The ACCEPT Study

Audit of Communication, CarE Planning, and DocumenTation

A multicenter, prospective study

Implementation Manual

Short Version

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

Clinical Evaluation Research Unit

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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 complete a questionnaire. Upon enrollment, the research coordinator will give the patients and family caregivers the questionnaires to complete. From the questionnaire 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, and 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; 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 and examine for the presence of 'Goals of Care" orders and 'DNR' orders. 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.

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 Short 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 will be provided to you by the Project Leader.

Training modules cover the following topics:

- Module 1: Study Overview Background, and Preparation
- Module 2: Respondent Eligibility Criteria
- Module 3: informed Consent
- Module 4: 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 complete a questionnaire.

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**.**

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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.

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	Not interested
Too upsetting	Too upsetting
Too tired	Too tired
Too sick	Discharge soon
Discharge soon	Can't hear well/deaf
Can't hear well/deaf	Can't see well/blind
Can't see well/blind	Other (specify): _____
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 Short 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 Short Questionnaire *Patient Version & Family Member Version*	ACP Short Questionnaire *Patient Version*	ACP Short 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.

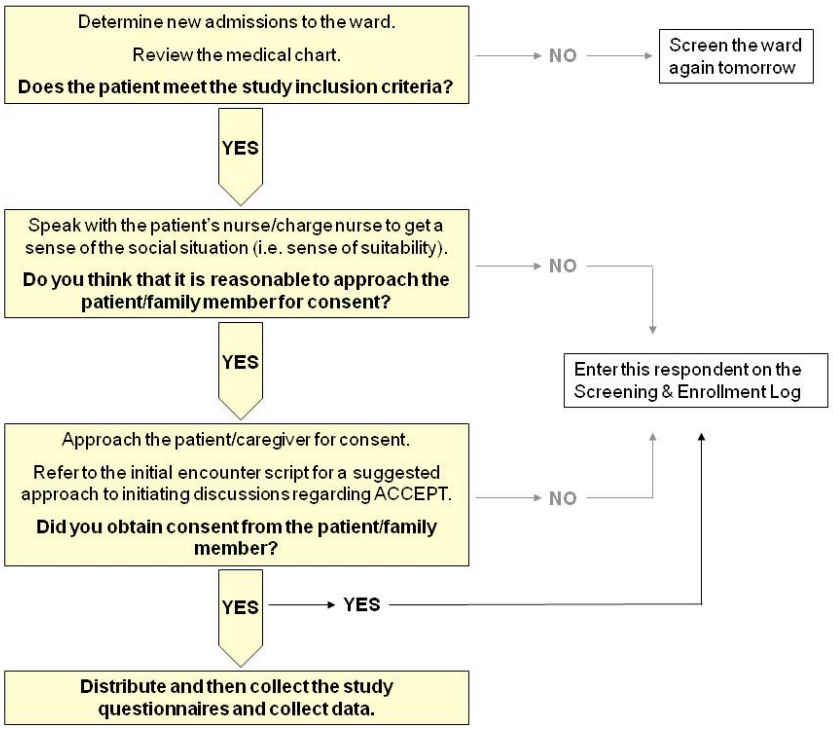
Patient/Family Member Confidentiality

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 48 - 50 provide further details concerning chart abstraction.

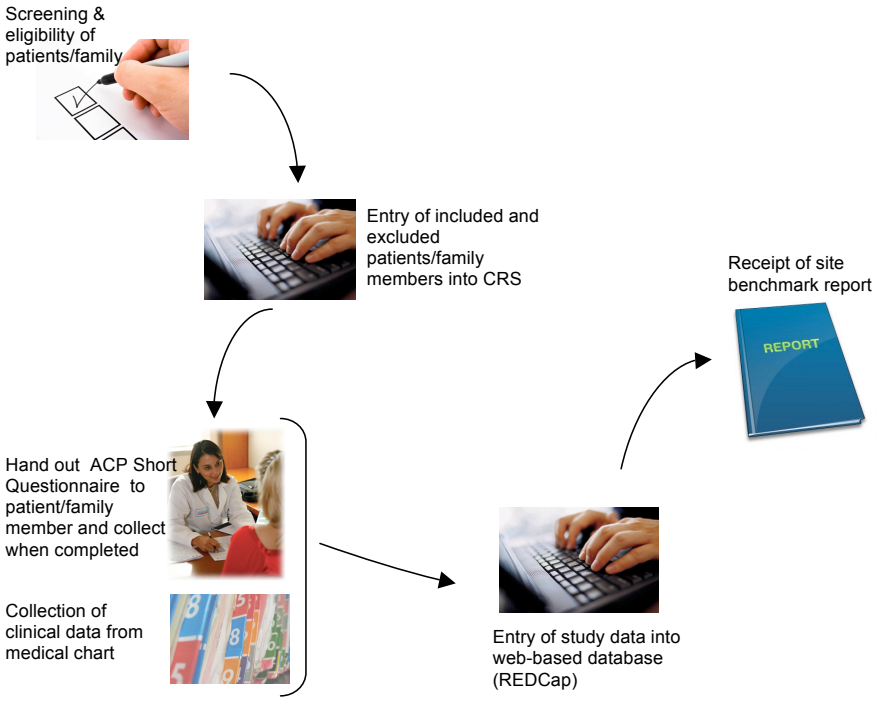
Screening/Enrollment Algorithm

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
Distribute and then collect 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.



Central Randomization System (CRS)

Documenting Screening Activities

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

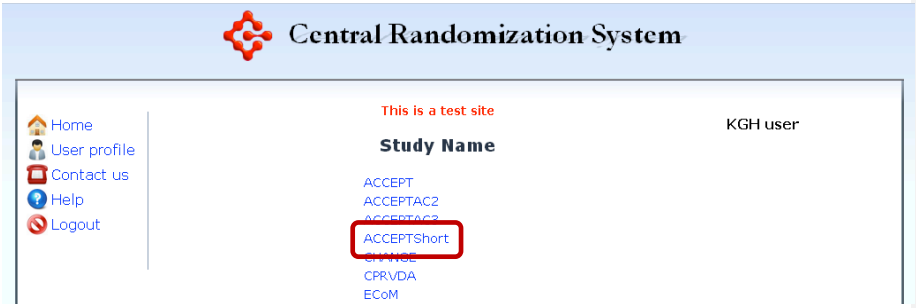
https://ceru.hpcvl.queensu.ca/randomize/

To Enter Screening Data and/or to Enroll a Patient

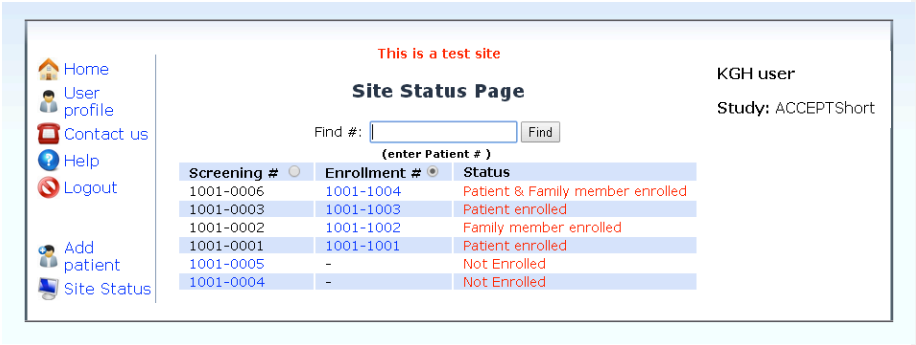
1) Log in to the CRS.

