Strategies and Tools for the Principal Investigator and Clinical Research Coordinator Conducting Palliative Care and End-of-Life Research

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Version 1.0

July 18, 2013

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Introduction: Purpose and Setting Expectations

The purpose of this handbook is to provide practical information to clinical researchers, particularly those conducting research in palliative and hospice care. While many aspects of clinical research are universal, research involving people receiving palliative and end-of-life (PCEOL) care presents unique needs and challenges that can complicate and even hinder the ability to conduct quality research. This handbook, which is based on experience of the Palliative Care Research Cooperative Group (PCRC), provides practical tips to facilitate successful conduct of PCEOL research.

1. Handbook Layout

The handbook is primarily written for two audiences: site Principal Investigators (PI) and clinical research coordinators (CRC). While the sections of the handbook are related, each section is written as a stand alone resource from which the reader can find suggestions on how to approach a specific topic (e.g., hiring a CRC).

|  |  |
| --- | --- |
| **Primary audience** | **Section** |
| Principal Investigators | [Sections 2](#_Section_2:_The) and [3](#_Section_3:_) |
| All | [Sections 1](#_Section_1:_) and [4](#_Section_4:_) |
| Clinical Research Coordinators | [Sections 5 - 8](#_Section_5:_) |

[Sections 2 and 3](#_Section_2:_The_1) provide practical suggestions and tools for identifying and hiring a CRC, followed by tips for how to the PI can best support the CRC throughout the duration of the research study. Referenced appendices are practical tools that can be adapted and modified to fit your organizational requirements. Examples of topics addressed in Sections 2 and 3 include:

1. Crafting a CRC job description to attract the candidates you need
2. Key skills (and how to identify them)
3. Sample interview questions and methods for assessing CRC skills during an interview
4. Establishing and recognizing the symbiotic relationship of the PI and the CRC
5. Identifying and providing necessary tools to the research team to support the research goals

[Section 4](#_Section_4:__1) discusses the importance and necessity of building and maintaining networks systems and processes with colleagues within and outside of your organization. Relationship building requires the commitment of and investment by both the PI and the CRC. Specifically:

1. How to leverage existing professional relationships to inform and promote your research study
2. Tips for getting leadership support and buy in
3. Suggestions on processes that lay the groundwork for conducting research

Sections 5 – 8 focus on the work conducted by the CRC. Examples of areas covered:

1. Tips for approaching potential study participants and family members
2. Scripts for providing informed consent
3. Strategies to establish and build rapport and trust with research participants
4. Potential pitfalls while recruiting and how to overcome them

When referring to the CRC, PI, or study participant, we will use s/he and her/him throughout the handbook to improve readability.

Our hope is that this handbook will be a living document -- added to and improved upon over time with additional tips, strategies, and nuggets of wisdom as we expand the PCRC to include more individuals, disciplines, perspectives and studies.

1. Methods

This handbook is the product of five surveys conducted by the lead author (REB) with CRCs at study sites involved in the first randomized controlled trial conducted by the Palliative Care Research Cooperative (PCRC). The second author (MBM), an experienced CRC, was interviewed over three sessions; the majority of the content of this handbook is based on her insights and contributions.

Over 100 pages of transcribed notes were reviewed using the tenets of grounded theory. Themes and main points were identified, synthesized and analyzed to form the handbook. It is designed to be a useful, accessible, down-to-earth tool for use in the trenches. The appendices are designed to facilitate operationalizing the concepts and suggestions provided throughout the handbook, and can be viewed as a toolkit for CRC hiring, orientation, and training.

**Acknowledgements**

We would like to thank the National Institute of Nursing Research for their generous funding of the Palliative Care Research Cooperative (Grant Number: 1UC4 NR012584), and for supporting our work and progress in palliative care and end of life (PCEOL) research.

