PALLIATIVE CARE RESEARCH COOPERATIVE



# Member Highlight

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

## Recruiting expansion at UNC

**By: Kelly Onyenwoke and Kathryn Wessell**

The research team at the University of North Carolina at Chapel Hill has enrolled 16 participants since receiving IRB approval on October 7th, 2011. We are currently recruiting from the inpatient Palliative Care consult service, inpatient Oncology, Geriatric, General Medicine, and Hospitalist services, outpatient Oncology and Geriatric clinics, and two home health and hospice organizations. We are also excited to announce that we have recently expanded our recruitment efforts to include a local Continuing Care Retirement Community (CCRC). CCRCs are communities designed for senior citizens to address the changing needs that come with the aging process, and include independent and assisted living components, as well as a skilled nursing element.

To start the process, we had to receive approval from the retirement community's resident research committee. We then met with key players at the facility to discuss logistics for the study, and to identify a staff member there who would serve as the liaison between the site and UNC. The liaison and site physicians worked together to create a list of residents who were eligible for the study and mailed those individuals a packet of information about participating in the study. Included in the packet is a study brochure, a general informational letter about the study signed by the PI, and a return post card for people to indicate whether or not they wanted to be contacted by UNC about the study.


Also included in the packet was a cover letter written by the facility to inform the residents of the approved research collaboration with UNC. We feel that this was a key component in gaining entrée into this community, and residents seem to be responding well to it. Those who received study information were able to communicate back to the study liaison whether or not they wanted study staff to contact them, and the liaison gave the study team the names and phone numbers of residents who were interested in learning more. Within the first week of collaborating with the retirement facility we have already enrolled one participant, and are excited about (hopefully!) enrolling more in the coming weeks!

*See more from UNC in "Needle in a Haystack" page 4*

## Rachel Walton joins the PCRC team at Duke

I'm thrilled to be joining the PCRC team this Spring! I am very passionate about being a part of new and innovative research in the healthcare field, as I've seen first-hand how imperative research is in improving both the quality of life of patients, as well as finding cures. Several years ago, I had the privilege of being the bone marrow donor to my sister for her treatment of cancer, and my sister's journey has not only driven my passion, but has propelled me into the capacity to want to work alongside those that are serving in this field.


## Rochelle Erickson - CRC Mayo Clinic

Rochelle Erickson started working for Mayo Clinic in 2000 as a medical secretary and then went to college and got an associate's degree in clinical research study coordination and began working as a study coordinator a little over a year ago. She is married and has two teenage children who are going to start college this fall. Her hobbies are sheep farming and anything to do with horses, and she loves country music, sitcoms, and lobster. She is looking forward to being involved with palliative care research as she believes everyone should have the opportunity to enjoy every day.


## Shirley Samuel - CRC Northwestern

I'm Shirley and I'm thrilled to join the PCRC team! I've been at Northwestern for 4 years now, mostly involved in basic science research. Decided to switch to clinical research since I no longer wanted to work with mice! I've travelled across the globe for school and obtained each of my degrees from three different continents - now I'm hoping to stay put in the US! I like what I do now, I have a fantastic PI and I'm keeping my fingers crossed for more recruitments in the days ahead - I also want to say kudos to Rachael and Jordan for helping me learn the ropes when I started and for still attending to my sometimes silly questions!

# Statin Trial enrollment summary (as of 4/11/2012)

| Site | Actual N |
|---|---|
| 01 - Colorado | 41 |
| 02 - Duke | 28 |
| 03 - Four Seasons | 12 |
| 04 - UNC Chapel Hill | 16 |
| 05 - UA Birmingham | 7 |
| 06 - Beth Israel | 1 |
| 07 - UW Madison | 6 |
| 08 - San Diego Hospice | 3 |
| 09 - Northwestern | 2 |
| 11 - Mt. Sinai | 1 |
| **Total** | **105** |

## Words of Wisdom

**By Marlene Mckenzie**

As I consider my role as clinical research coordinator for the statin study, I realize that I am a highly skilled sales person as well as a highly trained health professional. Though a little uncomfortable with the notion of being a "sales person" I disregard the stereotypes and analyze the qualities of really good sales people.. I know that the best salespeople are highly knowledgeable about their products, can describe what they are selling in language that I can understand, are very good listeners, respond to my questions and concerns and make me feel that I am in control. Awareness of these attributes helps me be a better CRC.