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

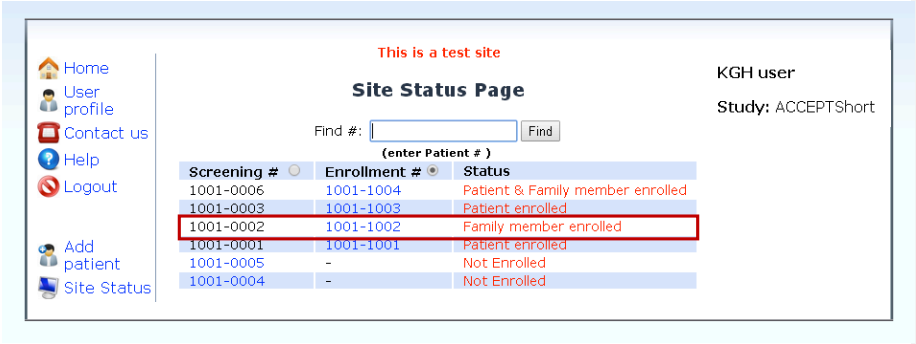
2) Select the ACCEPT Study (ACCEPTShort) from the list of studies.



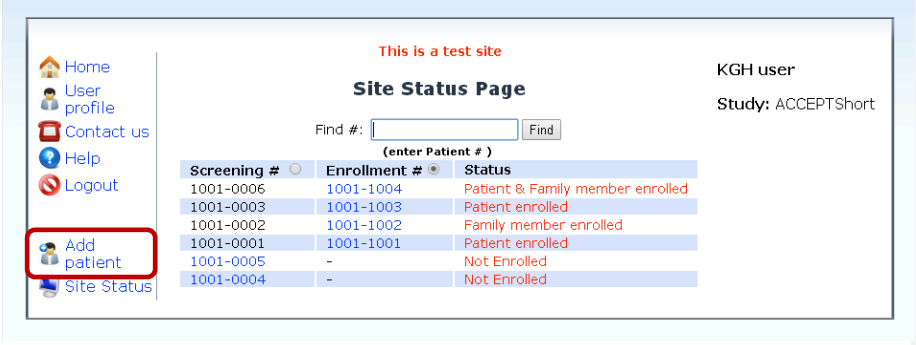
3) You will be brought to your Site Status page. This page will list all of the patient/family members you have screened and/or enrolled to date.



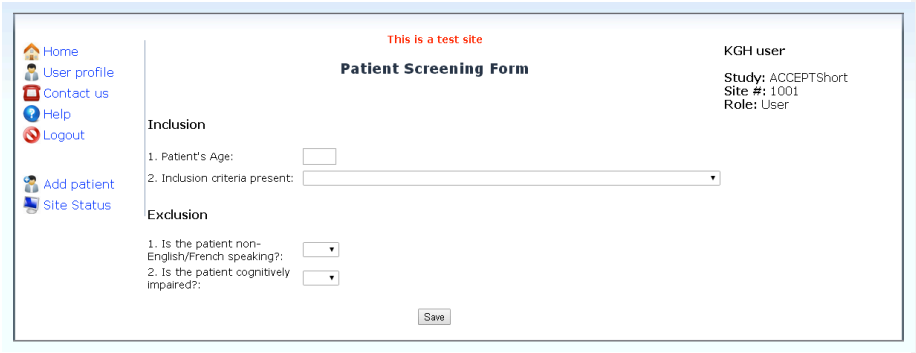
4) To view existing data simply click on the screening or enrollment number of interest. The Screening Form for that particular patient/family member will open.



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

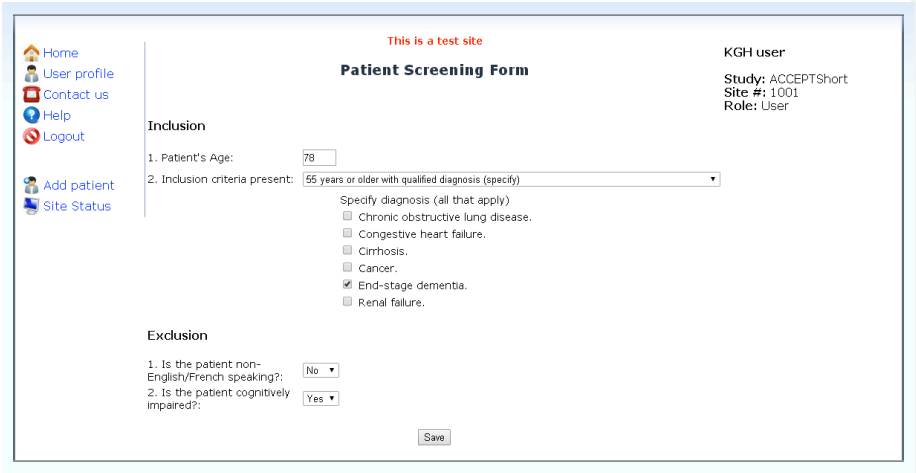


6) You will next be taken to the Screening Form. Patient eligibility criteria will always be the first data entry screen.



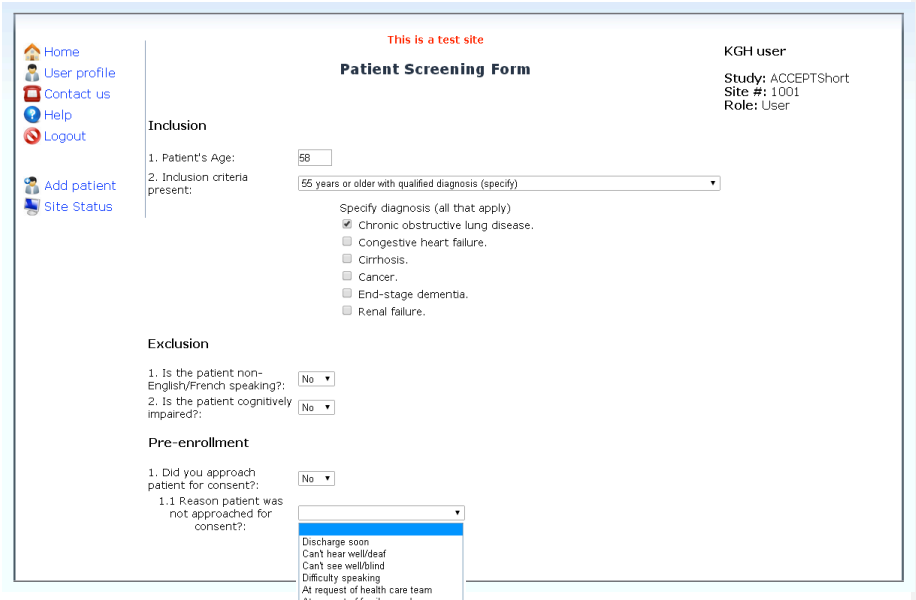
7) Enter the inclusion and exclusion criteria for the patient. Select SAVE.

a) In this case the patient is excluded.