The authors also would like to thank Kathryn Wessell and Kelly O’Daniel Onyenwoke from the University of North Carolina Chapel Hill, and Lisa Massie and Jennifer Short from Four Seasons Compassion for Life in Flat Rock, North Carolina for their invaluable insights and contributions.

# Section 1: Opportunities and The Importance of Palliative Care and End of Life (PCEOL) Research

The Palliative Care Research Cooperative (PCRC) was established in 2010, with foundational funding from the National Institute of Nursing Research that started in January 2011 (NINR; UC4NR012584). The PCRC’s overarching goals are to: (1) advance the evidence base underlying, and thus the quality of, palliative care and end-of-life (PCEOL) care; and (2) improve the science of cooperative group research. Thus, a central purpose is to facilitate—through a well-functioning cooperative group—the conduct of collaborative, rigorous, multisite PCEOL research studies. PCRC studies are intended to efficiently generate new knowledge that can be used to improve care and outcomes of PCEOL populations.

Specific aims of the initial PCRC grant were to: (1) build a national cooperative group for PCEOL research; (2) demonstrate the feasibility of the cooperative group and enable its evaluation and improvement by conducting a pilot randomized trial examining a question of current relevance to PCEOL clinical practice; and, (3) develop generalizable and scalable methods for assessing the cooperative group’s function and effectiveness.

Through conduct of the first PCRC randomized controlled trial (RCT), we were afforded the opportunity to design and build a cooperative infrastructure from the ground up while concurrently implementing a multi-site research protocol. These past three years have provided numerous learning opportunities! We are pleased to share our tips to Site PIs who hire, mentor, and support clinical research coordinators (CRCs), and give practical advice and tools to CRCs in the trenches who do the important work enrolling research participants to meet the study objectives.

We welcome the opportunity to learn from, share, and refine work completed to date so that we can improve and inform clinical practice and future research. We see this iterative process of evaluation/refinement/re-evaluation as a key component to learning. We are grateful to be in a community that embraces these ideals and recognizes that in creating a culture of learning we are able to continue to truly move the science forward.

# Section 2: The Critical Role of the Clinical Research Coordinator: Identifying and Hiring the Right Person for the Job

Clinical research is wide and varied, depending on the subject matter, the research question(s) being asked, the design of the protocol, and the settings in which it is conducted. Ethnographies, case studies, randomized controlled trials, drug registries, and prospective chart reviews are just a few of the types of research conducted in the clinical setting.

At first glance, the tasks of a research coordinator may seem pretty straightforward – s/he needs to know the research protocol, identify and approach potential research participants, explain the study to her/him, obtain informed consent, ask applicable research questions provided on standard case report forms, document answers, and enter responses into a database. However, in delving deeper into the nuances of the job, it becomes clear that this position is complicated, multi-faceted, and requires a unique skill set.

The research study design will determine what skills are necessary. For example, a study design that includes a retrospective chart review requires skills such as attention to detail, familiarity with clinical terminology / codes, and the ability to see patterns when reviewing a large amount of information. These skills are markedly different skills from those required in a study needing frequent and ongoing contact with study participants and their family members. By taking the time at the outset to thoroughly and carefully evaluate the needs of the study, compared to what the candidate(s) can and do offer, and determining if these two are harmonious will increase the probability of success.

1. Preparing for the interview – Needs assessment

While identification of the specific skills necessary for the study is a crucial first step, we are cognizant of the pushes and pulls that PIs face when staffing research studies and the many factors that influence the hiring and retention of staff. For example, funding a full-time CRC for one study may not be feasible due to budget restrictions, resulting in a staff person being assigned to multiple studies. Couple that with the natural ebb and flow of research study activities (periods of high intensity and activity / periods requiring fewer resources), and there may be times where two or more studies require significant CRC time. In turn, this may put more stress on the CRC, who will need the support and assistance from the entire research team(s) to ensure none of projects suffer, tasks don’t fall through the cracks, and staff don’t experience burn out.

