care team…		**Not at all Important**	**Not Very Important**	**Somewhat Important**	**Very Important**	**Extremely Important**	**Not at all Satisfied**	**Not Very Satisfied**	**Somewhat Satisfied**	**Very satisfied**	**Completely Satisfied**
1. asked you if you had prior discussions or written documents about the use of life-sustaining treatments.	❑ Yes ❑ No	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
2. offered to arrange a time when you and/or your family can meet with the doctor to discuss the treatment options and plans.	❑ Yes ❑ No	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
3. provided you with printed information about goals of care	❑ Yes										

- For each question in this section (column 1), first, you are asking the respondent 'Did this happen, yes or no?" (response provided in column 2).
- Next, we are interested in the perspective of the respondent, "How important is the case issue to them" (response provided in column 3).
- Next, we are interested in the perspective of the respondent, "How satisfied they were…" (response provided in column 4).
    - *NOTE: If the response to column 2 is "no" this question is not applicable.*

Section 5: CANHELP Lite

The CANHELP questionnaire is a formal, validated satisfaction with EOL care measurement tool. This questionnaire actually has 42 questions and several subscales but to shorten the interview time, we are only using the validated subscales pertinent to ACP.



1 0 | | - | | | |
Site Number Enrollment Number

Section 5: CANHELP Lite

The following questions include items that are considered important interms of quality of care for people with serious, life threatening illnesses. Please think about the health care that you have received ***during the past month (this includes your time prior to and during this hospital visit)*** from doctors, nurses and other health care professionals. For each question you will be asked to choose a number between 1 and 5 to indicate how satisfied you are with that particular aspect of your care – the higher the number, the more satisfied you are. If you choose option #1 '**Not at all Satisfied**", for example, you will be indicating that this aspect of the care you received did not meet any of your expectations of high quality care. At the other end of the scale, your choice of option #5 '**Completely Satisfied**' will indicate that this aspect of the care you received met or exceeded your expectations of quality care.

All answers are confidential and will not be shown to doctors or other health care professionals who are responsible for your care. There are no right or wrong answers. Completely honest answers are most helpful! Please note that some questions may not be relevant to your situation, as we are interviewing people who may have more serious health issues than yours.

Interviewer, please give CARD 5 to respondent. If the respondent attempts to convey that the question is 'not applicable or not relevant, then confirm with them they are 'satisfied' with the event and get their rating of satisfaction.

	1 – Not At All	2 – Not Very	3 – Somewhat	4 – Very	5 – Completely
Global Questions of Patient Satisfaction					
A. In general, how satisfied are you with the quality of care you received *during the past month*?					
Relationship with the Doctors					
1. How satisfied are you that your doctor(s) took a personal interest in you *during the past month*?					
2. How satisfied are you that your doctor(s) were available when you needed them (by phone or in person) *during the past month*?					
3. How satisfied are you with the level of trust and confidence you had in the doctor(s) who looked after you *during the past month*?					
Illness Management					
4. How satisfied are you that the doctors and nurses who looked after you *during the past month* knew enough about your health problems to give you the best possible care?					
5. How satisfied are you that you were treated by those doctors and nurses in a manner that preserved your sense of dignity *during the past month*?					
6. How satisfied are you that physical symptoms you had during the *past month* (for example: pain, shortness of breath, nausea) were adequately assessed and controlled?					
7. How satisfied are you that emotional problems you had *during the past month* (for example: depression, anxiety) were adequately assessed and controlled?					
8. How satisfied are you with the help you received with personal care *during the past month* (for example: bathing, toileting, dressing, eating)?					

ACCERT Questionnaire (PT version) 11/15
ACQ 12 June 2014 Final

Before reading the question, show the respondent CARD 5 and explain the response options.
Literally read the instructions at the beginning of the questionnaire. Also, explain that you are asking about their rating of care over the past month, regardless as to where the care occurred (at home, hospital or other location).

Section 6: Barriers & Facilitators

Section 6 offers the respondent an opportunity to share any barriers and/or facilitators they experienced concerning discussions with health care professionals about ACP. Write their response verbatim.

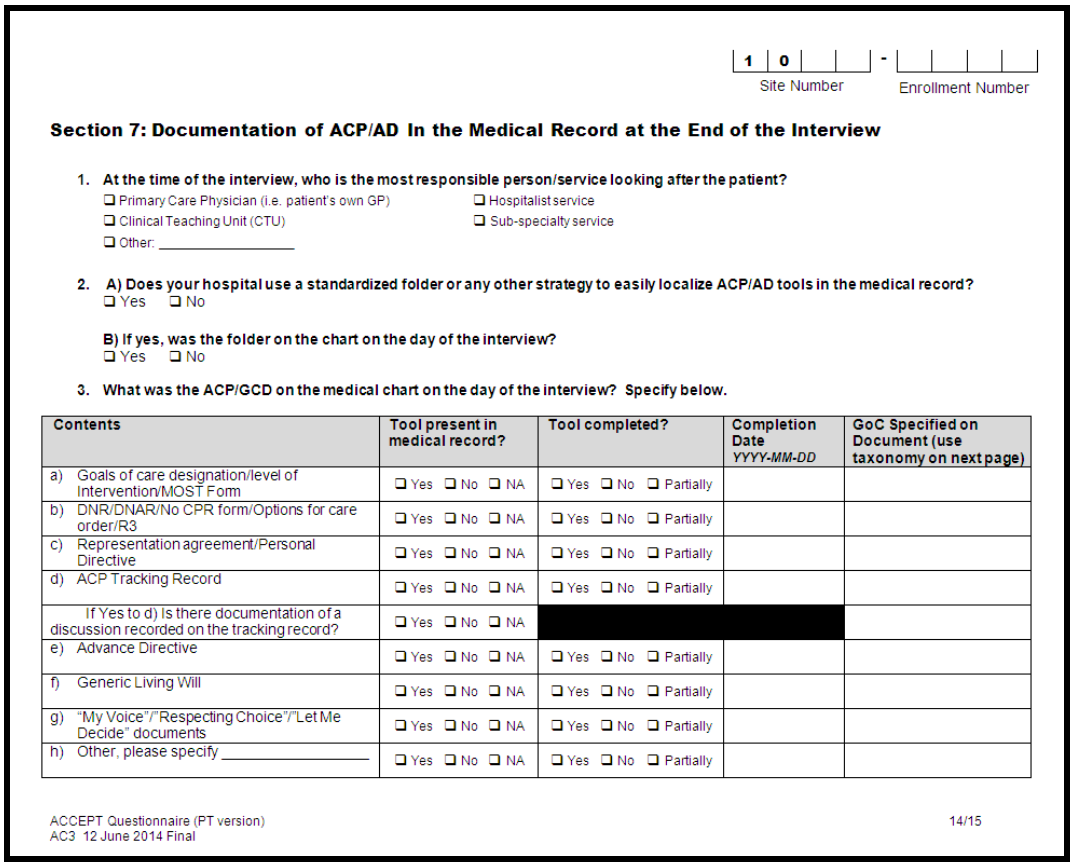
Parting Words to the Respondent at the End of the Interview

You have now completed the respondent interview portion of the ACP questionnaire. (The remaining section involves you going to the patient's medical chart to extract some information. Refer below for details concerning Section 7 of the ACP Questionnaire.)

At the conclusion of the interview please thank the respondent for their time and candor in sharing information about this important topic. If the respondent requests more information regarding ACP please refer them to the appropriate individual on the ward (e.g. Social Worker). It is also advisable to make a Progress Note entry into the patient's medical chart to alert any other members of the patient's care team that an interview regarding ACP was conducted. If agreeable with the ethics committee, the site may also leave behind a pamphlet or fact sheet concerning ACP. The Speak Up campaign has several generic tools that can be used and/or adapted (www.advancecareplanning.ca).

Section 7: Documentation of ACP/AD in the Medical Record at the End of the Interview

The purpose of this section is to record any ACP/AD documents found on the medical record at the time of the interview. This data collection can occur either immediately before the interview or immediately after.



1 0 - Site Number / Enrollment Number

Section 7: Documentation of ACP/AD In the Medical Record at the End of the Interview

1. **At the time of the interview, who is the most responsible person/service looking after the patient?**
   - ❑ Primary Care Physician (i.e. patient's own GP)
   - ❑ Hospitalist service
   - ❑ Clinical Teaching Unit (CTU)
   - ❑ Sub-specialty service
   - ❑ Other: _____

2. **A) Does your hospital use a standardized folder or any other strategy to easily localize ACP/AD tools in the medical record?**
   ❑ Yes ❑ No

   B) If yes, was the folder on the chart on the day of the interview?
   ❑ Yes ❑ No

3. **What was the ACP/GCD on the medical chart on the day of the interview? Specify below.**

Contents	Tool present in medical record?	Tool completed?	Completion Date *YYYY-MM-DD*	GoC Specified on Document (use taxonomy on next page)
a) Goals of care designation/level of Intervention/MOST Form	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
b) DNR/DNAR/No CPR form/Options for care order/R3	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
c) Representation agreement/Personal Directive	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
d) ACP Tracking Record	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
If Yes to d) Is there documentation of a discussion recorded on the tracking record?	❑ Yes ❑ No ❑ NA			
e) Advance Directive	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
f) Generic Living Will	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
g) "My Voice"/"Respecting Choice"/"Let Me Decide" documents	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		
h) Other, please specify _____	❑ Yes ❑ No ❑ NA	❑ Yes ❑ No ❑ Partially		

ACCEPT Questionnaire (PT version)
AC3 12 June 2014 Final
14/15

If both the patient and family member are interviewed, section 7 should be completed at the point of <u>first</u> contact. (i.e. after the first interview).

