



**Advance Care Planning Evaluation in Hospitalized Elderly Patients:
A multicenter, prospective study**

Guide to Completing Your Ethics Submission for the ACCEPT Study

Completing Your Initial Ethics Application

Every local ethics committee will have their own specific procedures and forms that will differ from the next. Generally speaking, all ethics committees require certain key points of information:

- Site Investigator and additional research personnel (ie. Research Coordinator)
- Purpose of the Study
- Methods
- Target number of participants and description of potential participants (eligibility criteria)
- Confidentiality/Privacy measures

The steps to completing your local ethics application are as follows:

1) Sites should identify where the application form can be found (whether on a website, or by contacting the Ethics Committee directly).

Typically, Ethics Committee applications can be found in two versions, the full review for studies that involve intervention and one for survey/observational studies. Given that the ACCEPT Study is an observational, questionnaire study, there is minimal risk to the patient/family member, it may be possible to use a shorter application form. In addition, for the same reasons as just listed, it is possible to request an expedited review; this means a single member of the ethics committee can review and approval the study, rather than having to go through a full ethics committee board meeting. We have provided you with a template of a letter (See Appendix A) to the Chair of the ethics committee requesting and expedited review. If you decide to use this letter, please feel free to tailor this letter to your specific needs.

2) Compile/prepare the necessary documents:

- Cover Letter addressed to the Chair of the Ethics Committee requesting expedited review (see Appendix A)
- Most recent protocol (see Appendix B)
- Most recent Study Questionnaires and Case Report Form (see Appendix C)
- Informed consent form (both patient and family member versions – Appendix D)
- Letter of Information outlining the study for potential participants (Appendix E)
- Advertisement Poster (Appendix F)
- Ethics approval from Kingston General Hospital, the lead centre (Appendix G)

3) Complete the ethics application form .

Useful sources of information for you as you work through the application form are the protocol and the ethics committee application form the lead centre in

Kingston (see Appendix G). Should you run into any questions that are not answered by these documents, feel free to contact the Project Leader, Janet Overvelde (613-549-6666 x6241).

Your local ethics committee will be able to answer any questions you may have concerning the submission and approval process at your institution.

Renewing Your Existing Ethics Approval

If you participated in the ACCEPT Study in 2011-2012, and your ethics approval from last year is still valid, you may be looking to renew your ethics approval for 2013. There have been a few revisions and clarifications to the procedures (all of which may be found in the updated implementation manual).

Some New Features for the next Audit Cycle (Jan 2013)

- There have been significant revisions to the questionnaires and case report forms based on feedback and experiences from the previous Audit Cycle.
- We have included a draft Bedside Letter to be given to patients and/or family members, providing them with information on the study and how to contact research personnel. Some sites have employed this method and found that it was helpful in facilitating a meeting to initiate the consent process.

Renewal Process

Most ethics committees require an annual renewal for projects with an existing ethics approval. The annual renewal process typically involves filling out a dedicated form (refer to your local ethics committee for specific procedures and forms). Some questions that usually are found on the annual renewal forms include:

- Recruitment update:
 - How many participants to date at your site
 - How many participants recruited at all sites to date (278 patients, 225 family members)
 - How many participants need to be recruited (target: 30 patients, 30 family members)
- Anticipated date for completion (target finish date for the next Audit Cycle: March 2013)
- Any issues previously encountered with recruiting participants, if applicable.
- Any newly identified risks/benefits, if applicable.
- Outline changes to study

For the next audit cycle, the study procedures remain the same. However there have been changes made to the ACP questionnaires. Updates to study tools should be included for approval by the ethics committee.

[Use Letterhead]

[Insert Address and Contact Information]

[Date]

[Name of REB Chair],
[Title of REB Chair]

Re: Advance Care Planning Evaluation in Elderly Patients. A multicenter, prospective study.
The **ACCEPT** Study

Dear Dr. [Name of Chair]:

I am writing to request REB approval for the ACCEPT Study. You will find the following documents enclosed:

- REB Application
- Protocol version: 17-Nov-11
- Appendix to the Protocol, including patient and family member questionnaires
- Informed Consent Form (Patient and Family Member Versions): 20-Sep-11
- Sample Letter of Information: 30-Nov-11
- Advertisement Poster
- Ethics approval from Kingston General Hospital: 5-Jan-11

Given the low risk nature of this observational questionnaire based study, we are requesting an expedited review. If any further material is required or other information is needed, please do not hesitate to contact me.

On behalf of [Site Investigator],

[Research Coordinator]
[Contact Info]

**Advance Care Planning Evaluation in Hospitalized Elderly Patients:
A multicenter, prospective study**

The ACCEPT Study¹

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¹ November 17, 2011

Summary of Current Proposal

Our health care system is under siege- an aging population, patients living longer with chronic illness, and an increasing demand for services at end of life contribute to escalating costs and utilization patterns that are unsustainable. In a recent national survey, more than 80% of respondents were concerned the quality of health care in Canada will decline as a result of increased strain on the health care system as our population gets older.¹ Advance Care Planning (ACP) may offer some assistance with reducing health care costs for older Canadians and yet, at the same time, improving quality of care. ACP is the process by which a person considers options about future health care decisions and identifies their wishes. An advance care plan is a verbal or written instruction describing what kind of care an individual would want (or not want) if they are no longer able to speak for themselves. ACP has been shown to increase the quality of life of dying patients, improve the experience of family members, and decrease health care costs.

Under the leadership of the Canadian Hospice and Palliative Care Association (CHPCA), clinicians, researchers and decision makers have been meeting for the past 3 years to develop a national strategy to implement ACP in Canada. The Calgary Zone of Alberta Health Services and Fraser Health Authority in British Columbia have led the nation in developing and implementing system-wide strategies to increase ACP amongst the population they serve. **However, there has been no evaluation of the effectiveness of these efforts from the perspective of patients and families;** many questions pertaining to the barriers and facilitators to implementation and the impact of ACP on outcomes in Canada remain. This study is not primarily about whether ACP works, it is more about how best to implement it. Decision-makers in these and other regions need this critical feedback from end users to inform future initiatives designed to improve the quantity and quality of ACP. Canadian researchers have recently developed and validated a satisfaction tool to measure patient and family perspectives on end of life (EOL) communication and decision-making. Building upon collaboration with decision makers and researchers interested in ACP, we have developed this proposal to evaluate ACP in 10 hospital sites in BC and Alberta with the overall objective of increasing the quality and quantity of ACP efforts specifically, and the overall quality of end of life (EOL) care in general. **We propose to conduct a prospective audit of current practice related to ACP in elderly patients at high-risk for dying and their families.** We will determine the extent to which these patients and families have engaged in ACP, what barriers and facilitators they perceive, and how satisfied they are with communication and decision making at the EOL. We hypothesize that current rates of ACP in these patients is low and that satisfaction with EOL communication and decision-making is suboptimal. Informed by a baseline evaluation of site strengths, weaknesses and barriers, we propose to develop tailored interventions to enable participating sites to improve their success with ACP during the entire grant cycle. By repeating the audit and feedback cycle annually, we will enable sites to make continuous efforts to improve their performance and be able to evaluate the effect of our audit/feedback/tailored intervention strategy compared to baseline. Additionally, for those patients who have engaged in ACP activities, we can compare their outcomes to those who have not. The insights we gain from evaluating and improving ACP will be disseminated throughout Canada via CHPCA.