If you are considering hiring a CRC, prior to writing a job description, posting the job announcement, or scheduling interviews, you may want to ask yourself these types of questions.

1. Will this study require frequent participant interaction? If so, will interaction be face-to-face? Telephone? A combination?
2. How will the data be collected? (Probe: Paper case report forms? PDA? Laptop?)
3. How much data will be collected at each time point?
4. How many steps are involved in putting together the data collection instruments for each time point? (Probe: is it complex? Straightforward?)
5. What type of education / certification is needed to be successful in this position? Why? (Probe: do they need to have a clinical degree? Clinical Research certification such as Society of Clinical Research Associates [SOCRA]?)
6. Do you expect the CRC to enter the data s/he collects or will this task be delegated? (Probe for detail-oriented, multi-tasking capabilities)
7. How much independence do you want to afford the CRC?
8. What is your style of management?
9. How would you characterize the work environment at your organization?
10. How important is it for this person to understand medical terminology or know how a hospital / hospice / doctor’s office is run?
11. What is your salary range? Will this attract the caliber of candidate you are seeking?
12. Why are you interested in pursuing a position in palliative and end of life care? (Probe: Subtly ascertain if the candidate is at risk of having unresolved grief. For example, the candidate may have a past experience dealing with the loss of a loved one – being immersed with research participants with advanced illnesses can be distressful to those who have not fully worked through their own grief.)

These and related questions will help you identify the optimal skill set of your ideal candidate.

1. Skill sets of a PCEOL Clinical Research Coordinator

Considerable time was spent by CRCs during interviews for this handbook, discussing the fundamental skills necessary to be a successful CRC, particularly in PCEOL research. Several characteristics were identified and are discussed below.

We recognize that PCEOL research is conducted in a variety of disparate settings, with a varied research population, at sites that have unique cultures, worldviews, and goals. Each of these characteristics directly influences how studies are conducted. Therefore, we encourage the reader to consider the outlined skills and weigh them against your own site’s characteristics. For ease of reading, we have divided the list of skills into “fundamental to the role” and “nice to have.” [Appendix A](#AppendixA) includes a sample job description that can be modified to fit the needs and requirements of your site and the position that you are filling.

### Fundamental to the Role

#### Belief in research

Coming from the vantage point that research is an important and valued endeavor required for building safe medical practice and advancing knowledge.

#### Be a “people person” Some examples:

Interview quote: *“…it is very important to be able to speak to people on all levels. My main experience has been working with people who have very low incomes, and didn’t have much education. And kind of a low health literacy level in general. But we also encounter people at the hospital - and it really varies. We have people who have PhDs and then we have people who didn't graduate from high school…you have to speak to doctors differently than you do to potential study participants too.”*

1. Be comfortable speaking with a wide variety of people.
2. Personable, approachable
3. Confident, self-assured presentation of self
4. Perceptive; able to read non-verbal cues
5. Not easily intimidated when questioned or challenged, or by talking with people who may be resistant to talking (e.g., busy clinicians, family members, sick people)
6. Even tempered and calm
7. Caring and supportive of people with advanced illnesses, while able to manage his/her emotions.

#### Able to juggle competing priorities

While this skill is often listed on resumes, there are a fair number of people who are unable to do this well. Describing “a day in the life of a CRC” may be useful to potential candidates to illustrate the number of concurrent activities being conducted in a single interaction. The shaded box below illustrates the complexity of collecting and observing information while maintaining composure and rapport.

When first approaching a potential research participant to discuss the study, the CRC is concurrently observing, collecting, and analyzing information from a variety of sources. In this one interaction, the CRC is assessing:

* The disposition of the person (and potentially other family members who are present). Are they receptive? Hostile? Protective? Confused?
* The potential participant’s condition(s) that may impact the CRC’s ability to communicate effectively (e.g., hard of hearing, declining mental status, experiencing medication side effects)
* The physical space in which the CRC is interacting with the person. Is it noisy? Are there a lot of people coming in and out? Is it hectic? Calm?
* How s/he is being perceived by the PCEOL patient and/or loved ones. Am I, as the CRC, coming across as knowledgeable, articulate, and professional? Are my actions and tone conveying warmth, compassion, empathy, and respect?