*"Driftwood, deadwood—what the hell's the difference?"*

**Delivery can make all the difference!**

I sell the statin study to health care professionals and to patients and their loved ones. With physicians / providers I confirm the enrollment criteria and let them know that even though they may be giving me permission to offer the study to the patient, the patient will always have the right to decide if they are interested or not. I confirm that I will get back to them if the patient enrolls to let them know if the patient will stop vs. continue taking statin meds.

With patients and families i break down the study in simple terms. 'If you sign up for this study you will either keep doing what you are doing now (keep taking your statin pill) or stop taking this one pill". I let them know that just because their doctor gave me permission to talk with them, they are the ones who get to make the decision. I reassure them that deciding not to be a part of the study is OK too. A person should always feel good about participating in a research study. By giving them control, they listen to the consent and more often then not choose to sign on because they want to contribute to advancing medical knowledge and helping other people in the future who are dealing with advanced life limiting illness.

# UNC Highlight continued....

## Needle in a Haystack

Like most of the sites for the Statin Discontinuation Study, the team at UNC has had its fair share of searching for that ever elusive "needle in a haystack." We are fortunate in that we have a limited HIPAA waiver, which allows us the ability to pre-screen charts to see if patients meet Part A eligibility criteria. Since we received IRB approval in October 2011, we have viewed 5,692 (!!!) patient charts (as of 4/19/2012). No, your eyes aren't playing tricks on you – you did read that correctly – 5,692 charts. Of those, only 2,137 were even prescribed a statin medication, and only 61 of those 2,137 met all of the Part A eligibility criteria. Of the 61 individuals who met all Part A criteria, only 13 also met all Part B criteria and consented and enrolled in the study. So all in all, we looked at almost 5,700 charts to have 13 people enroll. It just goes to show that patience and persistence are essential characteristics for those working on this study. It's tough out there! We are continuously looking for new recruiting opportunities through various venues, and are hopeful that our determined effort will pay off. If we can be of any help to other sites, please let us know. Also, if other sites have any additional ideas or recruiting suggestions, we'd be happy to hear them! Best of luck to all the CRCs in finding that needle in a haystack!
(*Update as of 4/26/12 – we're up to 15 enrolled participants!)

You were right: There's a needle in this haystack...

## *Views of UNC*

**Congratulations to Judie!** She received an impact score of 17 for her grant application to the NINR Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellows In Nursing Research (F31). The funding request is for her project titled **"Family Perceptions of Strategies to Facilitate End-of-Life Decisions."** which she hopes to begin in July 2012 pending notification from the Advisory council following their meeting on May 15th. Her abstact follows.

## Abstract

**Significance**: Family members of patients dying in the ICU are faced with agonizing dilemmas, the consequences of which may haunt them for a lifetime. Providing these family members with meaningful support and information is imperative. Nurses, by virtue of the time spent at the bedside and knowledge of patient and family needs, are in a unique position to support family members. The literature provides ample studies of how nurses perceive they are involved in EOL decision-making and several studies describing what family members perceive that they need from health care professionals in general. What is lacking is literature that describes the family members perceptions of the specific strategies that nurses use to support their decision-making and how family members respond to these strategies. Because nurses may act on instinct, the strategies they use may or may not be helpful to family members. The proposed study will build on prior work by exploring in greater depth the specific strategies that family members perceive nurses using and how family members respond to these strategies.

**Purpose:** This study aims to explore how family members respond to nursing strategies to support EOL decision-making, including family members perceptions of the strategies nurses use, how these strategies change over the trajectory of decision-making, and how these strategies affect their ability to make decisions consistent with the goals of the patient and their ability to cope with the stress of making EOL decisions.

**Methods:** In this prospective, longitudinal, qualitative descriptive study, I will identify ICU patients who are likely to need complex decision-making and use narrative style interviewing techniques to explore the family members' perceptions of the strategies nurses use and the effectiveness of these strategies. Participants will be recruited from a 16 bed adult medical ICU at Duke Hospital, a tertiary care university hospital system.

**Summary:** Knowledge from this study will pave the way for spreading expert nursing practices by leading to interventions targeting the areas identified as important by family members, most likely to improve their well being, and feasible in ICU environment. With this knowledge, nurses will be able to interact with families based on empirical data, rather than on instinct, and to help family members to make decisions that are consistent with the patient's goals and to cope with the burden of EOL decision-making.