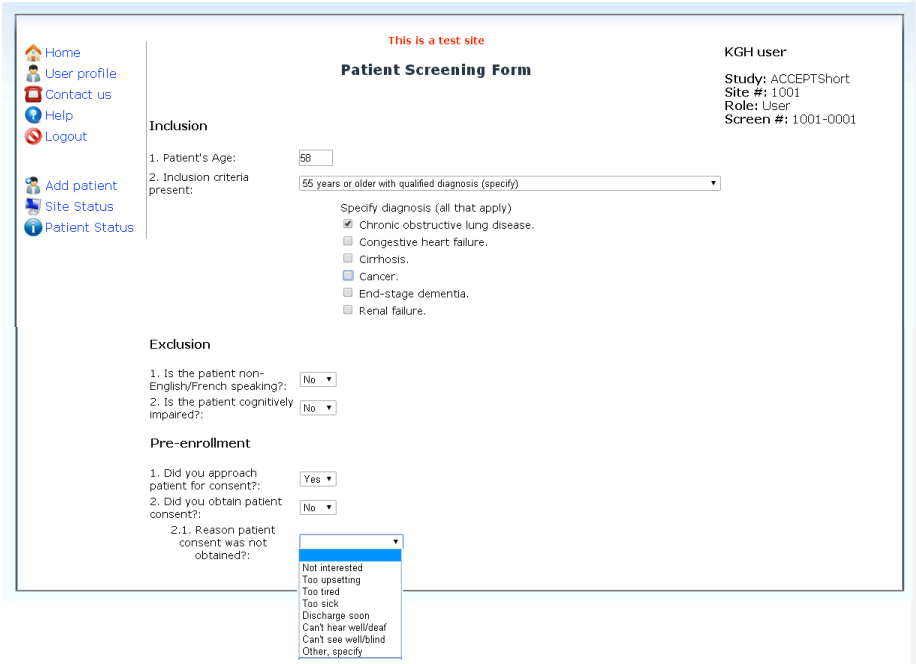


b) In the following cases the patient is eligible.

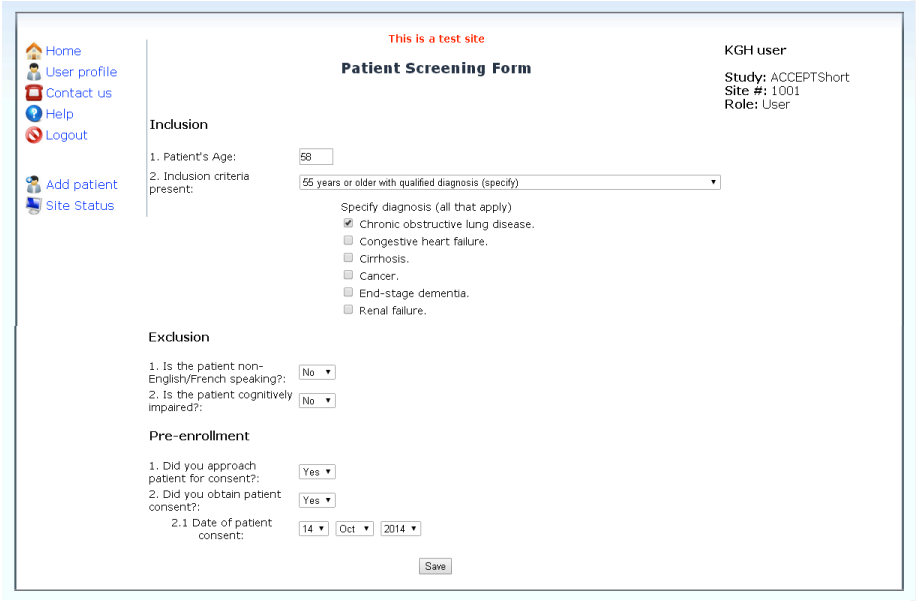
i) The patient is NOT approached for consent, indicate the reason why using the drop down menu, then SAVE the form.



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.

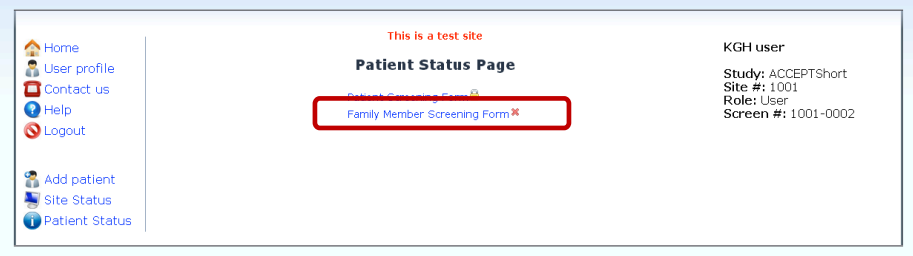


iii) If the patient is approached for consent, and consent is granted, record the date consent is obtained and then SAVE the form.



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.

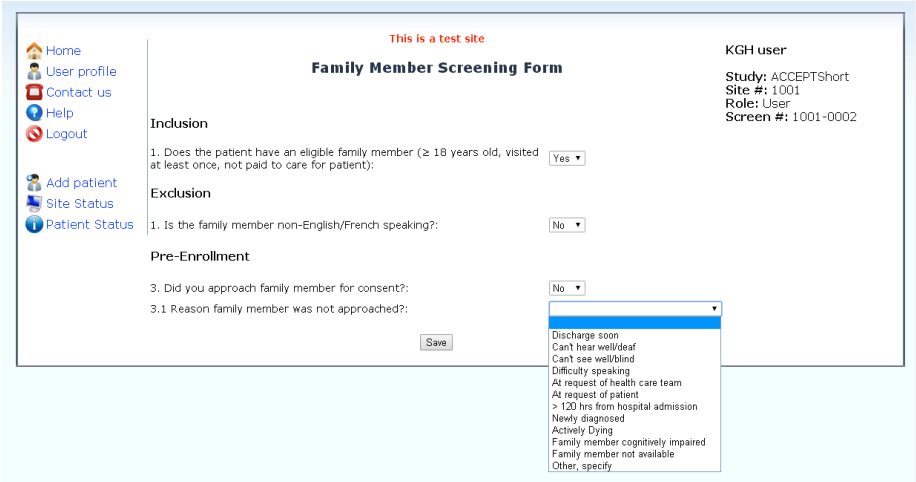


10) Enter the data for the family member.