Primary Objectives

The overall goal of this study is to inform decision-makers as the best strategies to implement advance care planning (ACP). Thus, the primary objective of this study is to determine, from the patient and families' perspectives, the prevalence of ACP and its various components, satisfaction with end of life communication and decision-making, and what barriers to improving the quantity and quality of ACP exist in 10 hospitals in Alberta and British Columbia.

Background Rationale

Dying in Canada: A Quality Finish?

More than 259,000 Canadians die every year.² This rate is increasing by about 3% a year and in the next 25 years, the number of deaths will almost double to approximately 425,000. Hospitals remain the major provider of EOL care as 70% of Canadians die in a hospital with one in five of these hospitalized deaths occurring in an ICU.^{3,4} There is growing literature from Canada and other countries describing the many challenges to providing quality end-of-life (EOL) care.^{5,6,7} In a recent landmark study conducted by our group, we demonstrated that the majority of elderly Canadians value quality of life and that avoiding the unnecessary prolongation of life through the use of technology and not being a burden to family are among the most important aspects of EOL care for elderly Canadians.⁸ Canadians also value having trust and confidence in the physicians looking after them, having physicians available to them, receiving honest information, and receiving help with difficult decisions about care near or at the EOL.⁸

We recently completed a multi-institution evaluation of quality EOL in over 350 seriously ill hospitalized patients (the same population targeted for this study) and their families in 6 institutions in Canada.⁹ We identified aspects they considered to be most important to quality care at the EOL and rated their level of satisfaction with those aspects. Aspects of care considered most important and that respondents were least satisfied with were then identified as high priority quality improvement targets. These priority targets included the feeling of peace, assessment and treatment of emotional problems, physician availability, and satisfaction that the physician took a personal interest in them, communicated clearly and consistently, and listened to them. Similar priorities were identified from family members' perspectives, but they identified additional priorities such as timely information about the patient's condition and discussions with the doctor regarding final location of care and use of technology at the end of life. Thus, we concluded that improved relationships with physicians, including better communication, decision-making, and advance care planning are high priority quality improvement targets to improve EOL care in Canada.⁹

Advance Care Planning

Investing in Advance Care Planning (ACP) is perhaps the single most important thing we can do as a society and a health care system to improve outcomes for care and to facilitate patient-centered communication at the EOL. ACP is a process by which a person considers options about 'future' health care decisions and identifies what his or her wishes are. 'Future' could have different meanings in different health care environments. In the acute care sector, it may pertain to future care planned for the current hospitalization as well as care that may be required in the future post discharge. In other settings, it may result in an advance care directive or a verbal or written instruction

describing what kind of care he or she would want (or not want) if he or she is no longer able to speak for his or her self as well as the values that guide them in making significant decisions. It also may result in a person being nominated as a substitute decision maker, someone to make decisions for the person if they are incapable due to injury or illness. ACP is best viewed as a process, not an event, which encourages dialogue between a patient, their family/friends/substitute decision makers, and the health care team.

The essential components of ACP at the individual level involve: 1) asking the patient about their personal values and wishes related to care provided at the end of life, 2) disclosing to the patient (and family) their prognosis, 3) discussing with them various treatment options, both risks, benefits and expected outcomes, 4) deciding on future care or goals of care if the patient is not able to engage in future discussions in a manner that is consistent with the patient's preferred role in decision-making, and 5) documenting these discussions and decisions in some way that is accessible to health care providers in various settings of care.

Poor Communication, Poor Planning, Poor Quality Death

There is emerging literature on the benefits of ACP but also the impacts when it is not present. In a paper published in the *New England Journal of Medicine* earlier this year, Silveira and colleagues reported the results of an observational, longitudinal study of 3756 elderly Americans and found that the majority need decision-making at the end of life at a time when they lacked the capacity to make decisions.¹⁰ Patients who had prepared advance directives received care that was strongly associated with their preferences and the majority preferred limited care or comfort care (only 1.9% wanted all care possible). In another observational study of terminal cancer patients, the absence of ACP in any of its forms was associated with worse patient ratings of quality of life in the terminal phase of the illness, worse ratings of satisfaction by the family during the terminal illness, and increased family ratings of anxiety and depression.¹¹ In contrast, when physicians and patients/families engage in ACP, there is less 'intensification of care' (use of intensive care units, life-sustaining technologies, or feeding tube insertions) and more usage of hospice services.¹¹ In a study of nursing home residents who had advanced dementia, written advance directives were independently associated with a lower rate of feeding tube insertion in this population.¹² In a recent randomized trial conducted in Australia, over 300 patients 80 years or more were randomized to ACP or usual care. Of those that received the ACP intervention, 108 (84%) expressed wishes or appointed a surrogate, or both. Of the 56 patients who died by six months, end of life wishes were much more likely to be known and followed in the intervention group (25/29, 86%) compared with the control group (8/27, 30%; $P < 0.001$). In the intervention group, family members of patients who died had significantly less stress, anxiety, and depression than those of the control patients.¹³ A recent systematic review of the evidence concluded that ACP can improve patient outcomes such as the completion of advance care plans, instructional directives (e.g. advance directives) or proxy directives (e.g. powers of attorney for personal care, etc), adherence to patient's wishes, and patient and substitute decision maker satisfaction, understanding, and comfort.¹⁴

Finally, there are suggestions from the literature that ACP can significantly lower healthcare costs during the final week of life.¹⁵ In patients who had terminal cancers, the mean (SE) aggregate costs of care (in 2008 US dollars) were \$1876 (\$177) for patients who reported EOL discussions compared with \$2917 (\$285) for patients who did not, a

cost difference of \$1041 ($P=.002$). At a system level, based on the number of cancer deaths reported in the US, this could translate into over \$75 million of savings per year.¹⁵

In summary, there are strong signals from the literature that ACP is associated with improved clinical outcomes and reduced health care costs. ACP has become an established standard of care from the perspective of Accreditation Canada.¹⁶ Accordingly, many practitioners world-wide have begun to implement various ACP tools and to make the systemic changes that would embed ACP into health care based on the initial success of the Respecting Choices program in the US.^{17,18,19}

ACP in Canada

The Canadian Hospice Palliative Care Association (CHPCA; Executive Director Sharon Baxter) has embarked on a five-year project to develop a National Framework on ACP for Canada – *Advance Care Planning in Canada: A National Framework and Implementation*. This Framework provides an organization of principles and practices to move forward the implementation of ACP. It has been developed through a national consultative process with over 100 experts from across country including representatives from the health, government, non-governmental organization, academic and legal sectors. CHPCA, through their national effort to champion ACP, will be a key partner in this grant. To our knowledge, there are 2 areas in Canada that have already begun a broad-based development and implementation strategy for ACP in their respective regions, Fraser Health (FH) Authority, BC and the Calgary zone of Alberta Health Services.