If blank documents are found in the medical chart (e.g. goals of care form, tracking record or My Voice workbook) they should be indicated as 'not present' in Section 7 of the questionnaire.

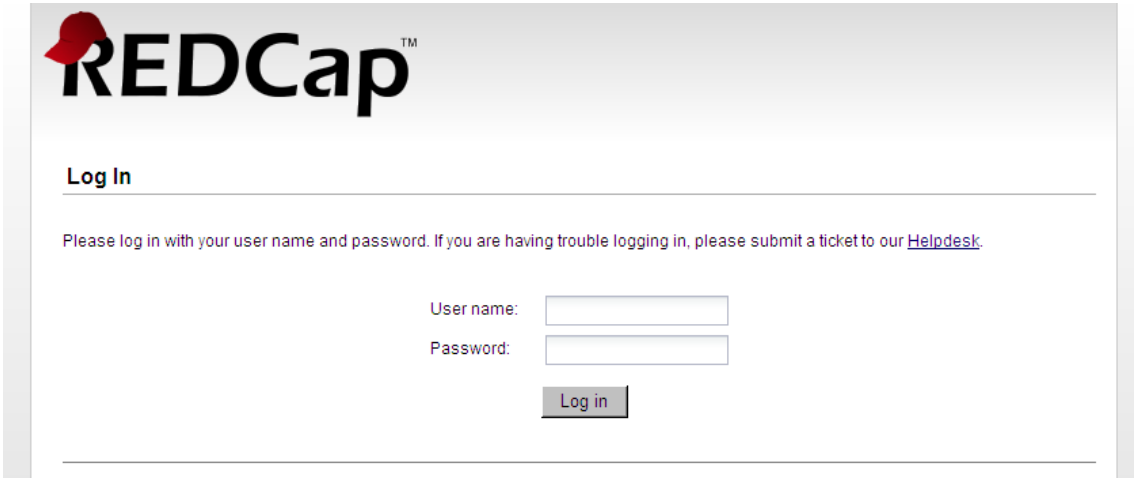
Some interviewers have noted that responses provided to them during the interview are not consistent with what is found documented in the medical chart. E.g. a patient indicates that they do not have any advance directives but a DNR form is found on the medical chart. This is an observational study, our role is to collect data and see what happens over the course of the patient's stay. Do not intervene with the respondent and try to correct any inconsistencies.

The only reason a study team member should intervene is if the patient experiences emotional/psychological trauma, induced by our interview, and help from the clinical team is required to deal with the situation.

REDCap (Data Entry)

REDCap is a web-based system that will be used as the ACCEPT Study database. REDCap may be accessed directly at:

https://ceru.hpcvl.queensu.ca/EDC/redcap/.



Once a respondent has been enrolled using the CRS, the study enrollment number will automatically be inserted into the REDCap database.

The following data must be entered into REDCap:

- Institutional Level Data (Assessment of Degree of System Implementation)
- Patient ACP Questionnaire
- Family Member ACP Questionnaire
- Case Report Form

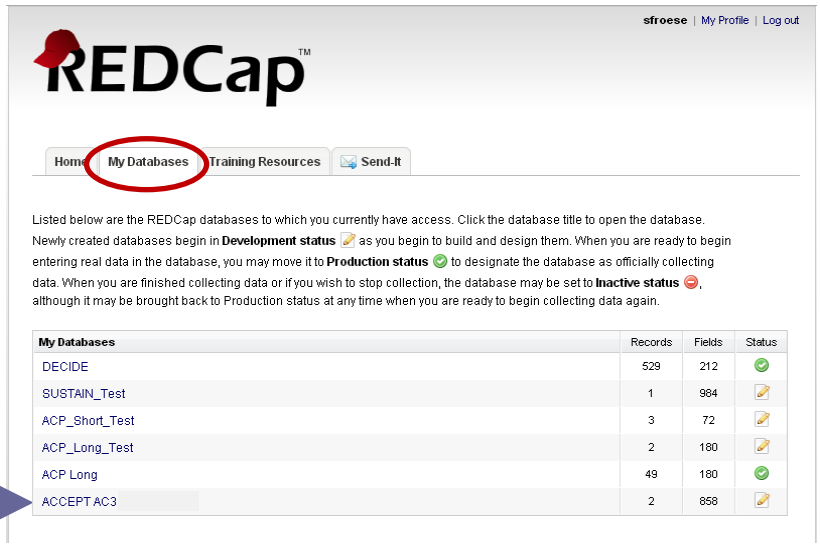
Basic Navigation

Each user can log into REDCap using the user ID and password assigned to them by the Project Leader at CERU.

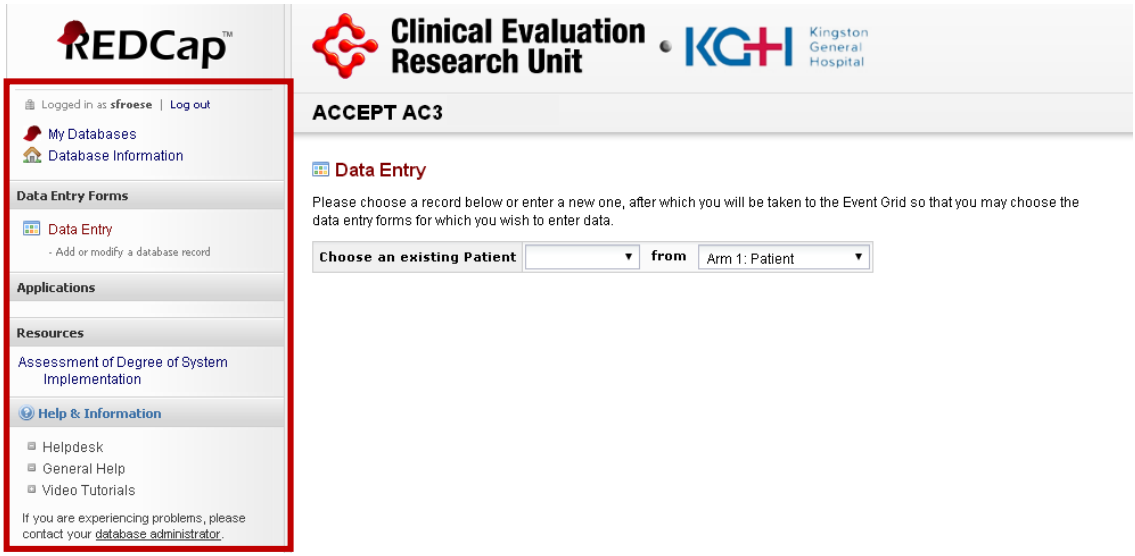
Your user password can be changed at any time by clicking “My Profile” after logging into REDCap.

After you log into REDCap, you will be brought to the Home screen. Select the "My Databases" tab to see a list of the CERU studies you have access to.

Select "ACCEPT AC3"

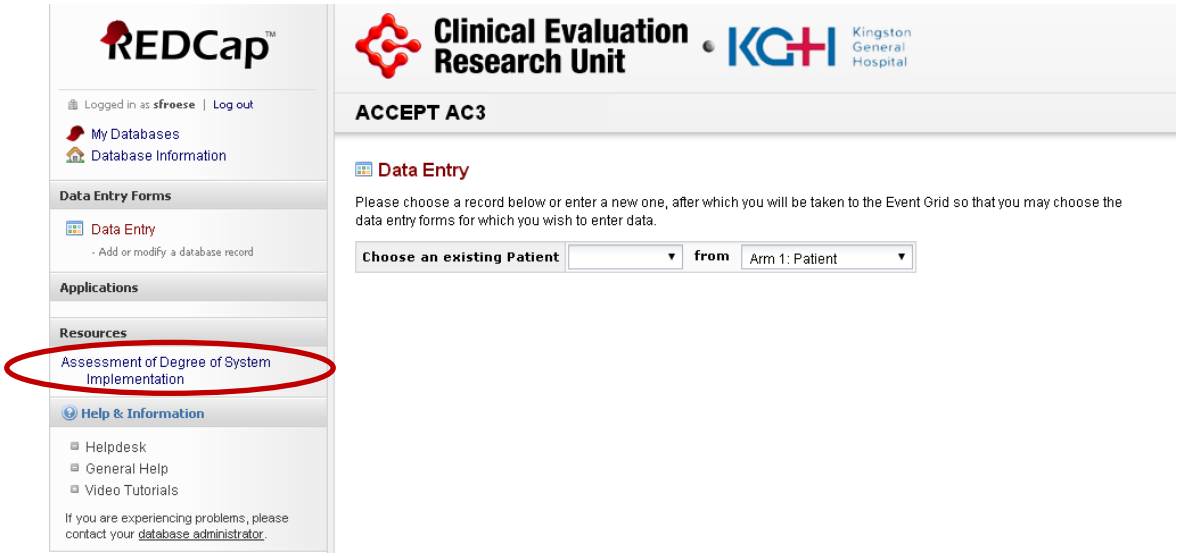


The left side of the screen is the main navigation panel.