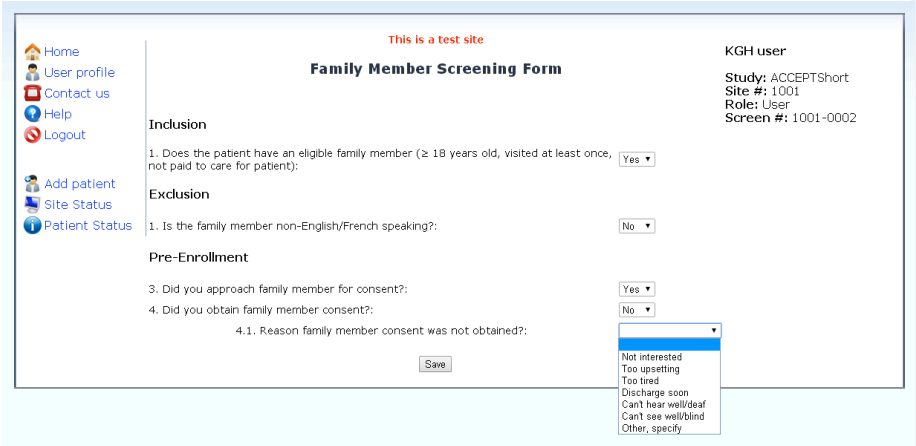
a) In this case the family member is excluded.

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

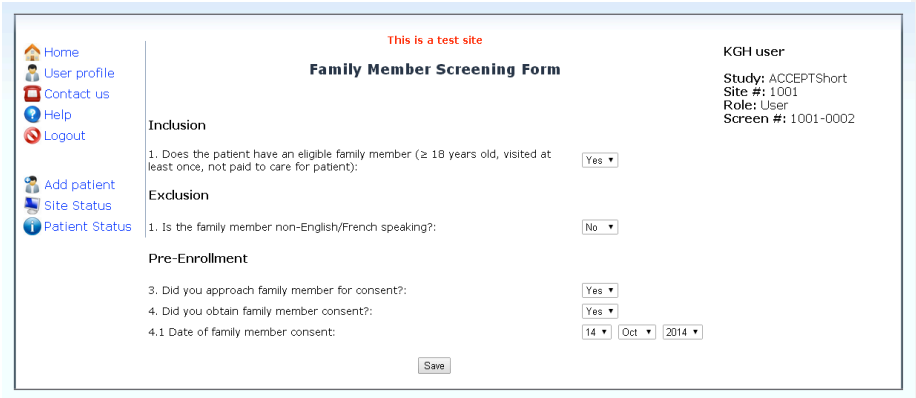
i) If the family member is NOT approached for consent, indicate the reason why using the drop-down menu, then SAVE the form.



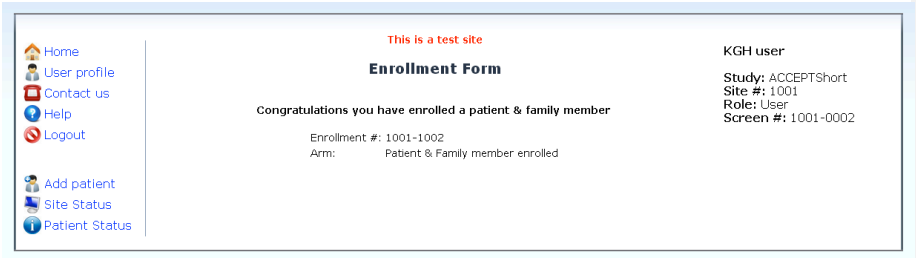
ii) If the family member is approached for consent, but declines to participate, indicate the reason why using the drop-down menu, then SAVE the form.



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

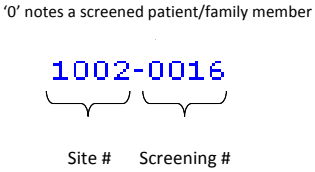


11) When a family member is enrolled you will see an enrollment confirmation form. Print this form for your study file. (The form will indicate whether you have both the patient and family member enrolled or just the family member.)

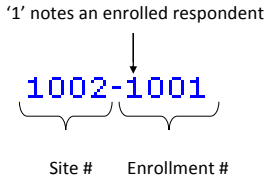


Unique Respondent Identification Numbers

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 Short 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 ?? for data entry instructions.

Patient /Family Member Data

Administering the ACP Questionnaires

The ACP Short Questionnaire is self administered. Once consent has been obtained the research coordinator will give the patient/family member the appropriate questionnaire. If both the patient and family member are participating, please ask that they complete the questionnaire on their own. It is important they do not influence each other's responses. Each site will need to develop their own strategy to collect the questionnaires. Options include:

- return at a scheduled time to collect the questionnaire
- leave an envelope and have a dropbox at the nursing station

General Instructions

1. Determine which ACP Short Questionnaire should be given to the Respondent (i.e. Patient or Family Member version).
2. Schedule a time to return and pick up the questionnaire or give instructions regarding a dropbox or other method of collection.
3. If you are around and the respondent does not understand a question, the research coordinator should not interpret the questions for the respondent.
4. If both the patient and family member are enrolled, have them complete the questionnaires as close to each other as possible. They can be completed up to 1 week apart, however, every effort should be made to have them completed as close to each other as possible.
5. If the questionnaire is started but not completed, do not discard the questionnaire as it can still be included.

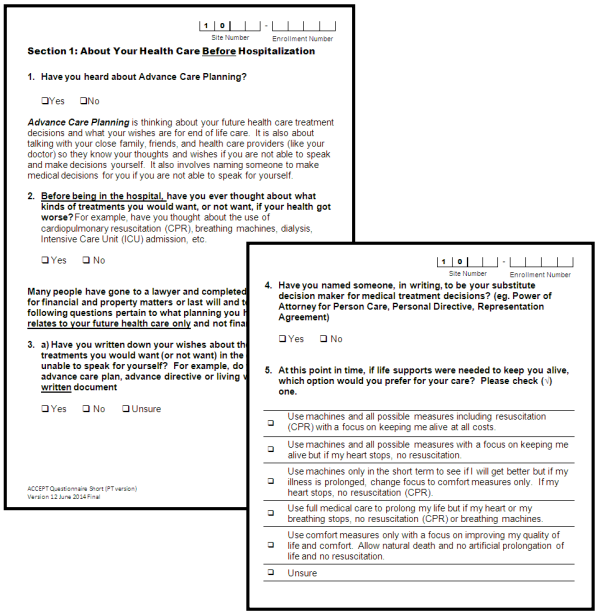
ACP Questionnaire Breakdown

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

Patient Version	Family Member Version
Section 1 ▪ Decisions About Your Health care Prior to Hospitalization Section 2 ▪ Goals of Care During Current Hospitalization Section 3 ▪ CANHELP Lite Section 4 ▪ Patient Demographics ▪ Frailty Scale	Section 1 ▪ Decisions About Your Relative's Health care Prior to Hospitalization Section 2 ▪ Your Relative's Goals of Care During Current Hospitalization Section 3 ▪ CANHELP Lite Section 4 ▪ Family Member Demographics ▪ Patient Demographics, if applicable ▪ Patient Frailty Scale, if applicable