Implementation of ACP in Fraser Health Authority

Over the past five years, under the direction of Dr. Doris Barwich and Ms. Carolyn Tayler (Clinical and Administrative leads for End of Life Care), the FH Advance Care Planning Initiative within the End of Life Care Program has been promoting regional best practices in patient/resident/client centred care by improving decision-making for capable adults and/or their substitute decision makers and by promoting best practices for clinicians through education and engagement. Approximately 1000 FH interdisciplinary providers have accessed on-line modules and 6 hour skills training workshops that promote ACP conversations, at both beginner and intermediate skill levels. Patients and families have access to planning tools including the My Voice workbook®, an E-book, and a 1-877 line that members of the public and health care providers can call for support. Posters in public areas such as GP offices, libraries and hospital waiting rooms and available in seven languages promote public awareness. An ACP video is available in 3 languages and has been used by a wide variety of healthcare professionals to promote ACP.

In 2006, the ACP team led by Barwich and Tayler implemented a Cardiopulmonary Resuscitation (CPR) & Do Not Resuscitate (DNR) Orders Policy across the twelve acute care sites in FH. Key changes included implementing the ‘Greensleeve’ which is a green transparent folder placed at the front of the acute care chart and is the identified place to house ACP documents as well as the completed DNR form, new forms which documented not only decision making regarding resuscitation but also the scope of medical therapy, and the process by which the decision had been made. Based on a recent chart audit of 498 charts in all sites within FH, the uptake has been excellent with a Greensleeve present in 63% of charts; a DNR order form present in 45.4% with documentation regarding scope of treatment in 84.5% of those charts.

In May of 2010 FH approved a new strategic initiative - *Talking it Thru: Medical Orders for Scope of Treatment*. This project will provide tools and resources to help care providers throughout FH initiate and track advance care planning conversations and ultimately translate them into a clear plan of care and medical orders. Importantly there will be documentation of both the identified key elements of Advance Care Planning *conversations* and the *outcomes* on a Medical Order for Scope of Treatment (MOST) form. The MOST form will standardize communication across care settings by replacing the current Do Not Resuscitate (DNR) Orders (acute care) and Levels of Intervention forms (residential care) in use in FH and will include decisions regarding other components of the treatment plan (E.g. tube feeding, mechanical ventilation, dialysis, etc). It is expected that the MOST project will enhance and “drive” the systematic implementation of ACP processes in all sectors across FH. However, to date, there has been no evaluation from a patient/family view point to inform ongoing implementation efforts.

ACP Implementation in the Calgary Zone of Alberta Health Services

Under the leadership of Bert Enns (Director, Palliative and End of Life Care), Tracy Lynn Wityk Martin (Quality Improvement Specialist), Paul Boucher (Critical Care physician) and Dr. Jessica Simons (Palliative Care Physician), the “Advance Care Planning: Goals of Care Designation (GCD)” policy for adults was introduced in the Calgary Zone of Alberta Health Services in November 2008 and it incorporates the principles of ACP. Similar to the MOST initiative above, this policy standardized communication across care settings by replacing the multiple resuscitation policies that existed throughout Calgary. It emphasizes the importance of discussions, within a process of shared decision-making, in order to integrate a patient’s preferences for health care with what is considered medically appropriate to provide. GCDs are medical orders that serve as a communication tool between health care professionals by giving guidance regarding *the locations* and *general intentions* of the care as well as *interventions* that are provided. Another communication tool - The ***Tracking Record for Advance Care Planning/Goals of Care Discussions***- documents ongoing discussions and decisions regarding goals of care. This form is transported together with the GCD order by means of a Greensleeve (same concept as used by FH) which has become a recognizable tool to house the important documents related to ACP and GCDs. Processes have been established to ensure Greensleeves and the contained documents transfer with patients across service streams. Additionally, pilot work within 5 specific clinical areas provided the opportunity to develop, trial, and produce a series of ACP “My Voice—Planning Ahead” resources- including a “My Voice” workbook, information brochures, introductory video, and teaching resources for both the public and health care clinicians.

During the spring of 2009, an extensive post policy implementation audit was undertaken throughout all sectors. Results revealed that only 40% of charts in the acute care sector had documentation of discussions related to ACP or GCDs in contrast to 89% in the long-term care sector. A Qualitative study provided some preliminary insights into some of the barriers and facilitators to patient participation in ACP.²⁰ Clinicians felt they received enhanced information that enabled them to provide medically appropriate care that aligned with patients’ wishes. These evaluation results lay the foundation for further work to explore the impact of ACP on patients and families.

The Need for an ACP Evaluation in Canada

Despite the efforts to implement ACP locally with FH and Calgary regions, to date, there has been no rigorous evaluation from the patient or family perspective to inform planners and clinicians as to the level of success and what remaining barriers exist. Knowledge users in these regions need this information to move forward with their implementation efforts and to enable them to muster sufficient resources to continue and even expand their work. Our community is not ready to conduct interventional trials until we have considered this important perspective from the patient and their family.

Critical to the ACP process are a disclosure of prognosis and a discussion of therapeutic options with associated risks and benefits. Researchers on our team recently completed 2 studies in the target patient population for this grant. In hospitals in Canada (including 2 hospitals participating in this study), we demonstrated that only 18% of patients who have advanced medical disease and 30% of their family members acknowledged that a physician had spoken to them about their prognosis.²¹ We found that patients and families who did have a discussion about prognosis were much more likely to be satisfied with their overall EOL care and specifically with EOL communication and decision making.²¹ Moreover, as mentioned previously, in a recent study, we measured satisfaction levels with EOL care using the recently developed CANHELP satisfaction questionnaire in over 350 elderly, hospitalized patients and their family members (same target population as the current study) and concluded that ACP was a high priority quality improvement target for improving EOL care in Canada.⁹

To further justify the need for an ACP evaluation in Canada, we note that the literature previously cited above, supporting the benefits of ACP, is largely drawn from the United States and from other jurisdictions that have different legislation and health care contexts. There are no published large scale studies demonstrating the clinical or economic benefit of ACP in the Canadian context. The new knowledge gained from the proposed prospective audit will significantly shape local, regional, and national ACP implementation efforts and further research. For the first time, we will get feedback from end users, patients and their families, as to their satisfaction with the process and potential barriers that will need to be overcome for implementation efforts to be more successful. By having relevant decision makers as partners of this research process, we can ensure that this new information shapes future policies and procedures in their local jurisdiction, further embedding ACP into the health care system.