#### Well organized and detail oriented

***Organization of time and materials****:* The planning of the day and/or week requires coordination of many moving parts, many of which may not be in the control of the CRC. Anticipating what may be needed and having materials and information available at all times is a very useful attribute.

**Tips for Staying Organized and Having the Right Materials:**

* *Keeping accurate records of the names and contact information of study participants, loved ones, physician(s) and other health care providers*
* *Knowing the preferences for how a physician prefers to be contacted (e.g., paged, texted, e-mailed) and his/her level of interest in and enthusiasm for this study*
* *Collecting and updating the schedule of medical rounds (if applicable) to increase your presence with potential referral sources*
* *Ensuring all materials such as paper case report forms (CRFs) for data collection, clipboard, pens, ID, directions to the participant (if applicable) are accessible*
* *Managing time wisely to be effective at conducting both follow up visits in the appropriate data collection windows as well as allowing time to screen and recruit new study participants*

***Detail oriented:*** As every researcher knows, accurate and complete data collection is the cornerstone of generalizable research. Accurate and complete data collection requires a level of detail in ensuring all items are collected in the manner specified in the protocol, and collected the same way at every time point. Furthermore, data collected on paper and then later entered into a database or other electronic data capturing system are at heightened risk, due to the possibility of transcription errors.

#### Previous experience conducting clinical or social research, particularly with the PCEOL population

Recruiting people from the PCEOL population has extra challenges. Because this population is at a vulnerable point in life, it is not surprising that they and their loved ones may be initially resistant to hearing more about and considering involvement in research. They may feel they are already overburdened. They may have a lot of questions about the study. Having the skills to evaluate the participant/family dynamic and not shy away from offering participants/ families the opportunity to participate in an endeavor that can make a difference for other people like themselves in the future is invaluable. Practicing different encounter scenarios prior to interacting with research participants may enhance the CRC’s level of confidence. Thorough knowledge of the research protocol, a belief in the research, and experience working with study participants has been effective for some seasoned CRCs to not get discouraged when a person declines to participate.

Interview quote: *“…that is something (the CRC) does really well; figuring out when to push a little bit and when to completely back off and give them space. We've had a few people that would have said “no, I don’t want to do it” to anyone but (the CRC). But she backed off and gave the family a few weeks to think about it and called them again and they've wound up enrolling.”*

#### Think on her/his feet / not easily flustered

Interview quote: *“…(need) someone who is not afraid to be around people who are very, very sick. It doesn’t necessarily mean the person has to have previous work experience – she may have had a family member who was very sick and died, or volunteer at a nursing home or something. This isn’t a job for everyone.”*

Offering PCEOL patients the opportunity to participate in a research study may be met with questions and concerns from both the patient and family members. Being able to calmly and articulately field these questions solidifies the impression of professionalism. While it may feel as if the questions are a challenge, they can also be viewed as an opportunity to further clarify or to think of things in a different way.

Rather than feeling challenged by questions, the CRC can invite further questioning, and thank PCEOL patients and families for raising important questions that help clarify and support their decision to participate in the study. Such a strategy invites a feeling of partnership and can divert a potentially negative interaction into a positive experience.

### “Nice to Have” Requirements

#### Clinical background / work in a medical setting

Having the knowledge of how the “business of medicine” is conducted can streamline the orientation process, depending on the complexity of your health delivery system.

#### Exposure to / experience with medical terminology and reviewing medical charts

Related to, but different from clinical background is a comfort level with medical terminology. Medical record review is often a component of clinical research. With the number of abbreviations and obscure terminology used in medical charts, previous experience with this nomenclature could prove helpful, thereby reducing the need for additional staff to carry out this aspect of research.