Institution Level Data

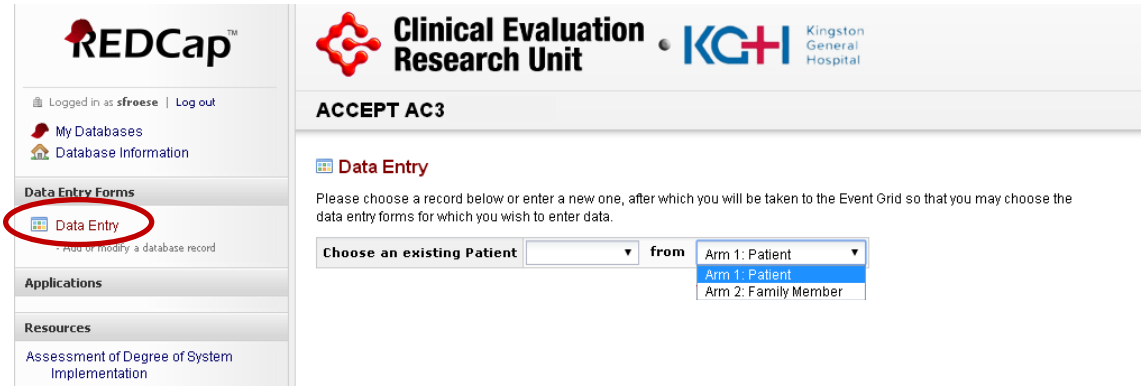
Select the "Assessment of Degree of System Implementation (ADSI)" link under the "Resources" heading to enter the responses to the questionnaire. Partially completed forms cannot be saved. All data must be entered at **one time**.



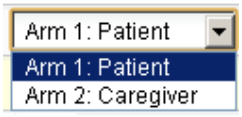
See page 32 for information regarding completion of the Institutional Level Data form.

Patient/Family Member Data

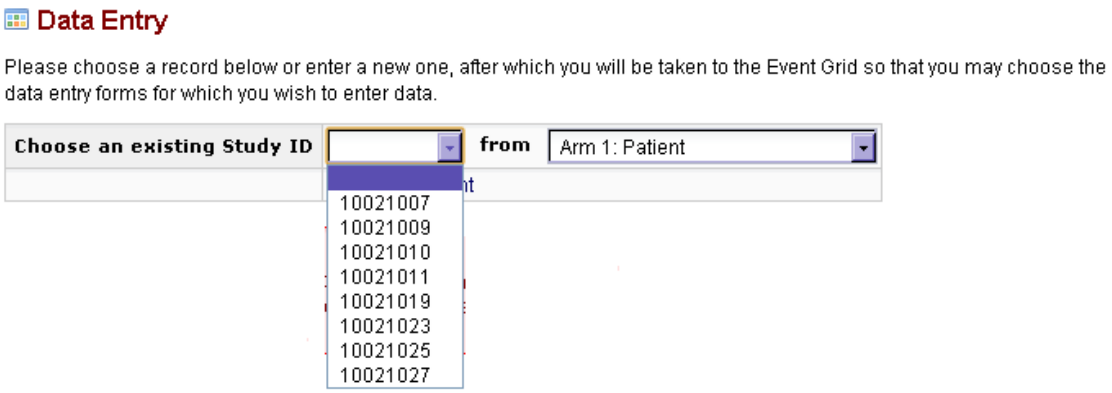
Select "Data Entry" on the left menu to choose from a list of respondents that are enrolled and ready for data entry.



Then use the drop-down menu to select the respondent type.



Once the respondent type is selected, a list of all corresponding enrollments can be found on the drop-down menu to the left.

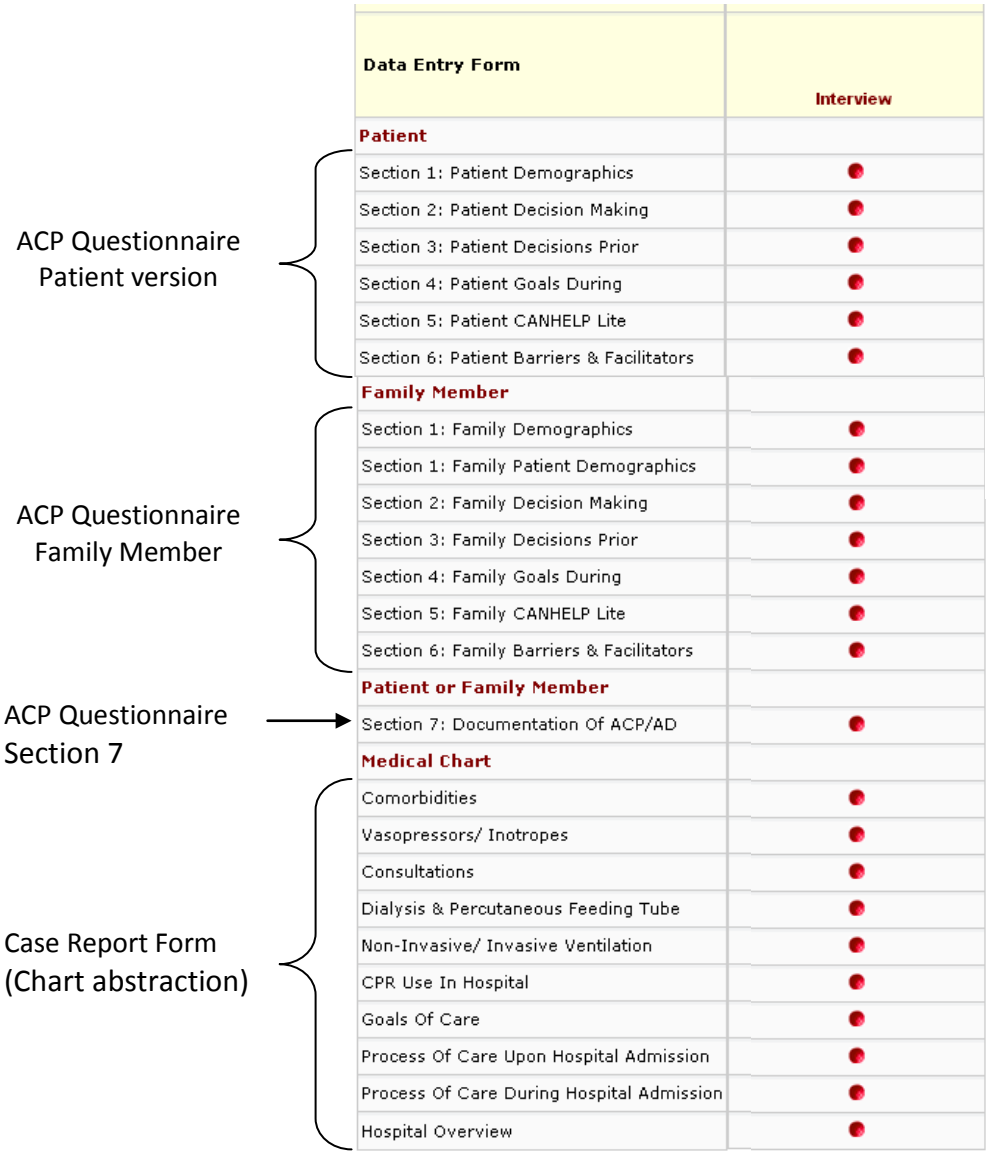


The enrollment numbers are added to REDCap once you have entered the inclusion/exclusion data into the CRS. (Refer to pages 21-29 for further details on enrolling respondents.)

Once an enrollment number is selected you will be brought to the “grid.”

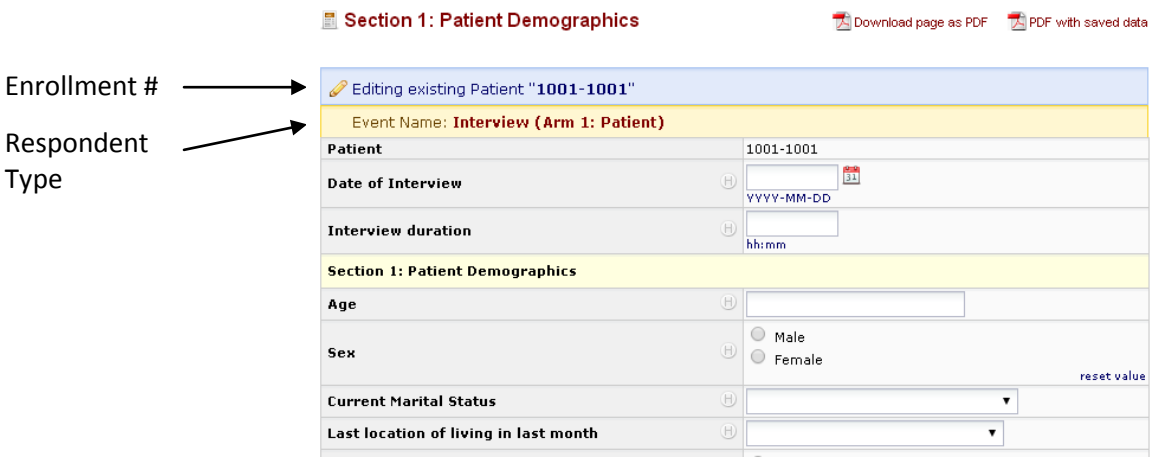
The follow grid lists all of the data required for the corresponding type of respondent:

The required data entry forms for a particular enrollment are identified by a “dot” in the “Events” column of the table.