Finally, some of the investigators on this grant have just completed a research priority setting exercise in partnership with the CHPCA and the ACP Framework Steering committee, a committee made up of over 15 representatives from the health care and legal community. We met face to face and had several conference calls to develop a comprehensive list of 17 ACP research topics and the criteria by which we were to judge their priority. We then consulted a broader group of clinicians, decision-makers, and researchers (n=100) to get their ratings of priorities.²² Preliminary results indicate that determining the impact of ACP on the quality of death and dying, understanding the preferred manner or method for patients and families engaging in ACP, and what barriers and facilitators exist from a patient and family perspective were the top 3 ranked research priorities.

In summary, evaluating ACP is a top research priority for our national community and we have a long track record of collaborating, as researchers and knowledge users in moving this agenda forward. More importantly, the signals from our own research in

Canada suggest that more support for ACP is needed by patients and their families and more research is needed to inform quality improvement in this area. This study is not primarily about whether ACP works, it is more about how best to implement it. The current challenge is to understand the impact of ongoing initiatives from patients' and families' perspectives. **We do acknowledge that there are other relevant perspectives to a broader program evaluation of ACP- health care professionals, administrators, system issues, etc.- but our focus for this evaluation is on patients and families.**

The Research Questions

Primary Research Questions

In recently hospitalized 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?
 - a. Does the patient have an advance directive or living will or some other written document expressing their wishes?
 - b. Has the patient and/or family been informed of the patients' prognosis?
 - c. Has the patient and/or family been informed about the expected benefits and burdens of various treatment options?
 - d. Has the patient considered how s/he wants to live in the final stages of life and what kinds of medical treatments they would want or not want?
 - e. Have they discussed this with their family? A health care provider? Which one? When was the last time? How often?
 - f. Did a health care provider ask them about their personal values and wishes related to care provided at the end of life?
 - g. Has there been a discussion about their goals of care with their health care provider? If so, are they aware of them?
 - h. Has there been a decision made about medical treatments at the end of life? If so, what role did the patient/family play in that decision-making and was this consistent with their preferred role?
 - i. Is there documentation in the medical record of the overall goals of care?
- 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?

Secondary Research Questions

- 4) Compared to baseline, what is the effect of an audit and feedback process coupled with tailored interventions on use of and satisfaction with ACP at the site level?
- 5) Compared to those patients who have not undergone an ACP process upon enrolment, what is the impact of ACP on patient/family satisfaction with care, use of life-sustaining technologies, and hospital resources during index hospital admission and long-term health care utilization?
- 6) Which components of ACP (a-i) are more strongly associated with overall satisfaction with EOL communication and decision making?
- 7) At baseline, compared to sites with low degrees of system level implementation, do sites with higher levels of system level integration have a higher prevalence of ACP and greater satisfaction with EOL communication and decision-making?

Study Design:

We designed this study using Graham and colleagues' Knowledge to Action (KTA) Model for Knowledge Translation (KT) as our framework.²³ Within the KTA Model, steps are informed by identification of knowledge-practice gaps, adapting knowledge to the local context, assessing barriers to knowledge use, tailoring of the KT intervention to overcome identified barriers, and evaluating outcomes. We have chosen a multicenter, prospective, study design that will involve a baseline audit of current practice, followed by 3 audit-feedback cycles with tailored interventions designed to improve ACP practice. The first audit would begin in April 16, 2011 and be repeated annually for a total of 3 years (period of funding). April 16 is significant in that this is National Health Decision Day in the United States and starting in 2011, Canada will be participating. During each sampling frame, we expect each site to collect data to answer the above study questions on 60 eligible patients and/or their family members in their institution. Following each audit cycle, the study team will provide the local/regional teams with benchmarked site reports. Local teams will review their sites reports and, with support from the study team, develop an action plan to develop their tailored intervention, tailored to their specific local needs. **Thus, within this observational study, we will have an opportunity to test specific tailored interventions and their impact on ACP.** The study team will be in contact quarterly with local teams to keep them engaged with the tailored interventions and motivated over the next 12-month implementation period. This cycle will be repeated every 12 months. A yearly cycle with ongoing review of local barriers to implementation will allow adequate time to make changes to the ACP implementation and repeat the next audit cycle. Many of these changes will require system level changes so the implementation of audit cycles less than a year apart may not be feasible. Audit and feedback is an important enabler that can facilitate behaviour change and potentially improve clinician adherence to the ACP process. The use of audit and feedback, with ongoing local assessment of barriers/needs is within the KTA theoretical framework we have chosen for this study²⁴

Setting:

We will conduct this study in the following hospitals with the co-investigators responsible for data collection and ACP implementation in brackets: In CZ, Foothills Medical Center, Peter Lougheed Center, and Rockyview Hospital (Enns, Wityk Martin, Boucher, and Simon); In the Edmonton area, Royal Alexandra Hospital (Kutsogiannis), University of Alberta Hospital (Bagshaw), and the Grey Nun's Hospital (Stollery); In FH, Royal Columbian Hospital and Burnaby General Hospital (Barwich and Tayler); in Vancouver Coastal Health Authority Vancouver General Hospital (Cummins) and St. Paul's Hospital (Dodek); and in Ontario, Kingston General Hospital (Heyland) and Hamilton General Hospital (You).

We justify working with multiple acute care institutions since that is where the patients at highest risk of dying are located and our previous work suggests there is low level of ACP occurring.²¹ **Study population:**

In this prospective audit of current practice, we will enroll patients who are at high risk of dying and/or their families (where available). We define this 'risk' by the following criteria:

1. 55 years or older with one or more of the following diagnoses:

- a) *Chronic obstructive lung disease* - 2 of the 4 of: baseline PaCO₂ of ≥ 45 torr, cor pulmonale; respiratory failure episode within the preceding year; forced expiratory volume in 1 sec ≤ 0.5 L.
- b) *Congestive heart failure* - New York Heart Association class IV symptoms and left ventricular ejection fraction $\leq 25\%$.
- c) *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, or c) Child's class B liver disease with gastrointestinal bleeding.
- d) *Cancer* - metastatic cancer or stage IV lymphoma.
- e) *End-stage dementia* (inability to perform all ADLs, mutism or minimal verbal output secondary to dementia, bed-bound state prior to acute illness)

OR

2. Any patient 80 years of age or older admitted to hospital from the community because of an acute medical or surgical condition and do not meet the criteria above.