Section 1: About Your Health Care *Before to* Hospitalization

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



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

Section 1: About Your Health Care Before Hospitalization

1. **Have you heard about Advance Care Planning?**

❑Yes ❑No

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

Many people have gone to a lawyer and completed for financial and property matters or last will and following questions pertain to what planning you h relates to your future health care only and not fina

3. **a) Have you written down your wishes about th treatments you would want (or not want) in the unable to speak for yourself? For example, do advance care plan, advance directive or living written document**

❑Yes ❑ No ❑ Unsure

ACCEPT Questionnaire Short (FT version)
Version 2.2 June 2014 Final

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Site Number Enrollment Number

4. **Have you named someone, in writing, to be your substitute decision maker for medical treatment decisions? (eg. Power of Attorney for Person Care, Personal Directive, Representation Agreement)**

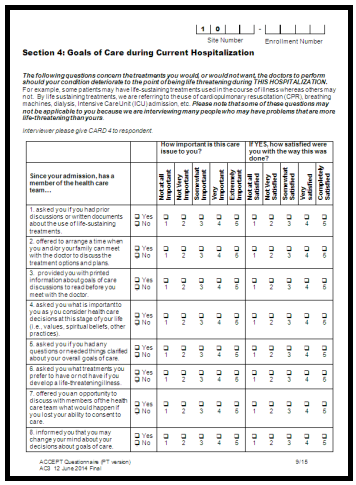
❑ Yes ❑ No

5. **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.**

❑	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

Section 2: 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).



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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

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ACD 12 June 2014 Final

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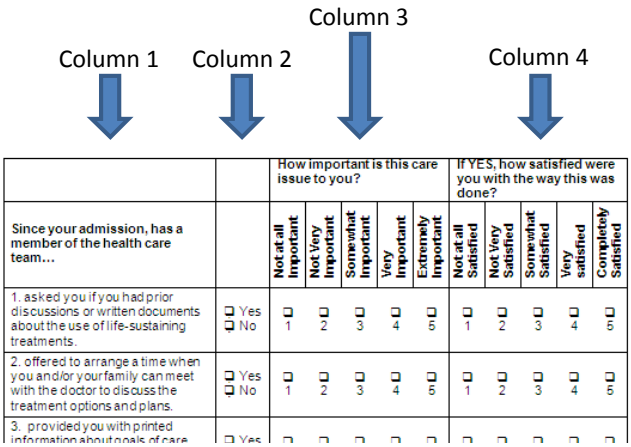


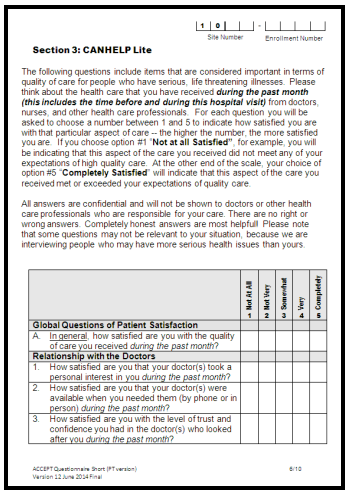
		How important is this care issue to you?					If YES, how satisfied were you with the way this was done?				
Since your admission, has a member of the health care team…		**Not at all Important**	**Not Very Important**	**Somewhat Important**	**Very Important**	**Extremely Important**	**Not at all Satisfied**	**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	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

Questions #1-14

- For each question in this section (column 1), first, we 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 3: 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.



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Site Number Enrollment Number

Section 3: CANHELP Lite

The following questions include items that are considered important in terms of quality of care for people who have serious, life threatening illnesses. Please think about the health care that you have received ***during the past month (this includes the time before 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 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 helpfull! Please note that some questions may not be relevant to your situation, because we are interviewing people who may have more serious health issues than yours.

	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*?					

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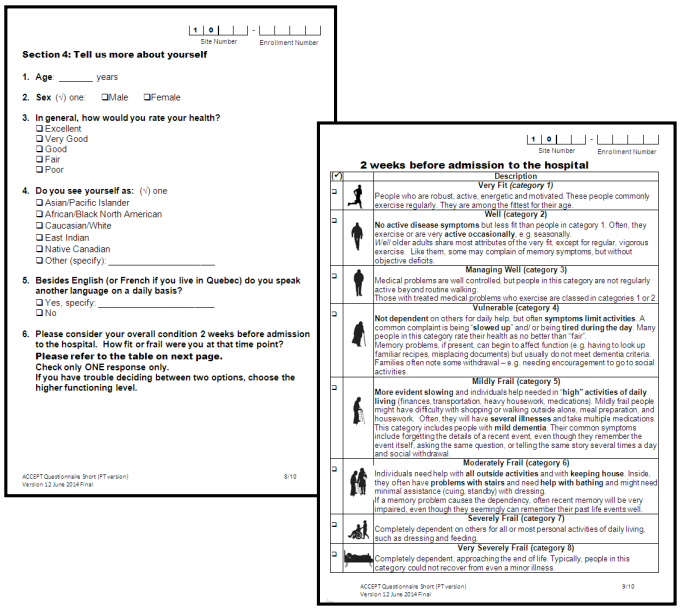
Section 4: Baseline Demographics

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.



1 0 - Site Number / Enrollment Number

Section 4: Tell us more about yourself

1. **Age**: _____ years
2. **Sex** (√) one: ❑Male ❑Female
3. **In general, how would you rate your health?**
   - ❑ Excellent
   - ❑ Very Good
   - ❑ Good
   - ❑ Fair
   - ❑ Poor
4. **Do you see yourself as:** (√) one
   - ❑ Asian/Pacific Islander
   - ❑ African/Black North American
   - ❑ Caucasian/White
   - ❑ East Indian
   - ❑ Native Canadian
   - ❑ Other (specify): _____
5. **Besides English (or French if you live in Quebec) do you speak another language on a daily basis?**
   - ❑ Yes, specify: _____
   - ❑ No
6. **Please consider your overall condition 2 weeks before admission to the hospital. How fit or frail were you at that time point?**
   Please refer to the table on next page.
   Check only ONE response only.
   If you have trouble deciding between two options, choose the higher functioning level.

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1 0 - Site Number / Enrollment Number

2 weeks before admission to the hospital

✓		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.