Data Entry Form	Interview
Patient	
Section 1: Patient Demographics	●
Section 2: Patient Decision Making	●
Section 3: Patient Decisions Prior	●
Section 4: Patient Goals During	●
Section 5: Patient CANHELP Lite	●
Section 6: Patient Barriers & Facilitators	●
Family Member	
Section 1: Family Demographics	●
Section 1: Family Patient Demographics	●
Section 2: Family Decision Making	●
Section 3: Family Decisions Prior	●
Section 4: Family Goals During	●
Section 5: Family CANHELP Lite	●
Section 6: Family Barriers & Facilitators	●
Patient or Family Member	
Section 7: Documentation Of ACP/AD	●
Medical Chart	
Comorbidities	●
Vasopressors/ Inotropes	●
Consultations	●
Dialysis & Percutaneous Feeding Tube	●
Non-Invasive/ Invasive Ventilation	●
CPR Use In Hospital	●
Goals Of Care	●
Process Of Care Upon Hospital Admission	●
Process Of Care During Hospital Admission	●
Hospital Overview	●

Click on the “dot” to open up a particular form.



Data Conventions in REDCap

- Dates should be entered using the YYYY - MM - DD format i.e. 2010 - 07 - 24. A drop-down calendar is available to enter dates. Single "click" on the icon and choose the appropriate month and year from the drop down boxes. Then "click" the appropriate day.
- Enter all times using the HH:MM 24-hour period format i.e. 22:37. **The colon must be entered.** Use leading zeros where applicable i.e. 01:28.
- Midnight should be entered as 00:00
- To access individual forms single click the corresponding "dot" on the event grid.
- To enter data directly into each field, **single click** on the left side of the mouse pointer and type information. Do NOT press enter after entering data into a field. This will cause the form to automatically save and bring you to a new screen that will allow you to return to the Event Grid.
- There should be NO blanks. If a respondent 'declined' to answer a question use the 'declined' response option. If a response is 'missing' use the 'missing' response option.

Saving Data

There are several options at the end of each form to save your progress:

Save and go to …. - This will save the form and automatically take you to the next form, without going to the grid.

Save and go to Grid - option will bring you to a screen confirming your progress has been saved and it will allow you to return to the Grid.

Save and Stay - option will save your progress and allow you to continue working on that form

Clear Form - will remove all data entered on a form and start over. *Be careful, once a form has been cleared we cannot retrieve previously entered data.*

Cancel - option will take you to the Event Grid screen. All newly entered data will be lost. Only the most recently saved version will remain.

Editing Data

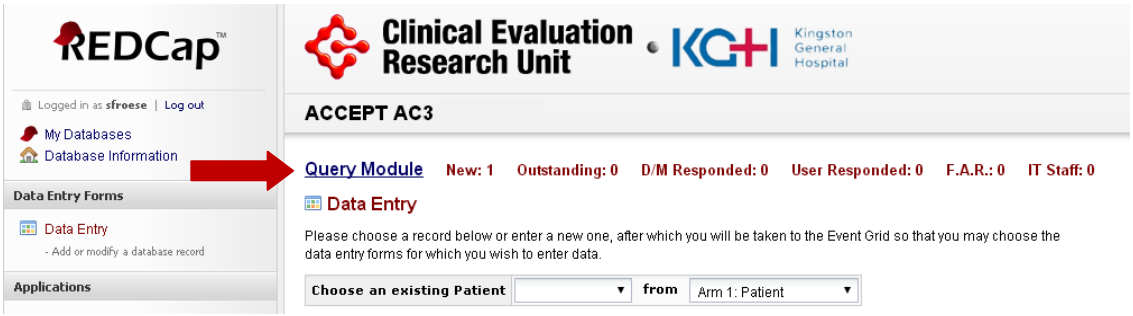
To edit previously saved information, access the appropriate REDCap form, change the appropriate field(s) and save the form. To ensure Good Clinical Practice is maintained, all changes will be tracked and logged by the computer program.

Query System

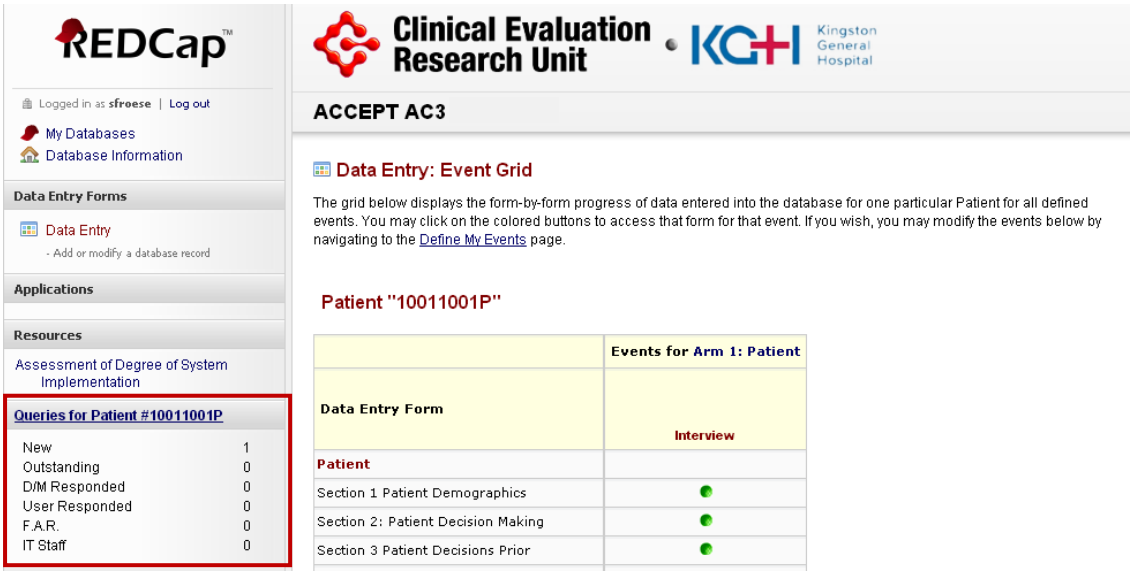
The query module will generate queries for all:

- Blank fields
- Blank forms
- Out of range values
- Date inconsistencies

The Query Module can be viewed by clicking on “Query Module” at the top of the page. This will allow you to see all queries across all patients.



To view all queries related to a specific patient, select an existing Patient ID from the drop down box. Then in the left sidebar you can click on “Queries for Patient…” to view all the queries for that patient.



You are responsible for all “New”, “Outstanding”, and “D/M Responded” queries.

You have two options when responding to queries:

Option 1 – the query is the result of a data entry error or mistake and you need to correct the data.

Option 2 – the data is correct and we would like you to provide confirmation/an explanation.

Query #	Event	Form Name	Error Message	Query Status
208614	Interview	Section 1 Patient Demographics	Missing **Interview Duration**	New

Option 1

1. In the query table click on the Form Name for the query you wish to address to be taken to the form.
2. Enter the corrected data and Save the form.
3. The next time the queries run that query will be removed.

Option 2

1. In the query table click on the Error Message for the query you wish to address.
2. Select the appropriate response from the drop-down list and enter a comment if required.

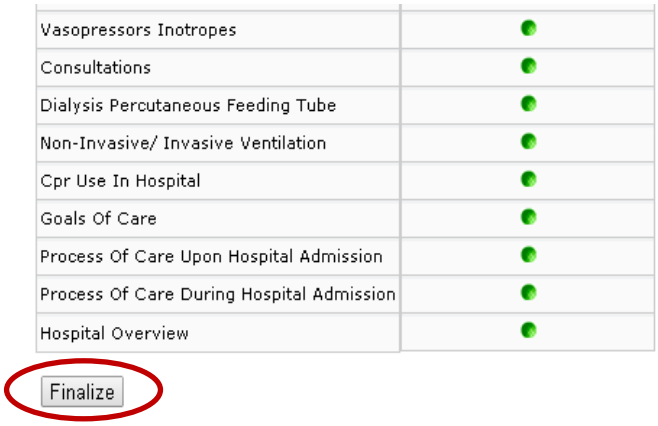
For those response options that require a comment, please provide a meaningful explanation. Data Management reviews the comments and will query you further if:

1. Not enough information is provided
2. Information is contradictory to entered data
3. Explanation unclear

Once all queries have been resolved you will be able to “Finalize” the data.
Please note that Data Management queries will also need to be resolved before the subject can be “Finalized”.