Judith A. Adams, RN, MSN, FNP-BC, ACHPN
PhD Graduate Student
Duke University School of Nursing

The PCRC is proud to be able to support and celebrate the accomplishments of junior investigators.

# Palliative Care Research Cooperative (PCRC) Team Operating Procedure: Procedure for Completion of Case Report Forms (CRFs) for PCRC Trial 10-01 (Statin Trial)

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 1 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
| Person responsible for this procedure: a PCRC CRC (staffed by a PCRC member institution) | Next review date: 27 May 2012 |
| Approved By: PCRC Coordinating Statistician | Created: 1 OCT 2010<br>Last Updated: 27 Feb 2012 |

## Palliative Care Research Cooperative (PCRC) Team Operating Procedure: Procedure for Completion of Case Report Forms (CRFs) for PCRC Trial 10-01 (Statin Trial)

### I. Background and Purpose

The purpose of this TOP is to provide guidelines and details concerning the procedures for completion of the CRFs for PCRC Trial 10-01 (Statin Trial)

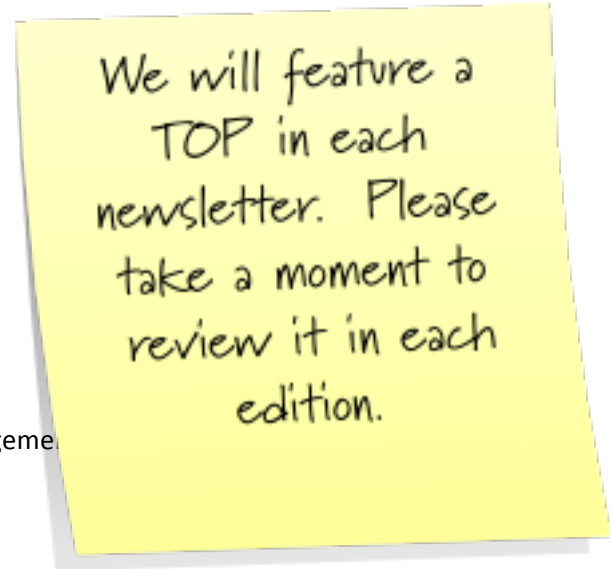
### II. Scope

Applies to all site personnel involved in completing case report forms for PCRC Trial 10-01.

### III. Definitions

Please see Top on PCRC Definitions for a complete set of definitions.

### IV. Procedures




**Complete List of Study Forms:**

Form A –Eligibility
Form B – Baseline Information
Form C –Contact Information
Form F – Baseline and Follow-up Interview
Form H – Medications
Form I – McGill Quality of Life Questionnaire (MQOLQ)
Form J – Edmonton Symptom Assessment System (ESAS)
Form R – Site Submission & SCDM Office Receipt Acknowledgeme
Form X – Adverse Event Reporting Form
Form X2 –Adverse Events – Supplemental Info
Form Y – Event Classification Committee Report on SAEs
Form Z – Study Summary: Tracking Mortality, Compliance and Willingness to Continue

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 2 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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| | Eligibility | Baseline | Weeks 1-4 | | Weeks 6-24 | | Weeks 28-52 | Adverse Event | End of Study |
|---|---|---|---|---|---|---|---|---|---|
| **Form** | | **Wk 0** | **Wk 1, 3** | **Wk 2, 4** | **6, 10, 14, 18, 22** | **8, 12, 16, 20, 24** | **28, 32, 36,40, 44, 48, 52** | | |
| **A** | X | | | | | | | | |
| **B** | | X | | | | | | | |
| **F Parts A and B** | | X | X | X | X | X | X | | |
| **F Part C** | | X | * | X | * | X | * | | |
| **F Part D** | | | X | X | X | X | X | | |
| **H,** | | X | | X | | X | | | |
| **I and J** | | X | | X | | X | | | |
| **X, X2** | | | | | | | | X | |
| **Z** | | | | | | | | | X |