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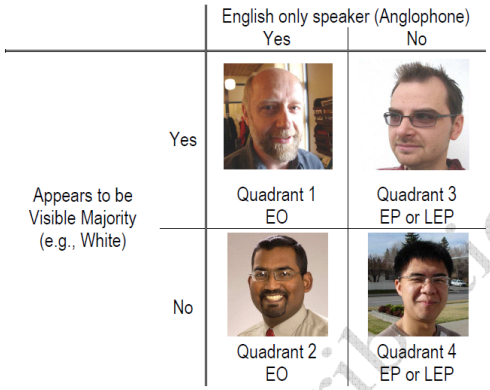
Ethnicity and Language

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 the 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 two (2) weeks prior to this admission to the hospital

In instances when both the patient and their family member complete the questionnaire, there may be a discrepancy between what is reported by the respondents. In these cases, always use the patient's response.

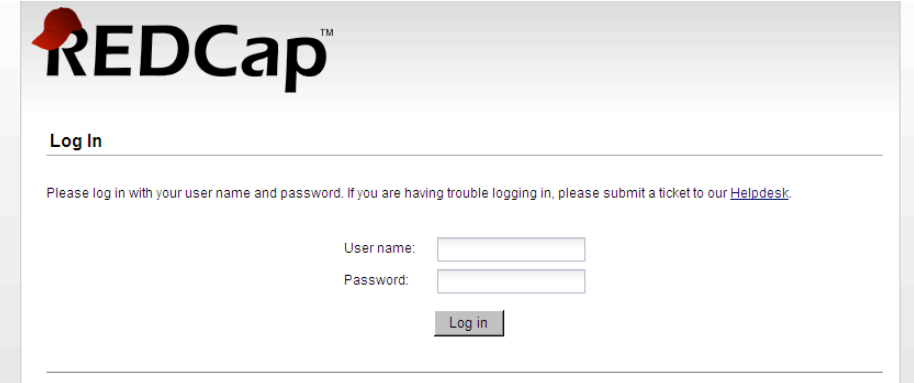
When you collect the completed questionnaire please thank the respondent for their time and candor in sharing information about this important topic. If the respondent requests more information regarding ACP please refer them to the appropriate individual on the ward (e.g. Social Worker). It is also 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).

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 Short Questionnaire
- Family Member ACP Short Questionnaire
- Case Report Form

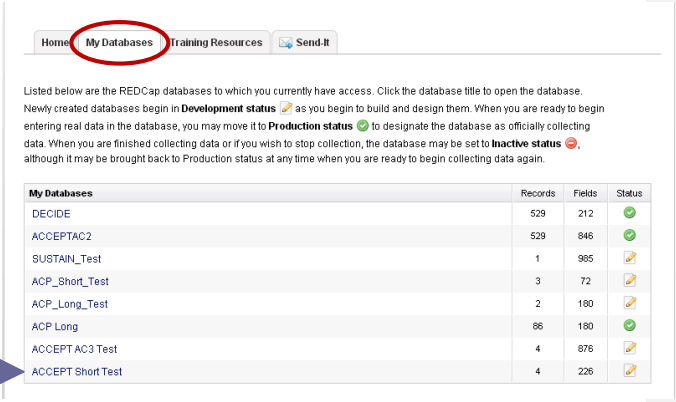
Basic Navigation

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

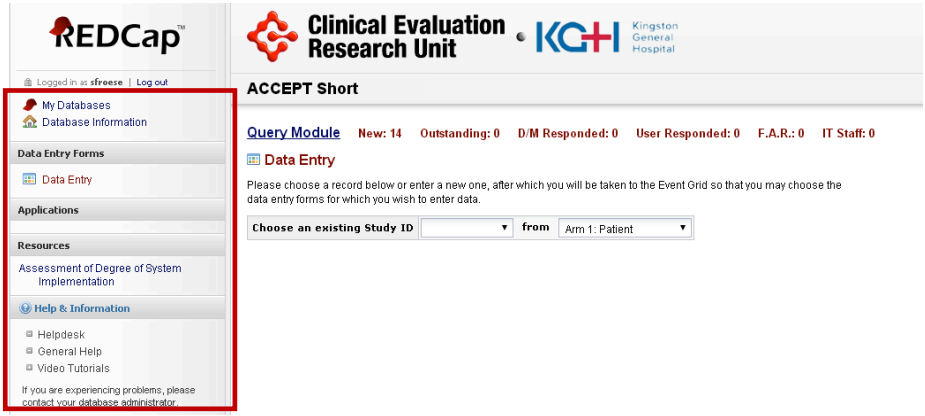
Your user password can be changed at any time by clicking “My Profile” after logging into REDCap.

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 Short"

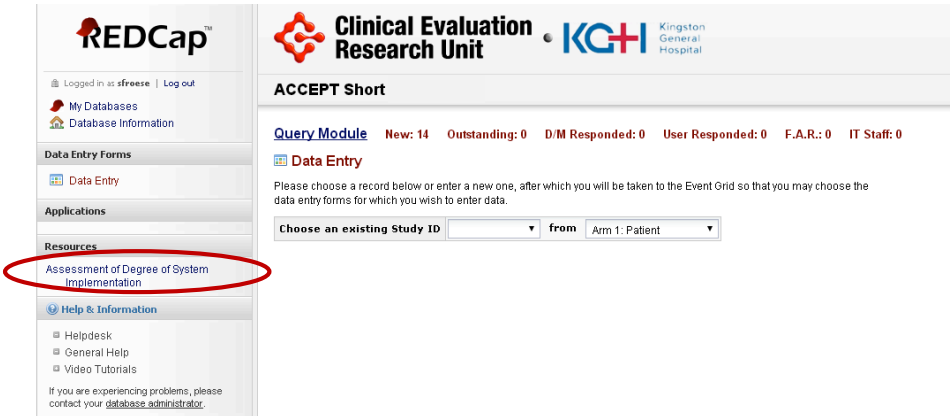


The left side of the screen is the main navigation panel.



Institution Level Data

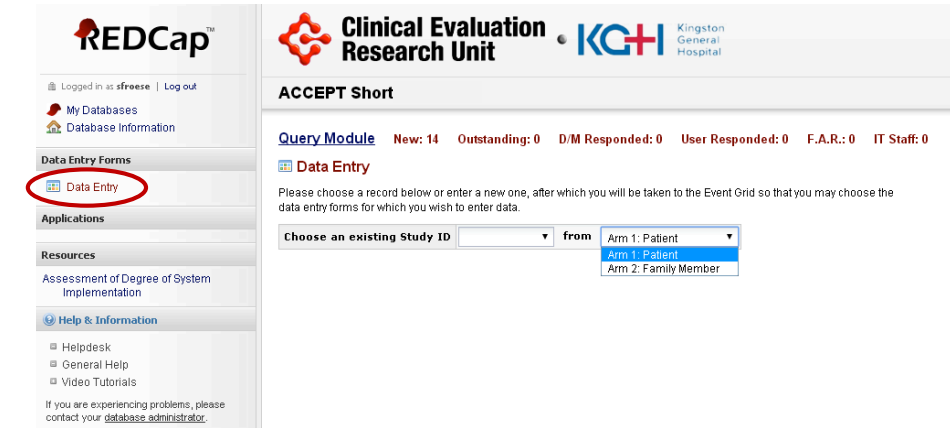
Select the "Assessment of Degree of System Implementation (ADSI)" link under the "Resources" heading to enter the responses to the questionnaire. Partially completed forms cannot be saved. All data must be entered at **one time**.