#### Certification as a Clinical Research Professional

While certification requirements differ to some extent, all are designed to prepare the CRC with the core knowledge necessary to conduct clinical research. Depending on the amount of time available to train and oversee the CRC, this certification may hasten the “on ramping” of your new employee.

#### Flexible work style/approach

Recruitment and follow up data collection do not always fit nicely in a Monday-Friday, 8 AM -5 PM work schedule. Thus, depending on the nature of the research study, it may be valuable to have a CRC who is able to be somewhat flexible with his/her schedule. This implies Site PI support of this model, and by empowering the CRC to manage his/her own schedule, meeting the study goals can remain the focal point.

### Preparing for and Conducting the CRC Interview

#### Prior to the Interview

It may be helpful to request potential candidates to prepare the following before the interview:

* Provide a brief (2-3 page) consent form and ask them to role-play with you as a new potential study participant that needs to be consented. (What to assess: Does s/he see informed consent as a document or a process? Is s/he able to convey the purpose of the study that is clear, understandable, and with use of appropriate (fifth grade) language? Did s/he leave any key component out of the consent?) (See [Appendix B](#AppendixB) for an example consent form.)
* Provide candidates with a brief protocol (perhaps one with some missing information) to review prior to the interview. Ask each to prepare three questions related to the protocol to discuss during the interview. (See [Appendix C](#Appendixc) for a sample protocol.)
* Provide a scenario in writing (e.g., having difficulty reaching a physician, not getting referrals from your main referral source, being in a recruiting slump, approaching a very sick, easily tired participant) and ask candidates to describe how they would handle the situation. (See [Appendix D](#AppendixD) for sample interview questions, including scenarios.)

#### During the CRC Interview

* Discuss the scenarios described in Section C.1 above
* Describe a time where s/he successfully deescalated a tense or heated situation at work
* Provide an example of how s/he is successful at balancing multiple competing demands
* Ask about tools s/he uses to keep organized
* What are some examples of stress relievers that s/he uses to stay grounded?
* Describe how s/he views the consenting process for potential subjects

# Section 3: Supporting the Success of the CRC

As is true with any employee, hiring is just the first step. The development of a successful CRC as a member of the research team takes thoughtful planning, and an ongoing commitment by the team leaders. People perform best when they feel valued, important, and know that they are contributing toward the overall goal(s). Support and nurturing of your team is essential for successful research.

1. Orientation

As will be discussed in more detail in Section 4, the design and organization of your site’s health delivery system should be a component of the CRC’s orientation, as it is in this system that s/he must identify and recruit potential research participants.

The inner workings, contacts, gatekeepers and champions should all be discussed.

Active and ongoing participation of the Site PI to identify and/or maintain relationships with partners within and outside of your organization is key to conducting successful research. Buy in from institutional leadership is essential to gain access to a potential pool of research participants.

B. Training/Education

An important component in training a research coordinator is to discuss and identify what is truly important to her/him, and how s/he views him/herself relative to the bigger picture of the entire research study. Spending time during training discussing each team member’s role and a general division of responsibilities can facilitate this.

If applicable, you may want to identify and discuss the resources (e.g., the Site PI, access to medical literature, classes) that are available to the CRC.

Recognizing that each site may have a different composition of team members, it is important to equip the CRC with the knowledge, skills, and materials to do the job. Study manuals, operating procedures, case report forms, equipment (cell phone, laptop, tablet, business cards) are examples of tangible tools. Gathering these may fall on the shoulders of the PI or other delegate, but it is important that these tools are accessible and that the CRC is not the sole person responsible for obtaining them.

Introducing the CRC to the healthcare settings in which s/he will be recruiting and interacting with potential participants, family members, and professional staff can be helpful. Taking her/him to each of the recruitment sites allows the CRC to get a feel for how clinical care is provided in each setting, and may even assuage any underlying anxiety about visiting places for which they are not familiar. Depending on your institution, we recommend that the PI and CRC visit a hospital ward, an outpatient clinic, an emergency department, a skilled nursing facility (SNF), and a study participant’s home.