***Note that for the short interviews, page 2 (Part C) of Form F is not completed.**

**Instructions for Completing Forms:**

**Form A –Eligibility**

1. Please fill out Form A – Eligibility in the following manner:
   a. Fill out Part A: Initial Screening for all participants screened for the trial and submit form if participant meets all the Part A eligibility criteria. Do not submit form (or enter information into the data base) if participant does not meet all Part A eligibility criteria.
2. Every participant who is eligible according to Form A, Part A should be assigned a Participant ID number. The Participant ID will be your site ID plus a three-digit number. For example, if you are site # 06 and this is the first individual who was screened and met all eligibility criteria on Form A, Part A, then the ID is 06001. You need to keep a log of the IDs assigned at your site. You can also access the DataTrak database to view the IDs that you have entered into database.
   a. Complete the remainder of Form A. If, while completing Part B it is determined that the person is ineligible, complete each known item in Part B and enter the participant ID number and all information collected into DataTrak with the initials ZZZ.
3. Form A should be dated using the date when the participant was determined to be either eligible or ineligible.
4. Additional explanations of the criteria are specified in the protocol.
   a. Declining functional status – see protocol

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 3 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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b. Requires ongoing therapy with statin drugs due to active CVD or sufficient risk of CVD? – This is determined by the primary treating physician.
c. If a potential participant fails one of the following, document as "Yes" to "Contraindications to continuing or discontinuing statins?"
    - exhibits no obvious symptoms of myositis
    - liver function tests are not > 2.5x upper limit of normal (ULN)
    - creatinine kinase is not > 2.5 x ULN
d. For history of cardiovascular disease (CVD), check "Yes" if they have any of the following:
    1. Acute coronary syndrome
    2. Coronary artery disease
    3. Angina
    4. Myocardial infarction
    5. Congestive heart failure
    6. Peripheral vascular disease
    7. Transient ischemic attack
    8. Stroke or cerebrovascular accident
    9. Carotid artery stenosis

5. If you discover that the information about eligibility (at the time eligibility was determined) was incorrect after a participant was randomized, the participant should be formally withdrawn from the study (complete Form Z).

**Form C – Study Participant Contact Information**

1. This form is a worksheet specifically to be used to record information that will assist with participant follow-up. You may modify this form in any way that is useful.
2. In addition to participant contact information, there is space to list the primary treating physician and two alternative contacts (e.g. family member). These may be particularly useful when you are having trouble contacting a participant so it is useful information to have at the beginning of the study.
3. DO NOT submit this form to the data management center as it has explicit study participant-identifying information.
4. This sheet is to be kept at the local site in a secure, locked place. It should be destroyed at the end of the research study.

**Form B – Baseline Participant Information**

1. Fill out Parts A through F from medical and administrative records, where feasible. Then query the participant for missing information.

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 4 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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a. In Part A, indicate primary insurance (See below):
   - Medicare includes fee-for-service and managed care Medicare participants
   - Medicaid includes fee-for-service and managed care Medicaid participants
   - Private insurance includes Blue Cross, commercial carriers, and private HMOs and PPOs
   - Uninsured includes an insurance status of "self-pay" and "no charge"
   - Other includes Worker's Compensation, TRICARE/CHAMPUS, CHAMPVA, Title V, and other government programs
   - When more than one payer is listed, the first-listed payer is used.

b. In Part B (Current Diagnosis), indicate a single primary diagnosis and provide the ICD9 code for this diagnosis. Please use only ICD9 codes (not ICD10). If the participant is unsure of the exact date of diagnosis, obtain approximate year. Probes such as "Was it more than 10 years ago?" should be used. The website to look this up is: *https://icd9coding.com*.

c. In Part C (History), please remember to record a response for each of the 19 questions. Review this section with the participant. Suggested language might be: "I see that you have had X, Y and Z. Are there any other major illnesses that you have experienced?"

d. In Part D (Statin History), four medications are combinations of a statin and another drug. If the participant is assigned to the discontinuation arm, please check with the physician about whether he or she wants to continue the non-statin component (e.g., Advicor (niacin), Caduet (amlodipine), Simcore (niacin), Vytorin (ezetimibe)).

e. In Part D (Statin History), if in the rare event that the participant is on more than one statin medication, indicate "Other" and write in the names of the additional statin medication(s).

f. In Part E, record measurements in inches and pounds.

g. In Part F (Labs), you may have many participants with the same set of normal values. To avoid entering the same information for each, you can identify that set of normal values with an identifier in the field associated with "Lab Identifier for normal ranges". For example, Denver may have two labs with normal values for both genders. Their lab identifiers might be Den1male, Den1female, Den2male, Den2female. The normal values only need to be entered for one participant using that identifier as long as the identifier is entered into all the subsequent baseline assessments. Each site will be responsible for maintaining its own list of lab identifiers.

h. Other information at baseline:
   - Administer Form I – McGill Quality Of Life Questionnaire (MQOLQ)
   - Administer Form J – Edmonton Symptom Assessment System (ESAS)
   - Fill out Parts G (Participant Concerns) and H (Smoking History) by questioning the participant.