OR

3. Any patient 55 to 79 years of age admitted to the hospital, who does not meet the above criteria and, in the opinion of the health care team (i.e. attending physician, resident, nurse or charge nurse), is not likely to survive beyond 6 months.

These clinical criteria identify a patient population that, on average, has a 50% probability of death in 6 months. We have successfully used these eligibility criteria and the recruitment strategy below in our previous evaluations of quality of care^{7,9}.

Beginning on a pre-specified day each April, we will approach consecutive, eligible patients and their family members from participating hospital units for enrollment into this study. Potentially eligible patients will be identified by the attending physician, medical residents, other healthcare staff, and by the study nurse as soon as possible after admission to the hospital ward (excluding ICU). Patients unable to communicate due to language (English/French only) or cognitive reasons will be excluded but if their family member is eligible and available, we will approach the family member. 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. 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, 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. If there is more than one family caregiver

available, we will allow them to select who participates. We will time our initial approach to be after 48-120 hours of 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. Using this approach, response rates in our previous studies ranged from 78-91%.^{7,9}

Upon enrollment, the research assistant will conduct separate interviews with patients and family caregivers so they cannot influence each other's responses. The research assistant will administer the questionnaires in a face-to-face interview. Based on our previous work, we expect each interview to take 40-60 minutes. On occasion, the interviews had to be interrupted because of patient fatigue, but in all cases, patients willingly resumed the interview at a later time. Most viewed the interview process as a therapeutic experience and not a burden. On a burden scale of 1-10 (1=no burden, 10=extremely burdensome), the median burden score was 1.6 (standard deviation 2.1). This is supported by a recent publication documenting that similar research interviews with terminally ill patients and their family members do not create undue stress.²⁵ We believe it is feasible to complete the interview with all the measurements described below.

Data Collection

From direct interview of either the patient and/or family 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 (²⁶), co-morbid illnesses using the Functional Co-morbidity Index (²⁷) and the Charlson Co-morbidity Index, (²⁸) and the Palliative Performance Status score as a measure of functional status. We will then administer a questionnaire that we will develop to evaluate whether the patient or family has engaged in ACP and to elicit their perceived barriers and facilitators to having these kinds of ACP-related conversations. (see Appendix A). Immediately following this questionnaire, the research coordinator will administer the CANHELP satisfaction questionnaire (described below). Upon completion, the research assistant 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 assistant will abstract data on hospital outcomes and resource utilization. To evaluate the long-term impact of ACP on health care resource utilization, we will create linkages with administrative databases in British Columbia and Alberta to enable us to describe and compare health care utilization beyond the index hospitalization over the next 12 month period.

To properly develop the ACP-related questionnaires used in this study, we have consulted experts in critical care medicine, palliative care medicine, nursing, and psychometrics. At 2 sites (Kingston General Hospital and St. Pauls Hospital), we plan to assess the clarity, sensibility, and acceptability of this questionnaire in 20-30 patients and families prior to the start of the study. In this pilot study, we will audiotape open-ended questions on the current version (Appendix A), to enrich our understanding of our respondents view ACP, with a view to generating closed ended responses after the pilot study. Further revisions will be made to other questions as well, if necessary, following the pilot.

Outcomes:

The primary outcomes of this study will be completion of ACP documentation and satisfaction with EOL care. As explained above, we will use a series of questions to ascertain if respondents have completed the various components of ACP. We propose to use the novel, recently validated *Canadian Health Care Evaluation Project (CANHELP) Questionnaire* to measure satisfaction from both patient and family perspectives. The details of the development and validation of the CANHELP questionnaire have been published elsewhere.²⁹ In brief, we generated items to be included in this questionnaire from a review of the published literature, focus groups with experts, and interviews with patients. We demonstrated that the CANHELP questionnaire correlates as expected with other established measures at the end of life (construct validity), has good internal consistency (Cronbach's alpha >0.70), and can be grouped into valid subscales.²⁹ For the patient version, there are 37 items in the following sub-scales: Relationship with Doctors (4 items), Illness Management (14 items), Communication (5 items), Decision-Making (4 items), Role of the Family (6 items), and Well-being (4 items). For the family questionnaire, the factors were Relationship with Doctors (4 items), Characteristics of Doctors and Nurses (5 items), Illness Management (10 items), Communication and Decision-Making (6 items), Involvement (7 items), and Well-being (6 items). We used response options to assess degrees of satisfaction using a 5-point ordinal scale ("1=Not at all satisfied"; "2=Not very satisfied"; "3=Somewhat satisfied"; "4=Very satisfied"; and "5=Completely satisfied") (see www.thecarenet.ca/CANHELP for more information and Appendix B for a copy of current questionnaire for both patient and family). We propose to use the 'Communication and Decision-making' domains of this questionnaire as our primary satisfaction outcome although we will describe the other domains and overall satisfaction in a secondary way. In addition, from our chart review, we will be able to describe the resources used during the index hospitalization including the use of life sustaining technologies, percutaneous feeding tubes, admission to ICU and total hospital stay (Appendix C). Finally, as we work with a number of institutions with varying levels of ACP activities, we have developed a questionnaire to be filled out by each site that catalogues the nature of the hospital and larger system level integration of ACP implementation (Appendix D). As we begin to understand the optimal implementation process from a patient/family point of view, we will then be able to describe what system level resources enable such performance.