Privacy regulations may vary across facilities and regions. The CRC needs to be informed of regulations that may impact his/her access to potential participant / patient populations and steps that need to be taken when data are shared between and across institutions such as assisted living facilities (ALFs), (SNFs), and hospices.

1. Team Building/Encouragement: Leadership Support

There will be times when CRCs face a recruiting “slump” or are otherwise discouraged or emotionally drained as a result of doing their work. Support comes in many ways. One suggestion is to regularly remember and honor that the CRC is interacting with people who have an advanced illness, many of whom are grappling with physical, emotional, and spiritual issues. The participants’ description of their symptoms and lives may affect the CRC in ways that were unanticipated.

People experience and express loss and bereavement differently, including how they cope. We recommend that the site PI and CRC openly discuss the likelihood that distressing feelings may be stirred up and ensure the CRC is empowered to ask for support when needed. This may be different for each site and/or person. For example, some CRCs may want one-on-one time with the site PI to discuss a difficult case or otherwise debrief. For others, having the permission to “blow off steam” by taking a walk or getting a cup of coffee, or having a mid-day workout is supportive. The culture of acceptance and appreciation of the emotional toll this work can have is yet another way to honor the work of the CRC and recognize the importance of his/her emotional health.

Interview quote: *“Sometimes when I have had a really bad day or even week (laughs), I come back to my office and play a five minute comedy sketch on YouTube. It just gets me out of my head, makes me laugh, and gives me perspective. Some days are just really hard, so you have to find ways to take care of yourself. I am lucky that I have a boss that understands this and I know that this is actually an accepted part of my job and I won’t get in trouble for watching YouTube for a few minutes.*

The CRC may need to be reminded that when a person with whom they discussed the study elects not to consent and participate in the research, the person is saying “no” to the study, not to the research coordinator.

Interview quote: *“It is really important to have a positive attitude. Because especially with this study, it is really easy to get negative sometimes when you are having weeks where you don’t enroll anyone. You can’t get down and just say ‘my gosh it's so hard.’ You have to brainstorm new ways to figure it out and not get defeated by it.”*

Strong Site PI support and availability are critical in these instances. Reinforcing the CRC’s contributions to and success in the research study over time not only fosters job satisfaction, but also ensures that she is valued and appreciated. Having someone to bounce off ideas, problem solve, debrief about situations that went well and those that did not go well, and be transparent about how things are going in general is essential.

# Section 4: Building Systems and Processes to Increase the Likelihood of Success

Being successful as a CRC requires the development of systems and processes to facilitate doing the job. These systems and processes are necessary at both the larger organization level, the macrocosm, and with the CRCs immediate study team, the microcosm.

1. The Organization’s Macrocosm

### Within your organization / entity

The importance of building and maintaining relationships with colleagues in your organization, at all levels is invaluable. This will take time and effort on the part of the Site PI, the CRC, and others members of the research team. We suggest tuning into and being observant of circumstances and events that can be leveraged to help build relationships and plan for collaboration in research studies. Seek these opportunities for networking. Examples include attending Grand Rounds when someone is doing work that relates to the study and introducing yourself at the end of the talk, attend conferences and seminars, fundraisers, etc. At the end of this chapter are two case studies illustrating steps taken to build relationships within and outside our organization.

In many cases, the CRC is asking for assistance from people without any remuneration (e.g., identify potential study participants in your clinic who are taking a statin). Your only “currency” will be how they are treated and how well you are able to maintain a professional relationship.

Below are questions you may want to ask yourself as you implement a study protocol and are determining the best ways to recruit.