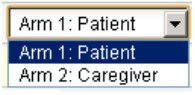
See page 26 for information regarding completion of the Institutional Level Data form.

Patient/Family Member Data

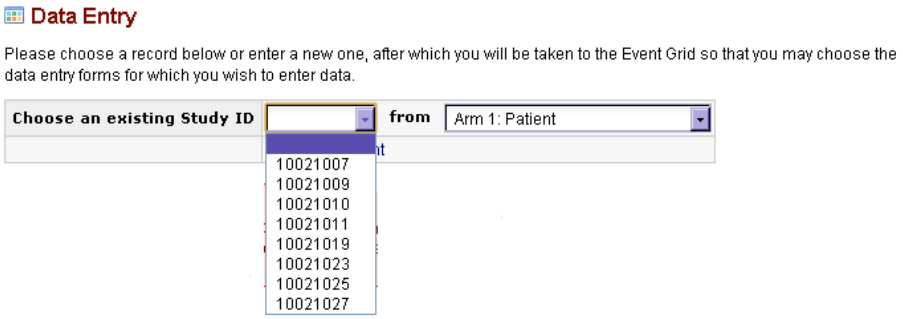
Select "Data Entry" on the left menu to choose from a list of respondents that are enrolled and ready for data entry.



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 page ?? 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.

ACP Short Questionnaire

ACP Short Questionnaire

Case Report Form (Chart abstraction)

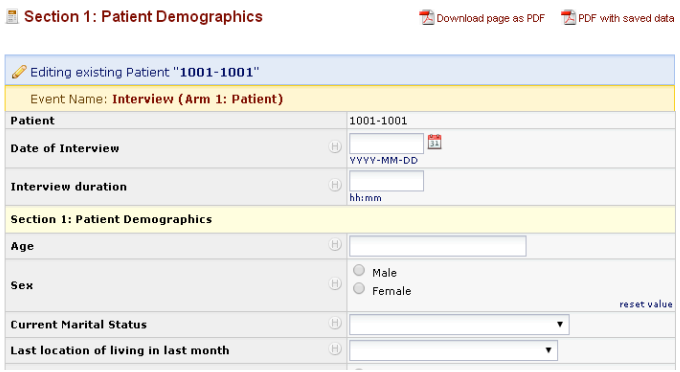
Data Entry Form	Interview
Patient	
Section 1: Patient Goals Before	●
Section 2: Patient Goals During	●
Section 3: Patient CANHELP Lite	●
Section 4: Patient Demographics	●
Family Member	
Section 1: Family Goals Before	●
Section 2: Family Goals During	●
Section 3: Family CANHELP Lite	●
Section 4: Family Demographics	●
Section 4: Family Patient Demographics	●
Medical Chart	
Section 5: Documentation of ACP/AD	●

Data entry for the ACP questionnaire is broken up into several forms. There is one form for each section of the questionnaire.

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

Enrollment #

Respondent Type



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

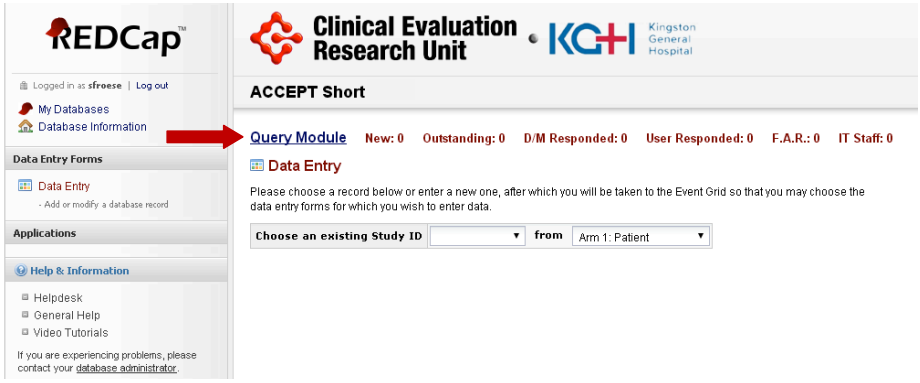
To edit previously saved information, access the appropriate REDCap form, change the appropriate field(s) and save the form. To ensure Good Clinical Practice is maintained, all changes will be tracked and logged by the computer program.

Query System

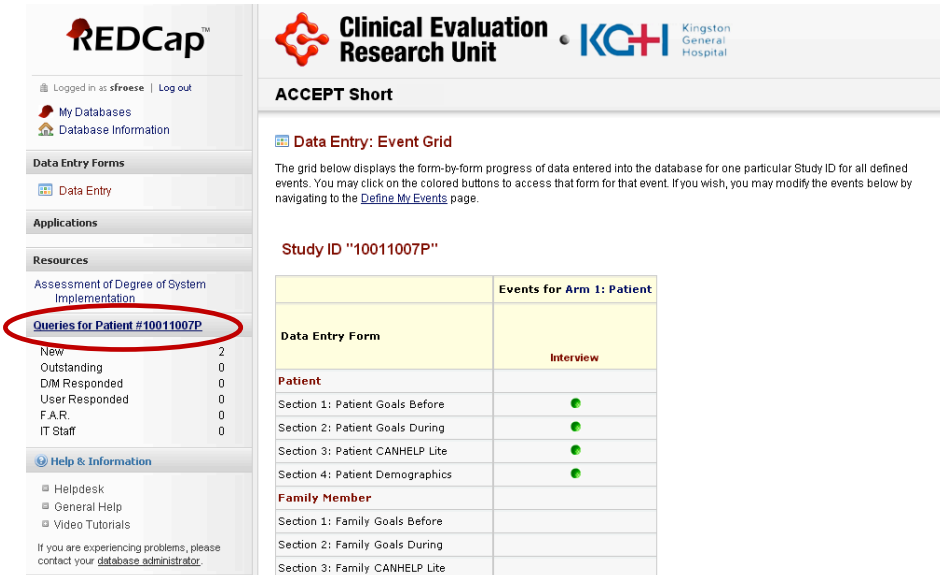
The query module will generate queries for all:

- 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

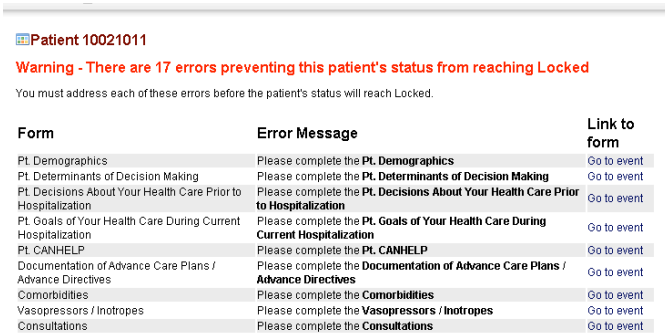
Once you have completed all of your data entry for a particular respondent type, you will need to "Finalize" your data. Finalizing your data tells CERU that you have no further work to complete regarding this respondent type.