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 5 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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**Form F – Study Participant Interviews**

1. Complete this form until the participant dies or refuses further follow-up. If you are unable to contact the participant/caregiver or receive a direct refusal please document it on this form. Examples of administrative barriers include Clinical Research Coordinator (CRC) illness, or other issues that prevent the CRC from completing the interview.
2. If participant is not able or willing to do the interview at the time he/she is called, ask if there is a time to call back, or if the caregiver can answer some of the questions. If it is not possible to complete the interview for the current week, ask if you can call again in another week. A single refusal should NOT automatically result in study withdrawal.
3. If your phone call is not answered, call back at a different time of day for up to 3 attempts (or fewer if your Internal Review Board (IRB) restricts calls back).
4. Schedule for Form F: Parts **A: (Interview Information), and B: (Current Status)** are obtained at baseline, then weekly*, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52.* Part **D: (Important Events)** follows the same schedule, omitting baseline. *Information to complete these sections* can be obtained from either the participant or a caregiver (e.g. family). Please indicate who provided the majority of the information. Part C, Page 2 **(In Depth Interview)** must be completed by the participant and is obtained at 0, 2, 4, weeks and then every 4 weeks until week 24.
    A. Detailed Notes:
    1. **Part B: Australia-modified Karnofsky Performance Status *(AKPS)*** See TOP 9 Performance status for instructions.
    2. **Part C: (In Depth Interview)** is obtained at 0, 2, 4, weeks and then every 4 weeks until week 24. At these time points the telephone interview (see above) will be extended to include the McGill Quality Of Life Questionnaire (MQOLQ), the Edmonton Symptom Assessment System (ESAS), and a single question about willingness to recommend. The responses to these three instruments must be provided by the participant, preferably without family or friends being present.
    3. **The McGill QOL Questionnaire (Form I) and the Edmonton Symptom Assessment (Form J)** should be completed in order and *prior to* Section D of Form F (Important Events – Hospitalization, ED visits, and CV procedures).
    4. **Question C7: Likelihood to recommend.** If the participant asks for a clarification of "current health care," indicate that this refers to the care provided by their palliative care team or the team of healthcare professionals responsible for

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 6 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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trying to help the person feel as good as possible for as long as possible (depending upon what the participant will understand).

5. **Part D: Important Events**

**Initial Question (not numbered):** If the response to "Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiac procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?" is "No" then the first part of the six Part D questions should have the response of "No," with the date fields left blank.

**a.** Question 3: Cardiovascular events include**:**

- Admission to a Coronary Care Unit
- Cardiac Catheterization
- Intra-aortic balloon pump
- Cardiac Valve Procedure – valvuloplasty
  - Open surgery
  - Percutaneous or minimally invasive procedure
- Cardiac Valve Procedures – valve repair
  - Open surgery
  - Percutaneous or minimally invasive procedure
- Cardiac Valve Procedures – valve replacement
  - Open surgery
  - Percutaneous or minimally invasive procedure
- Carotid Endarterectomy/Angioplasty
  - Open surgery
  - Percutaneous catheter ablation or minimally invasive procedure
- Coronary Angioplasty Also called percutaneous coronary intervention (PCI) and percutaneous transluminal coronary angioplasty (PTCA). There are several types of PCI procedures, including:
  - balloon angioplasty
  - atherectomy
  - laser angioplasty
  - coronary or cardiac artery stent
  - other Coronary Angioplasty procedure
- Coronary Artery Bypass Graft (CABG)
- Internal Cardioverter Defibrillator
  - insertion

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 7 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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  - replacement
- Pacemaker
  - insertion
  - replacement
- Heart Transplant
- Other, Specify

b. Question 4: New cardiovascular events are the same as listed above for Form A.
c. Questions 5 & 6: If a patient is hospitalized or goes to the emergency department for pneumonia or venous thromboembolism, complete both questions 1 or 2 and 5 or 6 (this will require two entries into DataTrak, one for question 1 or 2 and then again for question 5 or 6).