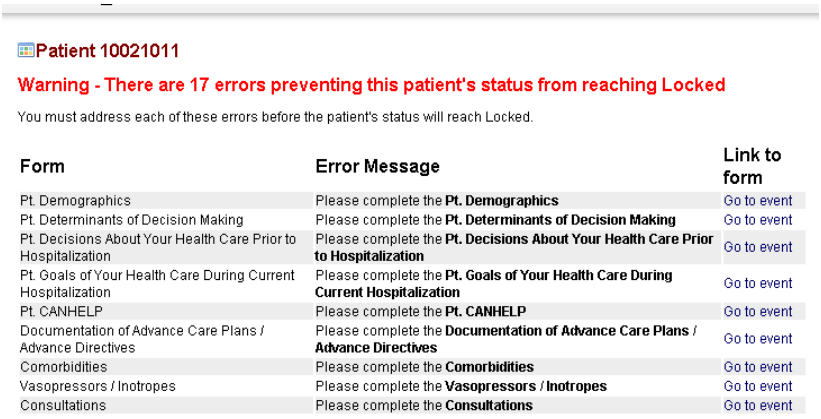
Finalizing Data

Once you have completed all of your data entry for a particular respondent type, you will need to "Finalize" your data. Finalizing your data tells CERU that you have no further work to complete regarding this respondent type.

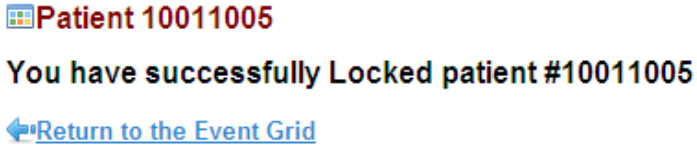


Note that you can only finalize the data once you have completed all the relevant forms for the respondent(s).

After selecting the "Finalize" button, you will be taken to a screen showing you any errors generated by the electronic system.



Each error identified must be addressed before you can lock the data. There is an individual link (Go to event) to the relevant form to address each error noted. Following resolution of all errors, the data will be "Finalized."

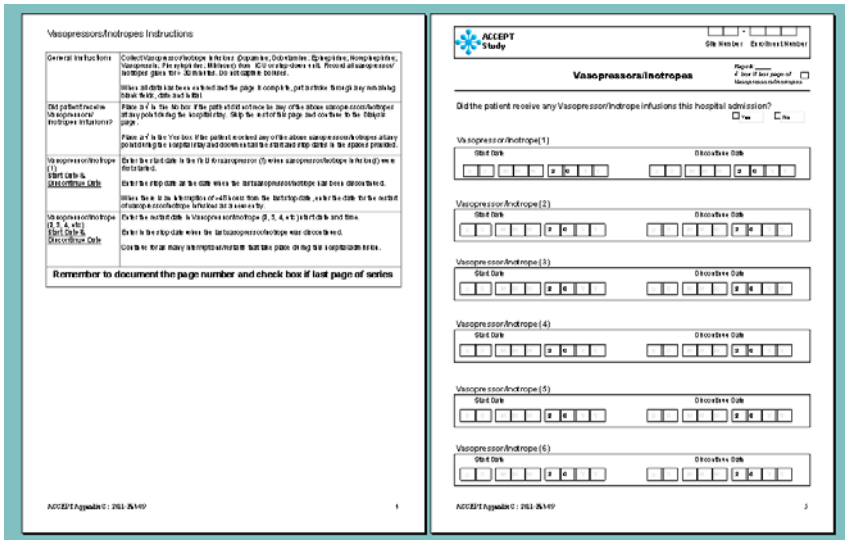


Once data is "Finalized" the site will no longer be able to modify the data. Any required changes must be made through the coordinating centre.

Chart Abstraction - Clinical Data Collection

At this point, the site has identified an eligible respondent (i.e. patient/family member), obtained consent, formally enrolled the respondent and administered the ACP Questionnaire. The next step is to complete the data collection for this respondent (i.e. medical record data abstraction).

Patient clinical data should be extracted from the medical record. We recommend recording the data onto the CRF Worksheets (refer to Carenet website). Though the use of the CRF Worksheets is not mandatory, it is recommended as a tool to facilitate data collection and minimize the need to pull medical charts at a later date. For information regarding the completion of CRF Worksheets, refer to Instructions located on the left-hand page.



Instructions

Worksheet Form

Chart abstraction is required for all types of enrollments (i.e. patient only, family member only, or both patient & family member). If both the patient and family member are enrolled, only one chart abstraction is required and should be entered with the patient's data.

Tips for Completing Chart Abstraction

- Orient yourself to the various sections of the medical chart
    - Paper charting
    - Electronic charting
- Determine any local standards used to document ACP/AD
- Sometimes there are several sources for the same information. Determine where you will always seek this information and <u>be consistent</u>.
  Example, Hospital Admission Date/Time
  The hospital admission date/time for a single patient can be found in several places, each entry may be different:
  - ✓ Arrival note listed on ambulance record
  - ✓ The first entry in the emergency department notes
  - ✓ Date/time logged in the hospital computer system (usually this is the most consistent source of information)

- If you have more than one individual extracting data at your hospital, work together to ensure you are collecting the same types of data in the same way.

For example, Consultations
One research coordinator finds a consult form for Transition Services however there are no notes, therefore the coordinator does not count this as having occurred and there is no entry made in the CRF.
Another research coordinator looking at a different patient chart finds a similar consult form for Transition Services with no notes. S/he feel that since it is in the medical chart it should be included in the data, it gets entered into the CRF.

Both research coordinators are collecting the same data in different ways which can cause inconsistencies across all of the data at their site.

Types of CRF Data

Comprehensive instructions regarding data collection can be found on the left-hand instruction page for each form in the CRF Worksheets. Some brief tips regarding the different types of data follow.

Comorbidities

This information can be found in multiple locations within the medical chart. Look for comorbidities in the admission notes, ED assessments, previous admission notes, progress notes and discharge summaries. Be sure to look at all sources to obtain a complete picture of comorbidities present at the time of hospital admission. Newly diagnosed conditions during the current hospitalization should not be recorded here.

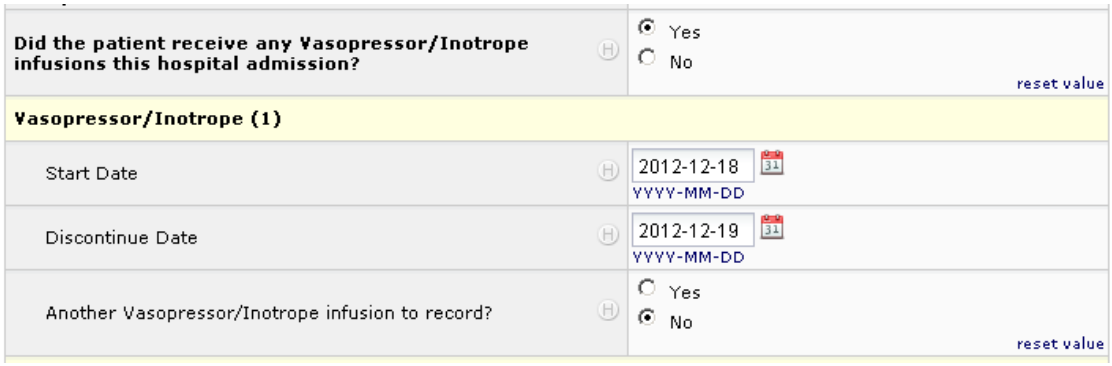
Comorbidities are categorized in the CRF according to body system then illness/condition. Collect only those comorbidities that appear on the CRF form.

Were any comorbidities present?	◉ Yes ○ No reset value
Check off all comorbidities present using the following taxonomy Only those comorbidities found on the taxonomy listing should be recorded	
Myocardial	☐ Angina ☐ Arrhythmia ☐ Valvular ☐ Myocardial infarction ☐ Congestive heart failure (or heart disease)
Vascular	☐ Hypertension ☐ Peripheral vascular disease or claudication ☐ Cerebrovascular disease (Stroke or TIA)
Pulmonary	☑ Chronic obstructive pulmonary disease (COPD, emphysema) ☐ Asthma
Neurologic	☐ Dementia ☐ Hemiplegia (paraplegia) ☐ Neurologic illnesses (such as Multiple sclerosis or Parkinsons)
Endocrine	☑ Diabetes Type I or II ☐ Diabetes with end organ damage ☐ Obesity and/or BMI > 30 (weight in kg/(ht in meters)^2
Renal	☐ Moderate or severe renal disease
Gastrointestinal	☐ Mild liver disease ☐ Moderate or severe liver disease ☐ GI Bleeding ☐ Inflammatory bowel ☐ Peptic ulcer disease ☐ Gastrointestinal Disease (hernia, reflux)

Vasopressors/Inotropes

Collect any of the vasopressor or inotrope infusions (listed on the instruction page) administered during the current hospitalization. Generally vasopressors and inotropes are only administered to patients in the ICU or step-down units, it will be a rare occasion where a patient will be receiving these types of infusions outside of these units.

Record any instance where a vasopressor or inotrope infusion is administered for greater than 30 minutes (do not record boluses). Only start and stop dates of vasopressor and inotrope infusions need to be recorded (i.e. doses are not required). If vasopressors/inotropes were stopped for greater than 48 hrs, then restarted, enter the second instance as a separate episode.



Did the patient receive any Vasopressor/Inotrope infusions this hospital admission?	(•) Yes ( ) No reset value
Vasopressor/Inotrope (1)	
Start Date	2012-12-18 YYYY-MM-DD
Discontinue Date	2012-12-19 YYYY-MM-DD
Another Vasopressor/Inotrope infusion to record?	( ) Yes (•) No reset value

Consultations

List all services that saw the patient during the current hospitalization.