Section 3: Family CANHELP Lite	●
Section 4: Family Demographics	●
Section 4: Family Patient Demographics	●
Medical Chart	
Section 5: Documentation of ACP/AD	●

Finalize

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.



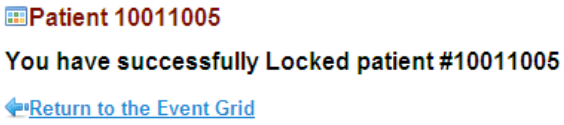
Patient 10021011

Warning - There are 17 errors preventing this patient's status from reaching Locked

You must address each of these errors before the patient's status will reach Locked.

Form	Error Message	Link to form
Pt. Demographics	Please complete the **Pt. Demographics**	Go to event
Pt. Determinants of Decision Making	Please complete the **Pt. Determinants of Decision Making**	Go to event
Pt. Decisions About Your Health Care Prior to Hospitalization	Please complete the **Pt. Decisions About Your Health Care Prior to Hospitalization**	Go to event
Pt. Goals of Your Health Care During Current Hospitalization	Please complete the **Pt. Goals of Your Health Care During Current Hospitalization**	Go to event
Pt. CANHELP	Please complete the **Pt. CANHELP**	Go to event
Documentation of Advance Care Plans / Advance Directives	Please complete the **Documentation of Advance Care Plans / Advance Directives**	Go to event
Comorbidities	Please complete the **Comorbidities**	Go to event
Vasopressors / Inotropes	Please complete the **Vasopressors / Inotropes**	Go to event
Consultations	Please complete the **Consultations**	Go to event

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.”



Patient 10011005

You have successfully Locked patient #10011005

Return to the Event Grid

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.

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 be consistent.
- 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.

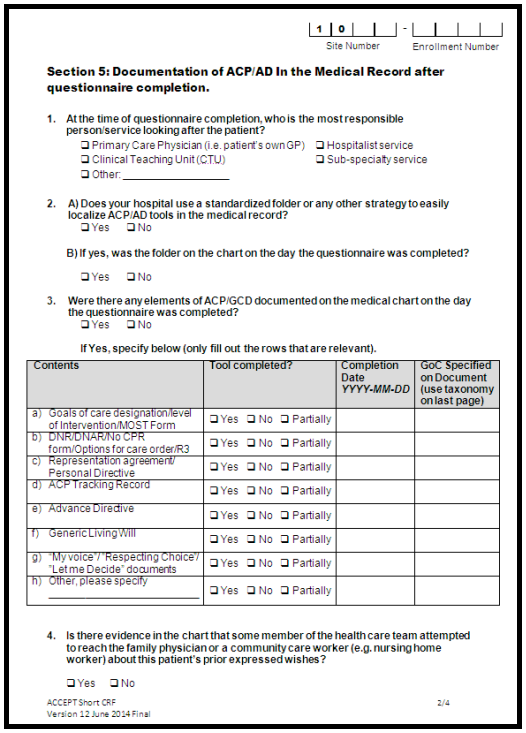
For example, Consultations
One research coordinator finds a consult form for Transition Services however there are no notes, therefore the coordinator does not count this as having occurred and there is no entry made in the CRF.
Another research coordinator looking at a different patient chart finds 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

Section 5: 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 5: Documentation of ACP/AD In the Medical Record after questionnaire completion.

1. At the time of questionnaire completion, 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 the questionnaire was completed?
   ❑ Yes ❑ No

3. Were there any elements of ACP/GCD documented on the medical chart on the day the questionnaire was completed?
   ❑ Yes ❑ No

   If Yes, specify below (only fill out the rows that are relevant).

Contents	Tool completed?	Completion Date *YYYY-MM-DD*	GoC Specified on Document (use taxonomy on last page)
a) Goals of care designation/level of Intervention/MOST Form	❑ Yes ❑ No ❑ Partially		
b) DNR/DNAR/No CPR form/Options for care order/R3	❑ Yes ❑ No ❑ Partially		
c) Representation agreement/ Personal Directive	❑ Yes ❑ No ❑ Partially		
d) ACP Tracking Record	❑ Yes ❑ No ❑ Partially		
e) Advance Directive	❑ Yes ❑ No ❑ Partially		
f) Generic Living Will	❑ Yes ❑ No ❑ Partially		
g) "My voice"/ "Respecting Choice"/ "Let me Decide" documents	❑ Yes ❑ No ❑ Partially		
h) Other, please specify _____	❑ Yes ❑ No ❑ Partially		

4. Is there evidence in the chart that some member of the health care team attempted to reach the family physician or a community care worker (e.g. nursing home worker) about this patient's prior expressed wishes?
   ❑ Yes ❑ No

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If both the patient and family member consented, section 5 should be completed at the point of first contact. (i.e. after the first questionnaire has been completed).

If blank documents are found in the medical chart (e.g. goals of care form, tracking record or My Voice workbook) leave the corresponding row blank.

Some Research Coordinators have noted that responses provided in the questionnaire 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.

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? (H)	◉ 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 (H)	☐ Angina ☐ Arrhythmia ☐ Valvular ☐ Myocardial infarction ☐ Congestive heart failure (or heart disease)
Vascular (H)	☐ Hypertension ☐ Peripheral vascular disease or claudication ☐ Cerebrovascular disease (Stroke or TIA)
Pulmonary (H)	☑ Chronic obstructive pulmonary disease (COPD, emphysema) ☐ Asthma
Neurologic (H)	☐ Dementia ☐ Hemiplegia (paraplegia) ☐ Neurologic illnesses (such as Multiple sclerosis or Parkinsons)
Endocrine (H)	☑ Diabetes Type I or II ☐ Diabetes with end organ damage ☐ Obesity and/or BMI > 30 (weight in kg/(ht in meters)^2
Renal (H)	☐ Moderate or severe renal disease
Gastrointestinal (H)	☐ Mild liver disease ☐ Moderate or severe liver disease ☐ GI Bleeding ☐ Inflammatory bowel ☐ Peptic ulcer disease ☐ Gastrointestinal Disease (hernia, reflux)

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=155&Itemid=97