Proposed Analysis:

Research Questions (RQ) 1-3: The analysis of this study will largely be descriptive. To meet the primary objectives of this study, we plan to produce a benchmarked report that shows, for each site, their prevalence of the components of ACP amongst their patient population, satisfaction scores, and the noted barriers and facilitators to enable each site to improve its performance year to year. Overall site-averaged summary figures will display the distribution of ACP usage rates, barriers and facilitators, and mean satisfaction with EOL communication and decision making by site over time. RQ 4: A one-way repeated measures analysis of variance will be used to test the statistical significance of change in site-averaged ACP rates and satisfaction over time. RQ 5: Patient/family satisfaction, use of life-sustaining technologies and use of hospital resources will be compared between patients who have and have not undergone an ACP process. More formally, a linear mixed effects model at the patient/family level

with site as a random effect will be used to assess if satisfaction with EOL communication and decision-making (dependent variable) is associated with the use of ACP (independent variable) before and after controlling for relevant patient characteristics. A similar logistic mixed effects model will be used to examine the association of ACP use with use of life sustaining technologies and hospital resources. To reduce the impact of missing questionnaire data we will impute missing values using the EM algorithm³⁰. If more than a trivial amount of data are missing, then we will employ multiple imputation as our primary analysis and will perform sensitivity analyses to examine the potential impact of missing data on our conclusions. To evaluate the long-term impact of ACP on health care resource utilization, we will create linkages with administrative databases in British Columbia and Alberta to enable us to describe and compare health care utilization beyond the index hospitalization over the next 12 month period. RQ6: The association between overall satisfaction with EOL communication and decision making and use of each component of ACP will be described by the coefficient of determination (R^2). The individual R^2 will be compared descriptively, and bootstrapping (at the site level to account for potential within site dependencies) will be used to provide confidence intervals around the R^2 estimates and to test if the difference between R^2 values is more than can be attributed to random sampling error (i.e. chance). RQ7: An overall baseline system level integration score will be calculated for each site. Site averaged baseline ACP prevalence and satisfaction with EOL communication and decision-making will be plotted against the system level integration score, and Spearman's correlation coefficient will be used to summarize the strength of the association and test for its statistical significance.

We chose to enroll 30 patients and/or family members per site to provide a representative sample of the site's performance within the constraints of the budget. If we conservatively assume that 5% of the total variance in ACP use is attributed to differences between hospitals (i.e. ICC=0.05), then we will be able to estimate the overall proportion of ACP use to within 10.5% 95% of the time.

The Team

To conduct this evaluation, we have assembled a key group of decision makers and researchers that have considerable experience and expertise in the content matter and research methodology. The Principal Investigators for this project are Drs. Daren Heyland MD, MSc (Researcher) and Doris Barwich (Knowledge User) and they will be responsible for the overall execution of the project. Dr. Heyland is a critical care physician, the Director of CARENET (a national collaboration of EOL researchers), and the Director of the Clinical Evaluation Research Unit (CERU) at Kingston General Hospital which will function as the coordinating center for this study. Along with Drs. Dodek and Kutsogiannis, they have completed several prior research projects involving collecting sensitive data from elderly seriously ill hospitalized patients and their families. Dr. Barwich is a Palliative Care physician and the Program Medical Director for the End of Life Care Program in Fraser Health. Carolyn Tayler is the Regional Director for End of Life Care in Fraser Health and they have jointly been responsible for the ACP implementation to date in their Health Authority. They will be responsible for the ongoing implementation and evaluation efforts in Fraser Health and will be in a strong position to use the information gathered from this project to inform future care in their region as well as the various provincial and national initiatives they are involved with.

Dr. Cummins, General Internal Medicine at VGH, and Dr Douglas McGregor, the Regional Medical Director for Palliative Care in Vancouver Coastal Health Authority will complete the BC Team.

Similarly, Bert Enns, Tracy Lynn Wityk Martin, and Drs. Jessica Simon and Paul Boucher have been and will continue to be responsible for ACP evaluation and implementation in the Calgary Region. These respective Co-investigators in Calgary and Fraser Health have led the nation in formal ACP implementation programs; this type of evaluation could not be conducted in other settings where likely the compliance with ACP practice is too low and there are no system funded personnel ready to act on the information that arises from the evaluation. Dr. Peter Sargious will join the team as a co-investigator/Knowledge User as the Medical Director, Chronic Disease Management, Alberta Health Services and will work to ensure learning from the initiative is embedded in disease management algorithms and infrastructure throughout the province. Drs Stollery (Edmonton) and Bagshaw (Edmonton) and You (Hamilton) join our collaborative as site investigators from their respective institutions.

In addition to these members of the study team, we have partnered with Dr. Ana Johnson, Canada Research Chair in Health Policy who will be responsible for the resource utilization and cost data collection and analysis and Dr. Tasnim Sinuff, a CIHR-funded expert in knowledge translation. She will be responsible for work with the data analyst to ensure optimal audit and feedback strategies. Sharon Baxter, Executive Director of the CHPCA will also be a Co-investigator/Knowledge User on this project and will be responsible for working with her staff to see that results and information arising from this project are disseminated through CHPCA's ongoing communication channels which consist of 4,000 people and organizations on their membership email list, 11 list serves, relationships with 11 provincial hospice palliative care associations and over 30 national organizations as partners through the Quality end of life care coalition of Canada. Andrew Day at Kingston General Hospital is the study biostatistician.

Limitations

An alternative strategy to evaluate the effect of ACP in Canada would be to conduct an RCT of the optimal ACP process compared to usual care. However, we don't know the optimal process as data from the patient/family perspective is lacking. Moreover, since some sites/regions have already started to implement some tools, we can learn from their experience. Thus, this study will produce novel insights into that optimal process from a patient/family perspective and will inform future evaluation studies of ACP, perhaps even randomized trials. Another limitation of the current study is our focus on English speaking participants. We justify focusing on the English language for this initial evaluation because we wish to assess how English-speaking patients and family view ACP conversations and the process that has been conducted in English (the predominant language of BC and Alberta). Subsequent studies will look at the impact of translation and cultural interpretation of ACP in non-English speakers. Finally, we acknowledge that patient/family perspectives are only one determinant to successful ACP implementation. Health care providers, administrators, and system issues will also impact on success and future studies will have to evaluate these aspects. However, we have developed a questionnaire to measure and describe system-level involvement in ACP in participating hospitals (see Appendix D).

Integrated Knowledge Translation Strategy

In accordance with CIHR's KT mandate, we have planned to conduct this study using integrated KT from the outset.³¹ The study team and our end-users have worked together to develop this study protocol. We have collaborated on developing the research questions, the methodology, and tools development. Following the completion of the study, we will work together to interpret the findings and disseminate the research results. Using this approach, we believe that our end-product should produce research findings that are more likely to be relevant to and used by the end-users. As already mentioned, our team includes a large network of physicians and decision makers from British Columbia and Alberta engaged in this ACP evaluation project.³² This collaboration is especially important in the area of ACP to optimize our study findings and the end-of-grant implementation of our results.³³