1. Identifying the way(s) that you are going to identify potential study participants.
2. If you will use an electronic health record (EHR), ensure that the PI and CRC have access and the right ”privileges” needed to get the necessary information.
3. Identify collaborators and together design strategies that will work well to meet both the study objectives and department work flow.
4. Where are you going to recruit within your organization?
5. Some sites have a single recruitment pool (e.g., stand-alone hospice). Other sites are more complex.
6. On a medical campus it may be feasible to recruit at the inpatient hospital, as well as other settings serving those with advanced illnesses (e.g., outpatient clinics). This requires thoughtful planning, and the identification of contacts within each of the departments/locations.

Suggestion: Schedule a short meeting with the department head / manager of the unit and describe the study and what you need from the department/staff. Ask if there are people within the dept. you also should speak with to ensure your “message” is heard. You may need to speak with several people before you find that person with whom you can rely on to give you regular referrals. Getting buy in at the managerial level first may be useful starting place.

1. What do you need from others in your organization?
2. Be clear and specific about what you require (the “what, when, how”) and look for ways to minimize burden from the people you are asking for help.

Suggestion: Reassure people from whom you are asking help that they do not need to explain the study to a potential participant; rather, you are looking for help in identifying potential candidates. You, as the CRC, will explain the study and if the person agrees, you will obtain consent and enroll the participant.

1. Keep your requests for help simple. It really could be as easy as putting a label of a potential study participant in a provided notebook. Out of the box thinking is highly recommended!
2. How much time and effort are you asking the front line clinical staff to devote each day to assisting with identifying potential study participants?

Tip: With the professional staff, be respectful of their time. Only communicate when needed. However, don’t apologize for doing your job – you have a right to conduct this research and it involves interacting with professional staff. Just make sure to thank them

1. Do you have the ability to provide incentives to those who assist you?
2. How do you show appreciation for someone assisting you in meeting recruitment goals?

Simple acts of kindness such as a handwritten note, a friendly welcoming face, and a verbal thank you all communicate that you care and value their efforts.

1. What is the best way to communicate with professional colleagues?
2. E-mail? Paging? Phone calls? (Because this may be different for each provider, a tracking sheet with these details might be useful for you to keep and maintain.)
3. What sort of “reminders” will you deploy to keep this research study in their minds?
4. How often will you contact them for referrals?

### Outside entities / community

Depending on the study protocol and your health delivery system, outside entities and community members may be included in your research. Establishing these connections may not be the sole responsibility of the CRC; rather, the PI (or sub-investigators) can and should take a lead role in building relationships and partnership.

Developing formalized procedures in how the partnership will actually work will sustain the partnership over the duration of the project. Here are some suggestions to help formalize these processes:

**Start communication at the highest level**

* Identify ways that the partnership will benefit and support the objectives of each organization. Collaborate around strategies for conducting research in their facilities. Identify what they are willing to do for you and how they may benefit from collaborating on the study.
* Identify key people with whom the details can be discussed, and processes / procedures be collaboratively developed that are acceptable to all parties.
* Plan communication mechanisms throughout their organization.
* Develop strategies for ongoing communication on how the project is progressing and how challenges will be addressed.

Tip: When contacting outpatient clinics by telephone, always ask the staff “what is the best way to talk with Dr. \_\_\_\_\_\_\_\_\_.” The staff can often direct you to the appropriate person so that you spend your time efficiently telling your story or needs to a person best equipped to address it.

* Acknowledge and thank partners for their support and collaboration.

Face-to-face communication with community physicians is important in building your collaborative system. Schedule a time to go to their office. Get to know the front staff and lead nurse and present yourself as the person with the warm smile who cares about people with advanced illness. This will facilitate future face-to-face and telephone contact.

Tip: When you reach and speak with the community physician by telephone, at the end of the call, ask him/her for the best number to reach her/him in the future. Having a direct line can be a big time saver.