**Form H – Medications**

1. Fill out Part A – Medications, to document medications taken in the past week. "Medications" includes all prescriptions (both ongoing and time-limited e.g. a course of antibiotics) as well as over-the-counter medications intended to relieve symptoms (e.g. NSAIDS). Do not list vitamins, minerals or herbals.
2. To reduce the burden on the participant, it is suggested that you copy the list of medications from the previous assessment and 1) ask if they are still taking each of those (if not cross out on form) and 2) ask if they have started any new medications.
3. Count the number in each column and record at the bottom of the form.

**Form I – McGill Quality of Life Questionnaire (MQOLQ)**

1. Introduce the MQOLQ, saying: "I'm going to ask you some questions about your thoughts and feelings on some issues that you may not have thought about before. I'd like you to answer the questions as best you can."
2. Read the instructions to the participant as outlined on the form, then go through the example.
3. Remember that the answers should be given in the context of their experiences over the past two days.
4. Give the participant the option of answering Part D. This section is optional. If they choose to answer, document their response in writing. If the participant opts to complete this section, record the participant's response to the greatest extent possible (phrases are acceptable), in writing. The participant ID, date and week number are recorded at the top of the page. If the response is not legible, it should be transcribed (e.g. typed). The response will be submitted with Form F to the Statistical and Data Management (SCDM) center.

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 8 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
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**Form J – Edmonton Symptom Assessment System (ESAS)**

1. No special instructions needed to administer the ESAS.

**Form R – Site Submission & SCDM Office Receipt Acknowledgement**

1. For any batch of forms submitted to the SCDM office, enter a check-mark for each form submitted for each participant. (See TOP – Submission of Data Forms to SCDM office for additional instructions).

**Form X –Adverse Events –** See TOP – AE reporting for instructions

**Form X2 –Adverse Events – Supplemental Info –** See TOP – AE reporting for instructions

**Form Y – Event Classification Committee Report on SAEs** – See TOP –ECC for instructions

**Form Z – Study Summary: Tracking Mortality, Compliance and Willingness to Continue**

1. This form will be completed on all participants. Part C is completed when a participant withdraws (refuses further follow-up or withdraws consent). The remainder is finalized when a participant dies or at the end of 12 months of follow-up.
2. Part A -Death or 12 months: If participant dies, record date of death and cause. If the patient is alive at 12 months indicate status and date.
3. Part B -Compliance: This section may be completed prior to the end-of-study.
   - If a patient is assigned to continue statins and subsequently discontinues statins, please document the date and reason. Continue follow-up interviews as scheduled. If a person stops taking statins for a short period of time (e.g., while hospitalized they stopped but once they were discharged they continued) this does NOT constitute stopping statins. (However, if the patient is NOT on statins at the time of consent, then they are ineligible for the study.)
   - If a patient is assigned to discontinue statins and subsequently restarts statins, please document the date and reason. Continue follow-up interviews as scheduled.
4. Part C -Withdrawal from follow-up: If the participant indicates that he/she does not wish to continue with the follow-up interviews, indicate the reason, date and if withdrawal is limited to further telephone assessment or to all follow-up (e.g. medical records and survival).

**Incomplete interviews**

| Palliative Care Research Cooperative | |
|---|---|
| TOP Number: TOP 12 | Page 9 of 9 |
| TOP Title: Procedure for Completion of CRFs<br>Written by: Diane Fairclough | Effective Date: 27 Feb 2012 |
| Person responsible for this procedure: a PCRC CRC (staffed by a PCRC member institution) | Next review date: 27 May 2012 |
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There will be occasions when a participant is clearly tiring and the interview should be discontinued or shortened. Please use the following guidelines:

- Baseline interview: If the missing information is one of the three scales that must be completed by the patient (McGill QOL, ESAS (symptoms) or willingness to recommend question), try to schedule another time within the next 2 days.
- Follow-up interviews: Priority should be given to obtaining information on the primary endpoint (survival) in Form F Part B and the "important events" (i.e., Form F part D). If the follow-up interview is the long assessment, revert to the short assessment and document in Form F (Part A).

**Completion of data collection out of window**

The window: For data collected weekly and bi-weekly, data may be collected at the target data collection date plus or minus 2 calendar days. For data collected every four weeks, data may be collected at the target data collection date plus or minus 5 calendar days.

If you are outside the window by a couple of days, complete the assessment as if it is the short follow-up visit.

In the event data cannot be collected (at all) at a given timepoint, document the missed visit on Part A, Form F.

**History of Changes**