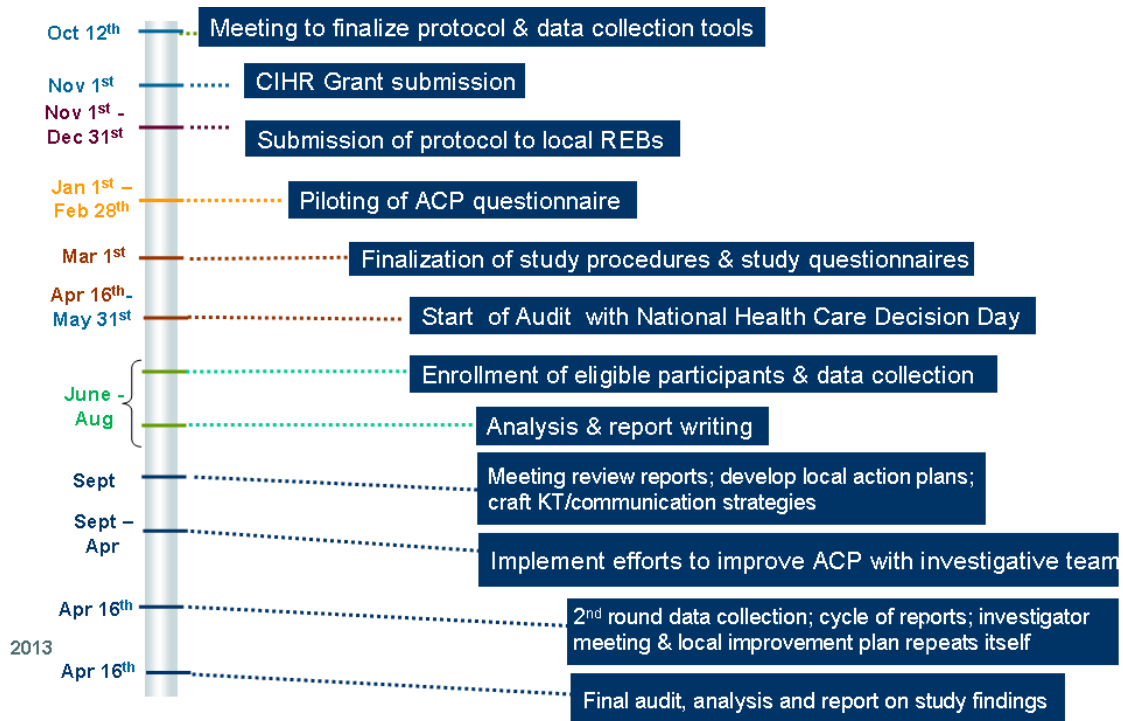
Using "CIHR's Knowledge to Action Process" model,³¹ yearly evaluations will be conducted for each site/region to identify any gaps in the ACP implementation process. As barriers to ACP are identified in our interviews with patients and families, specific tailored interventions will be developed and adapted for each. These tailored interventions will be designed and implemented with all project members at each individual site/region through conference calls and our annual face to face meetings. KT interventions associated with improving the processes of care, including education³⁴ and reminders to staff³⁴, facilitated by opinion leaders³⁵ will be used.

The evaluation cycle will continue every year to continually improve ACP implementation and to reduce barriers. At the end of the study, project findings will be disseminated through manuscript submissions to peer reviewed journals and also presented at national/international conferences. Moreover, a new web-based repository (www.acplanning.ca) will be created for stakeholders interested in ACP. The repository will contain current information on ACP practice along with ACP questionnaires/tools for clinicians, decision-makers, and researchers to use. At CERU, Heyland and his colleagues manage a critical care nutrition website that houses guidelines and implementation tools and we host an annual audit and feedback process that has over 200 ICUs participating annually from all parts of the world. We envision refining the questionnaires and tools and developing the website in a similar way as we have done for nutrition (for more details, see www.criticalcarenutrition.com).

Significance:

This will be the first large scale evaluation of ACP in Canada. 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 reduce overall health costs.

Research Timelines



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[Use Site Letterhead]

STUDY INFORMATION AND CONSENT FORM

Patient and Family Member

Advance Care Planning Evaluation in Elderly Patients:

A multi-center, prospective study.

The ACCEPT Study

Introduction

You are being invited to take part in a research study. Research studies such as this one involve only those individuals who choose voluntarily to take part.

In order to decide whether or not you wish to participate in this study, you need to understand enough about its risks and benefits to be able to make an informed decision. This consent form provides detailed information about the study. The doctor or study research coordinator will discuss the study with you. Before agreeing to participate, you might wish to talk about it further with your friends and family. Once you understand the study, you will be asked to sign this form if you wish to participate. You will be given a copy of the signed form to keep as a record.

This study is being conducted at [Your site] as well as twelve other Canadian hospitals. [Site Investigator and Co-Investigators] will be supervising the study at [Your Site]. Questionnaires for this study have been developed to document perspectives and activities related to advance care planning and treatment decision making from patients and their family members. This study has been approved by the [Site's Research Ethics Board].

Why Is This Study Being Done?

A significant part of health care involves caring for people who are seriously ill and are at risk of dying. Most elderly patients are too sick to participate in decisions about medical care in such a condition. Hospital doctors will often ask patients early in your hospital stay whether they would want or not want "resuscitation" (an attempt to restart the heart and lungs if the heart stops). Some may find the question alarming if it is the

first time they have ever thought about it, or others may have considered their treatment choices in the past and have had discussions with their family and their doctors about their wishes.

Discussing plans for any future medical treatments is called “advance care planning.” Advance care plans concern the medical treatments a person wants or does not want in the event their physical condition declines as a result of an accident, medical emergency, old age, or getting sicker from a chronic illness. Comfort measures to control symptoms such as pain, shortness of breath and anxiety are treatments provided to all. Other technological treatments may be discussed with patients with their doctor. For example, some patients may have life sustaining measures such as breathing machines, dialysis, or cardiac resuscitation used in their course of illness whereas others may not. The “DNR” or “Do Not Resuscitate” is an example of a treatment decision that doctors may discuss with patients. A DNR decision and other decisions about care patients want if they are unable to speak for themselves should be written down and put in the hospital chart.

Discussing advance care plans is important but this can be a difficult topic for doctors, patients and their families. The purpose of the study is to hear your views about these kinds of conversations and help us develop ways to make communication about advance care planning more open, and effective.

Advance Care Planning (ACP) has been shown to increase the quality of life of very sick or dying patients, improve the experience of family members, and decrease health care costs. However, we do not know how often Canadians, like your self, participate and engage in advance care planning. In this study, questionnaires will be used to collect information about patients and family caregivers' views about ACP and their satisfaction with care. This is a three year study that is being conducted at twelve sites across Canada.

How Many People Will Take Part in the Study?

At [Your Site], a total of 60 patients 55 yrs of age and older and/or their family members will take part in the study annually. Nationally, there will be 720 participants in 12 other Canadian centers annually.

What Is Involved in the Study?

If you consent to participate in this study, the study research coordinator will record information about you (such as education level, home location, ethnic group, income bracket, and religion) that might affect your perspectives and thus your answers to the survey questions that will later be asked. Information about your health condition(s) and treatments you received in hospital will be taken from your hospital chart. You will be asked about your general abilities to manage activities at home prior to hospital admission. We will then ask you several questions related to ACP. The study interview will take about 30-40 minutes to complete.