RACE (Rapid Assessment of Critical Event)/Code 66 refers to medical emergent response teams (ie. Code blue teams). There will not likely be an order for the RACE team, but the consult is implied during medical emergencies (ie. codes).

Check yes or no if any of the following consultations were ordered	
RACE Team or Code 66 or Code Blue	○ Yes ◉ No reset value
Critical Care or Critical Care Outreach	○ Yes ◉ No reset value
Home Care/Transition Services	◉ Yes ○ No reset value
Social Work	◉ Yes ○ No reset value
Spiritual Care	○ Yes ◉ No reset value
Palliative Team	○ Yes ◉ No reset value
Palliative Home Care	◉ Yes ○ No reset value
Geriatrics Team	◉ Yes ○ No reset value

Dialysis

Record any new episode of acute renal failure requiring any form of dialysis from the current hospitalization. Record start and stop dates.

Dialysis	
During this hospital admission was there a new onset of renal failure requiring any form of dialysis?	◉ Yes ○ No reset value
Start Date	2012-12-05 YYYY-MM-DD
Was dialysis continuing at the time of hospital discharge?	○ Yes ◉ No reset value
Discontinue Date	2012-12-10 YYYY-MM-DD

Percutaneous Feeding Tube (PEG)

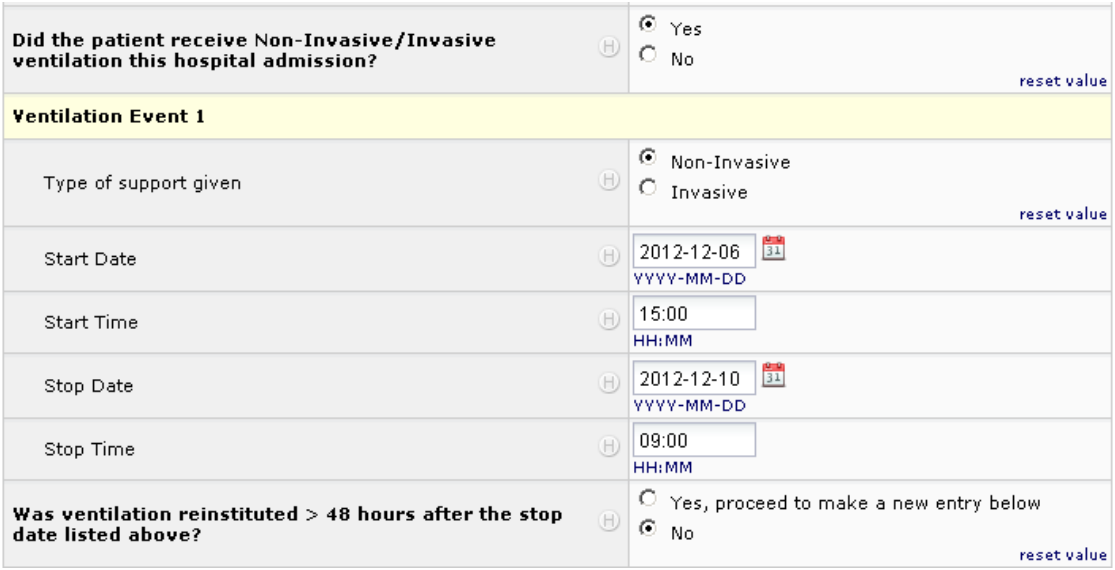
Document any instance where a PEG was inserted and removed during the current hospitalization. If the patient has a nasoenteric or nasogastric tube, do not record.

Percutaneous Feeding Tube	
Did the patient arrive at the hospital with an existing percutaneous feeding tube in place?	○ Yes ◉ No reset value
During this hospital admission did the patient ever have a percutaneous feeding tube inserted?	◉ Yes ○ No reset value
Insertion Date	2012-12-06 YYYY-MM-DD
Was percutaneous feeding still inserted at the time of hospital discharge?	○ Yes ◉ No reset value
Removal Date	2012-12-10 YYYY-MM-DD

Mechanical Ventilation (Non-invasive and Invasive)

Record any instance of invasive or non-invasive mechanical ventilation support during the current hospital stay. Note: Nasal prongs, facemask or supplementation O2 are NOT considered non-invasive ventilation since the patient still breathes spontaneously and not assisted.

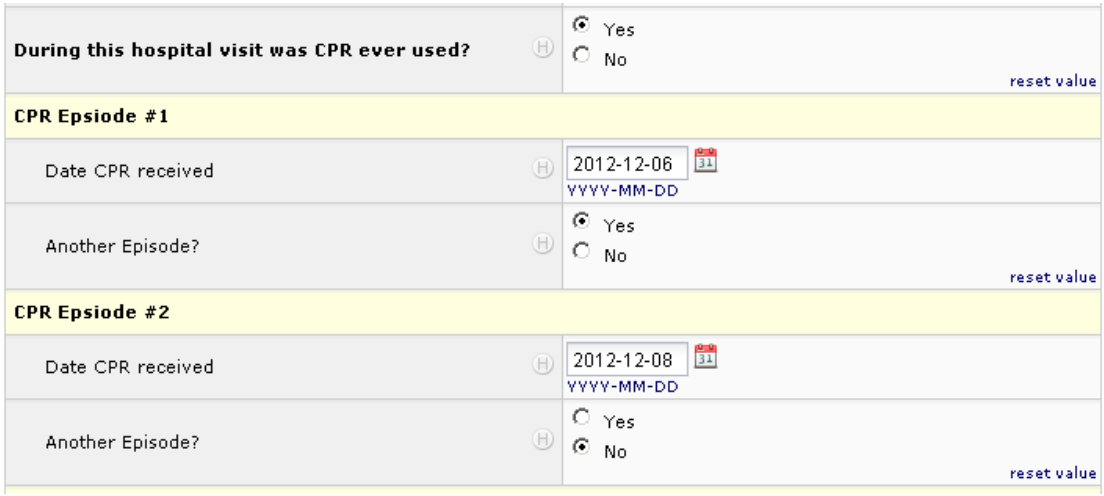
Document the start and stop date/time for each episode of mechanical ventilation. If mechanical ventilation was stopped for greater than 48 continuous hrs, then restarted, enter the second instance as a separate episode.



Did the patient receive Non-Invasive/Invasive ventilation this hospital admission?	◉ Yes ○ No reset value
Ventilation Event 1	
Type of support given	◉ Non-Invasive ○ Invasive reset value
Start Date	2012-12-06 YYYY-MM-DD
Start Time	15:00 HH:MM
Stop Date	2012-12-10 YYYY-MM-DD
Stop Time	09:00 HH:MM
Was ventilation reinstituted > 48 hours after the stop date listed above?	○ Yes, proceed to make a new entry below ◉ No reset value

CPR Use in Hospital

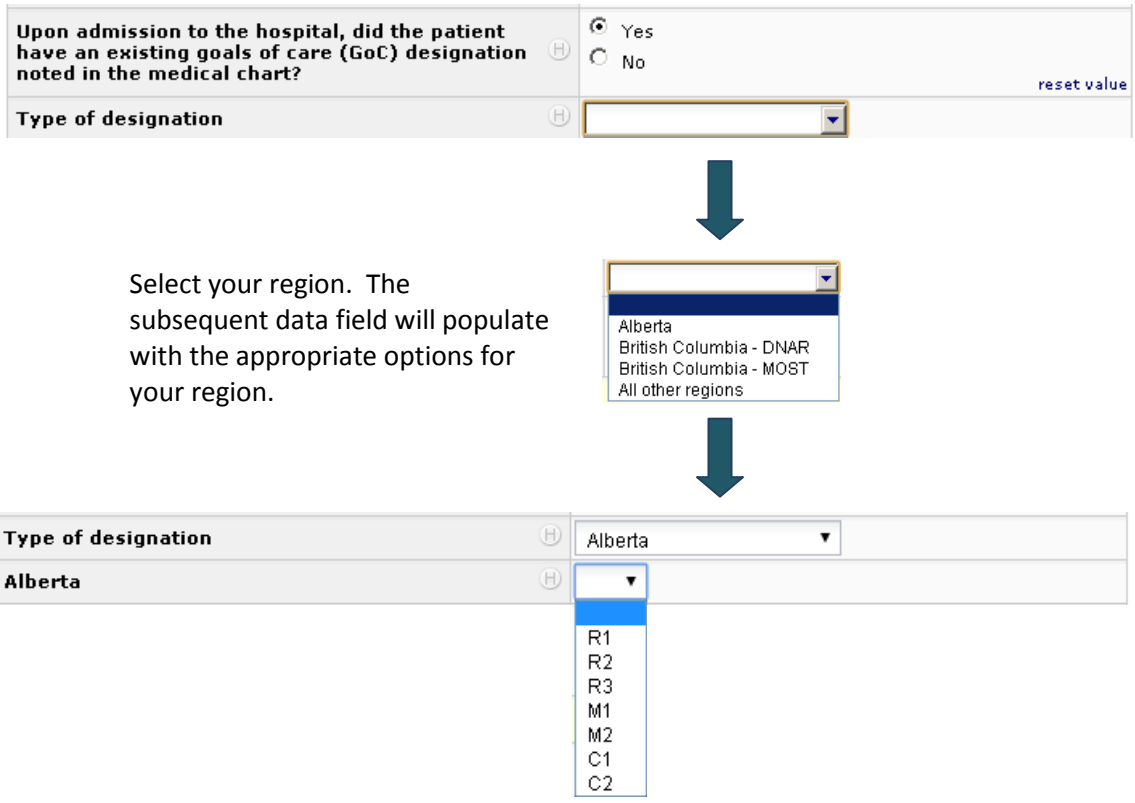
Enter each episode separately. If a patient received CPR multiple times in a single day, document it only once.