The information you provide is for research purposes only and will remain strictly confidential. The health care workers directly involved in your or your relative's care will not see your responses to these questions – if you wish them to have the information, please bring it to their attention yourself.

What Are the Risks of the Study?

There are minimal risks to participating in this study. Participants may find it upsetting to talk about advance care planning, and questions relating to your condition at this point. Please tell the interviewer if you need to take a break or rest. If you consider some of the questions too personal you can decide not to answer these if you wish. You may choose to withdraw from the interview at any point.

Are There Benefits To Taking Part in the Study?

Some participants in this kind of research have found their involvement to be beneficial because they were encouraged to talk about their health care experience and concerns.

Although you may not benefit directly from participation in this study, the information gained will help to improve the quality of care patients like yourself or your relative receive in the future.

What are the Alternatives to participating in the study?

The alternative to participating in the study is not to participate. You or your relative will continue to receive the best medical therapy, without prejudice whether or not you choose to take part in this study.

What About Confidentiality?

All information gathered in this study will be kept strictly confidential; your anonymity and your relative's anonymity will be protected at all times. You and your relative will be assigned a study number that will be used as your identifiers in study records. The information collected from all participating centers, will be sent to the Clinical Evaluation Research Unit (CERU) in Kingston, Ontario for data analysis. Data will be stored behind locked doors and made available only to qualified study personnel at CERU who are coordinating the study, and the Research Ethics Board that oversees the ethical conduct of this study at your hospital. Names and personal information will not be made available to anyone who is not involved in this study unless disclosure is required by law.

The information collected will be stored and maintained confidentially for 5 years after your participation in this study. At no time will you be identified in any presentation or publication arising from this study.

Remember, the information you provide is for research purposes only and will remain strictly confidential. The health care workers directly involved in your or your relative's care will not see your responses to these questions – if you wish them to have the

information, please bring it to their attention yourself.

What Are the Costs?

You will not be paid for taking part in this study. Taking part in this study will not result in added costs to you.

Your Rights As a Participant

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Deciding not to take part or deciding to not fully complete the study questionnaires, will not affect the care you (your relative) receives nor will it result in a loss of benefits to which you or he/she may otherwise be entitled. By signing this consent form, you do not waive your legal rights nor release the investigators and sponsor from their professional responsibilities.

Conflict of Interest

No conflict of interest parties have been identified.

What To Do If You Have Questions

If you have any questions about this study or your rights, you can meet with the doctor who is in charge of the study at this institution. That person is:

[Site Investigator], Co- Investigator
Phone: [Phone #]

The Head of the responsible department at [Your Site] is:

[Department Head], Head, Department of Medicine
Phone: [Phone #]

If you would like advice regarding your rights as a research subject or about ethical issues related to this research, you can contact a member of the research ethics board (the group of people who review research studies to protect the rights of research subjects). That individual is:

[REB Chair]
[Title]
Phone: [Phone #].

Participant Statement and Signature Section

My signature on this consent form means the following:

- I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me.
- I have been given sufficient time to consider that above information and to seek advice if I chose to do so.
- I have had the opportunity to ask questions which have been answered to my satisfaction.
- I am voluntarily signing this form.
- I will receive a copy of this consent form for my information.

Name of Participant (Print)

Signature of Participant

Date (dd-Mmm-yyy)

I have explained the nature and purpose of the study and the risks involved to the study participant. I have answered all questions to the best of my ability.

**Name of Person Obtaining
Informed Consent (print)**

**Signature of Person Obtaining
Informed Consent**

**Date
(dd-Mmm-yyyy)**

My signature below signifies that the study has been reviewed with the study participant by me or by my delegated staff and the participant's questions have been answered. My signature may be provided at a date later than the participant's, as I may not be present at that time.

Name of Investigator (print)

Signature of Investigator

**Date
(dd-Mmm-yyyy)**



QUEEN'S UNIVERSITY HEALTH SCIENCES AND AFFILIATED TEACHING HOSPITALS ANNUAL RENEWAL

Queen's University, in accordance with the "Tri-Council Policy Statement, 1998" prepared by the Medical Research Council, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada requires that research projects involving human subjects be reviewed annually to determine their acceptability on ethical grounds.

A Research Ethics Board composed of:

Dr. A.F. Clark, Emeritus Professor, Department of Biochemistry, Faculty of Health Sciences, Queen's University (Chair)

Dr. H. Abdollah, Professor, Department of Medicine, Queen's University

Dr. R. Brison, Professor, Department of Emergency Medicine, Queen's University

Dr. M. Evans, Community Member

Dr. S. Horgan, Manager, Program Evaluation & Health Services Development, Geriatric Psychiatry Service, Providence Care, Mental Health Services Assistant Professor, Department of Psychiatry

Ms. J. Hudacin, Community Member

Dr. B. S. Kisilevsky, Professor, School of Nursing, Departments of Psychology and Obstetrics & Gynaecology, Queen's University,

Ms. D. Morales, Community Member

Ms. P. Newman, Pharmacist, Clinical Care Specialist and Clinical Lead, Quality and Safety, Pharmacy Services, Kingston General Hospital

Dr. W. Racz, Emeritus Professor, Department of Pharmacology & Toxicology, Queen's University

Ms. S. Rohland, Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute

Dr. B. Simchison, Assistant Professor, Department of Anaesthesiology, Queen's University

Dr. A.N. Singh, WHO Professor in Psychosomatic Medicine and Psychopharmacology Professor of Psychiatry and Pharmacology Chair and Head, Division of Psychopharmacology, Queen's University Director & Chief of Psychiatry, Academic Unit, Quinte Health Care, Belleville General Hospital

Dr. E. Tsai, Associate Professor, Department of Paediatrics and Office of Bioethics, Queen's University

Rev. J. Warren, Community Member

has reviewed the request for renewal of Research Ethics Board approval for the project "**Advance Care Planning Evaluation in Elderly Patients. A Multicenter, Prospective Study. The ACCEPT Study - Pilot Phase**" as proposed by **Dr. D. Heyland** of the **Department of Medicine**, at Queen's University. The approval is renewed for one year, effective **January 05, 2012**. If there are any further amendments or changes to the protocol affecting the participants in this study, it is the responsibility of the principal investigator to notify the Research Ethics Board. Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other adverse events must be reported within 15 days after becoming aware of the information.

Albert F. Clark

Date: December 12, 2011

Chair, Research Ethics Board

Renewal 1[x] Renewal 2 [] Extension [] Code# DMED-1352-11 Romeo file# 6005791