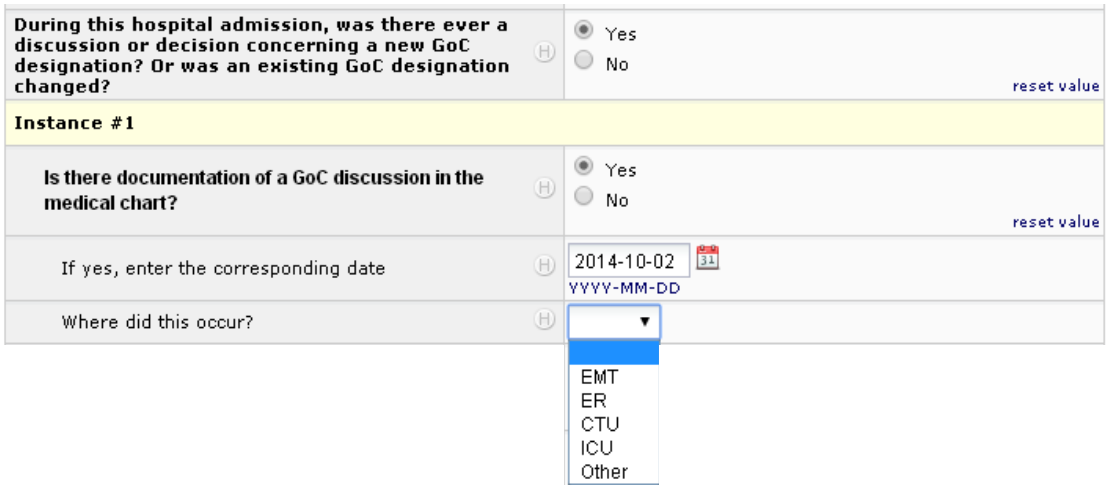
Goals of Care (GoC) Discussions

From the chart, document any goals of care *discussions* and/or goals of care *decisions.*

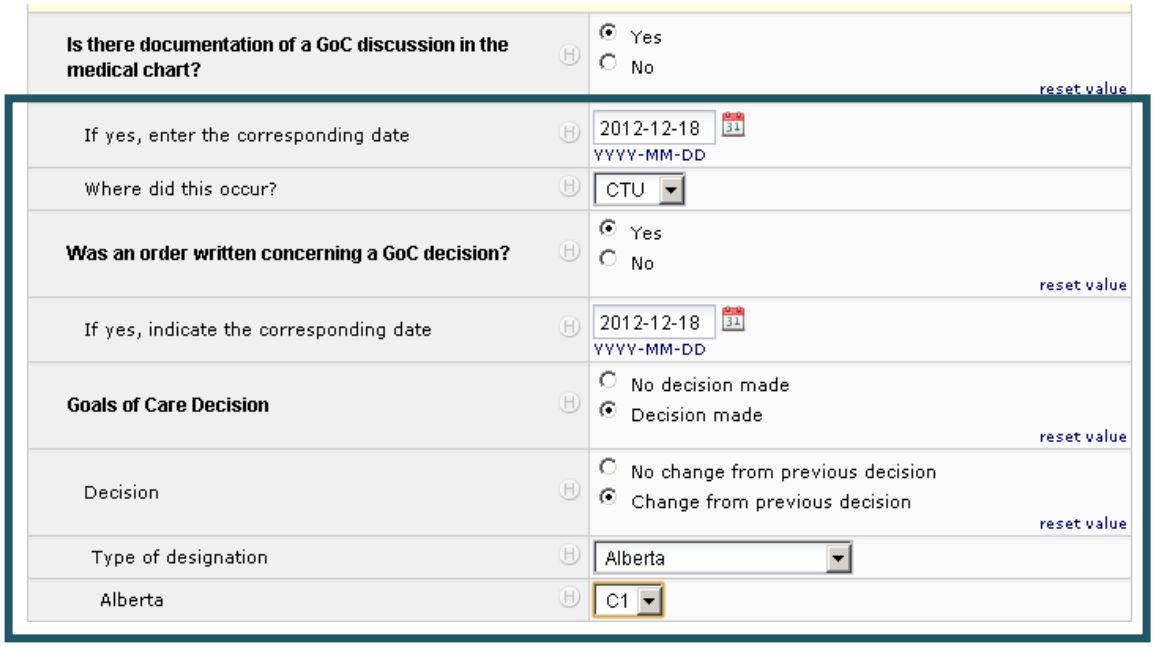
The patient may have a pre-existing goals of care decision noted at the time of admission (e.g. transfer from another hospital where a GoC discussion/decision already occurred).



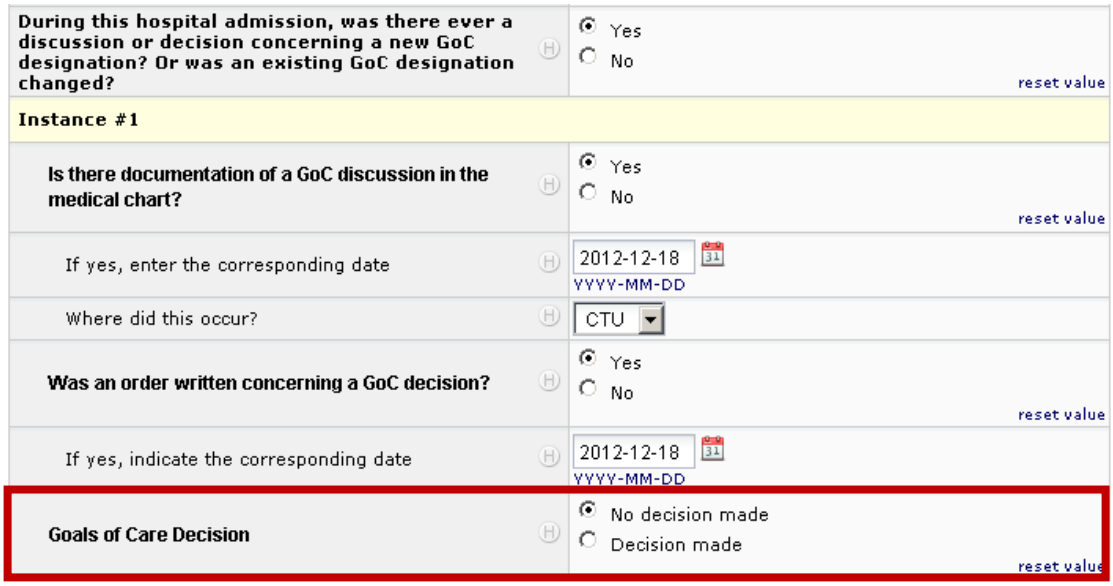
There can be <u>new</u> GoC <u>discussion</u> during the current hospitalization, <u>with</u> or <u>without</u> an associated decision.



Example 1: Documented GoC discussion, <u>with</u> an associated decision.

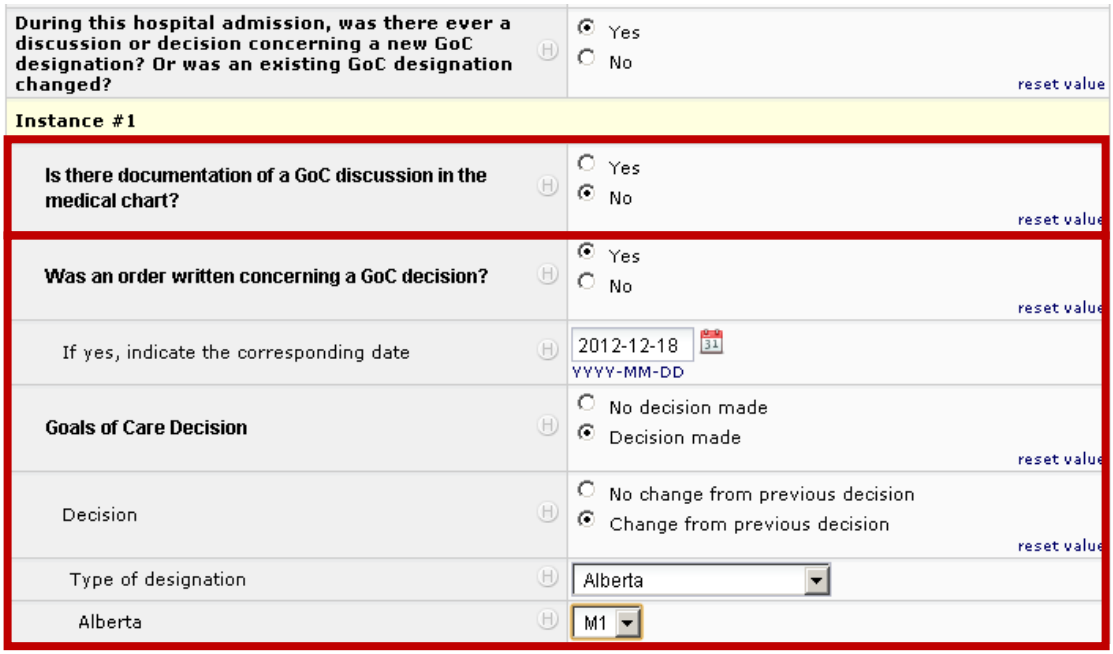


Example 2: Documented GoC discussion, without an associated decision.



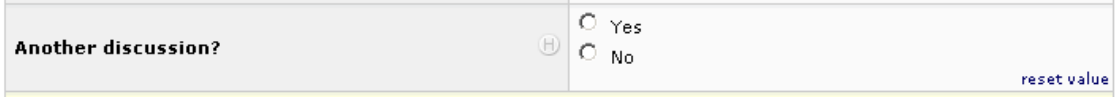
There can be a new GoC decision noted in the medical chart in the absence of any evidence that a discussion ever occurred.

Example 3: Documented GoC decision in the medical chart without a documented discussion.



If there are multiple GoC discussions/decisions in the medical chart, list each instance in chronological order.

Add a new instance by indicating 'yes' in the field below.

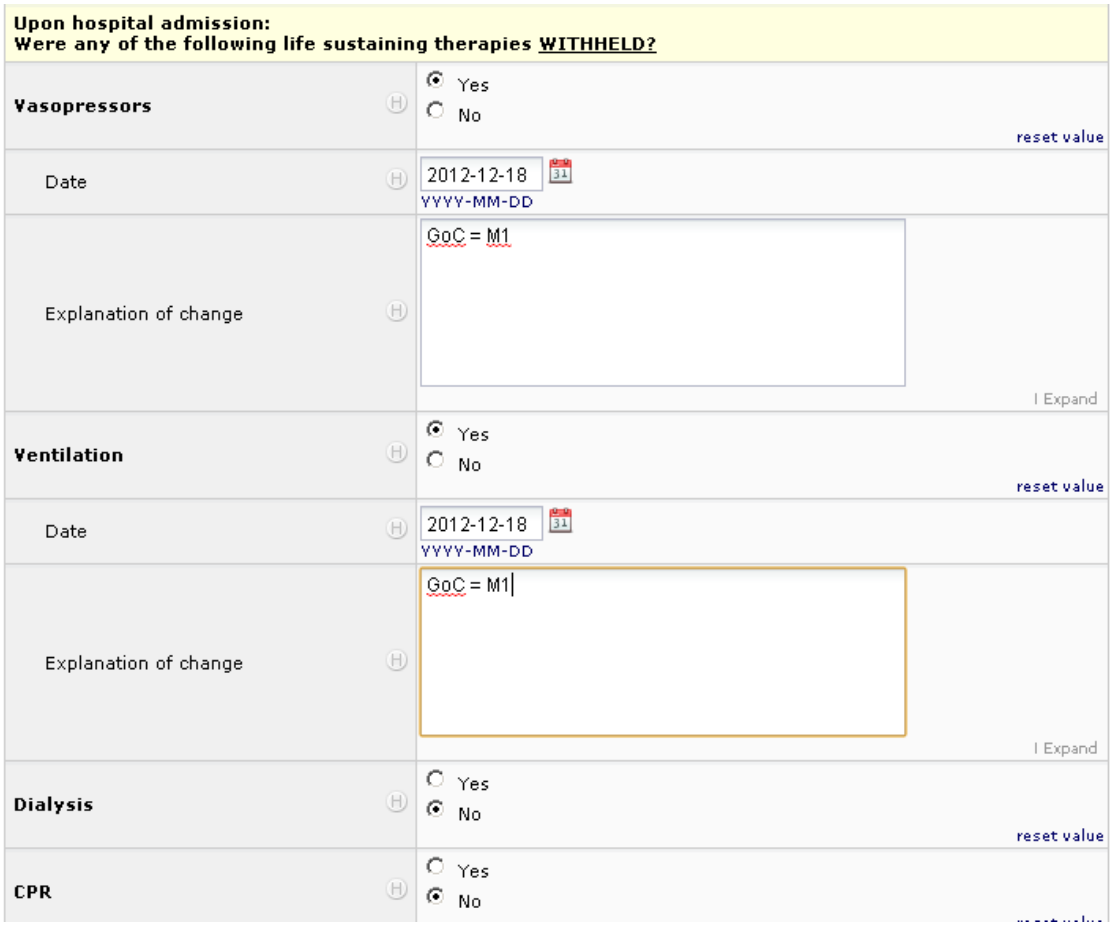


Processes of Care – Upon Hospital Admission

Document orders written ± one day from the current hospital admission to withhold or withdraw life sustaining therapies.

For hospitals that use a GoC designation system (e.g. Calgary M1, M2, etc…) ensure that you take the definition of a GoC designation into consideration when you are collecting processes of care data.

> For example, a patient has a GoC designation of M1. By definition M1 means vasopressors and mechanical ventilation are to be withheld. Therefore on the Process of Care form you need to indicate that vasopressors and ventilation are 'withheld.'



Processes of Care – During Hospital Admission to Before Hospital Discharge or Death

Document any orders to withhold or withdraw therapy from 24 hrs after the current hospitalization began until hospital discharge or death.

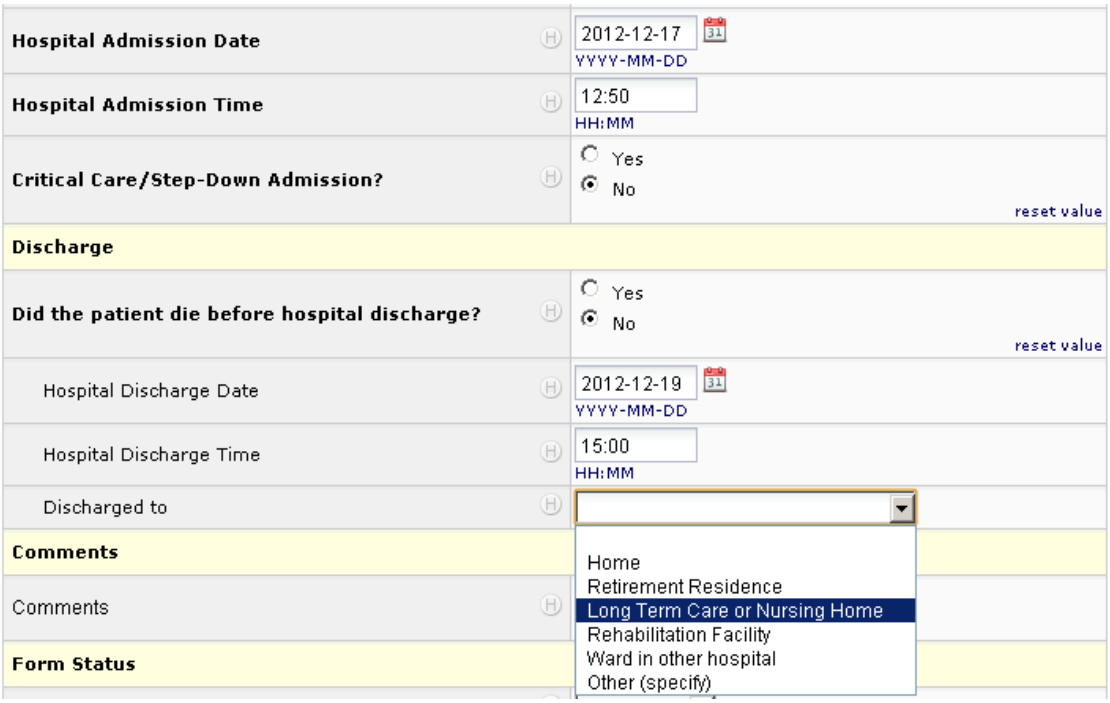
For example, if a patient in Alberta has a documented change in GoC from M1 to M2.

From after the time of hospital admission to before hospital discharge or death: Were any of the following life sustaining therapies WITHHELD?	
Vasopressors	○ Yes ◉ No change from upon hospital admission reset value
Ventilation	○ Yes ◉ No change from upon hospital admission reset value
Dialysis	◉ Yes ○ No change from upon hospital admission reset value
Date	2012-12-19 YYYY-MM-DD
Explanation of change	Discussion with family resulted in a change from M1 to M2. Expand
CPR	◉ Yes ○ No change from upon hospital admission reset value
Date	2012-12-19 YYYY-MM-DD
Explanation of change	Discussion with family resulted in a change from M1 to M2. Expand

Index Hospitalization Overview

Record the patient's admission and discharge dates from hospital. Include any instances when the patient was admitted to the ICU or step-down unit.

If the patient is discharged from the hospital, indicate to which location they were discharged to.



Documentation

All worksheets and documents used to collect Patient/Family Member data should be retained by the research site in the study files. They will be important sources of information to refer to if the coordinating centre has any queries regarding your data.

Appendix

Please refer to the Carenet website for the appendices mentioned.
http://www.thecarenet.ca/index.php?option=com_content&view=article&id=186&Itemid=106