1. The CRC’s microcosm

### Within your study team

1. Maintain visibility and let your needs be known
2. Verbalize your priorities
3. Have regular access to and meetings with the Site PI and other team members
4. Identify your “back up” person and connect with him/her regularly for updates on the study progress
5. Plan to celebrate milestones and success

### Organizing your work: developing tracking and communication systems

1. Maintain a calendar with upcoming visits, tasks, notes, and reminders
2. Keep a tracking system of the health care providers you contact, particularly as you navigate the various departments / clinics/ locations from which you recruit. Include names, e-mail, primary phone, secondary phone, and any other pertinent notes.

*Rationale: You may have to start by contacting those in leadership positions within a department / organization and get the buy-in. They can open the door for you to talk and work with those on the front lines who will actually help you identify potential participants. You may have to talk with several people in a group before you drill down to the right person. Keeping good notes along the way shows professionalism and legitimizes your role – you have talked to the “powers that be” and have a right to ask for his/her help.*

1. Keep a tracking system of potential participants, their physician(s), other health care providers, loved ones, contact information etc., as consistent with the IRB-approved study protocol. Keep this in a separate, locked location away from the other study data.

*Rationale: Having as much contact information as you can saves time when trying to get in touch with participants and/or health care providers.*

1. Plan ahead to ensure you have enough supplies (e.g., paper CRFs, pens, clipboard, etc.) before you interact with a potential participant or health care provider from whom you are seeing help (see [Appendix E](#AppendixE) for a CRC checklist of materials and supplies.)

*Rationale: To establish rapport and trust, people need to feel as if you take yourself and your job seriously, and you have come prepared to do your job.*

1. Keep a list of potential study participants you are “following” who did not meet the eligibility criteria when you first approached them. They may meet criteria soon.

*Rationale: People with advanced illnesses may experience rapid change in their status. While they may not have met inclusion criteria when first approached, they may be potential candidates in the near future.*

1. If collecting data on paper CRFs, ensure each participant file has all forms, in order, and is clearly labeled. Store in a locked filing cabinet.
2. If appropriate, develop a recruitment brochure / handout. You may develop one for health care providers and one for potential participants. Obtain IRB approval for the brochure(s) to be used as recruiting tools.

[Appendix F](#AppendixF): A typical Monday morning for a recruiter in a University setting illustrates how CRC tasks could be organized, prioritized, and planned. Below are two [case studies](#CaseStudy1) of how relationships were leveraged and systems were established within and outside of an organization.

**Case Study: Building a system within your organization**

Our goal in conducting the statin study was to establish a collaborative relationship with our outpatient oncology service.

As a first step, the Site Principal Investigator (Site PI) met with the head of the oncology department to explore interest in collaborating and to gain support for recruiting participants within the oncology department. Once obtained, the project director and CRC were given time at the monthly oncology physician group meeting to provide an overview of the project, explore interest and solicit strategies for recruiting. They also obtained the names of key people in the department with whom they should meet. The department practice manager was identified as a key contact. The project director and CRC arranged a meeting and asked the practice manager to invite other key people in the department to attend the meeting. The clinic supervisor attended and the agreement was made that in the future, the nursing supervisor would be the contact person for the CRC to implement the project. The practice manager invited the CRC to attend the upcoming monthly all staff meeting to provide an overview of the study and solicit input on how potential study participants might be identified. Suggestions included: a) putting HIPAA forms in pockets outside patient rooms b) providing a notebook for each “team area” where staff would put a label of any patient taking statin medication.

The CRC circulated through the clinical team areas daily to maintain visibility and pick up any labels. When no names of patients on HIPAA forms, and no labels in the provided notebooks appeared, it was time to dig deeper to find a strategy that really could work.

The CRC met with the nursing supervisor to try to identify ways that potential participants might be identified. The CRC specifically sought to understand the department work flow, recognizing that any strategy that did not fit in conveniently with the daily operations was not likely to succeed. Ultimately, it was learned that part of the responsibility of the medical assistant staff in both the oncology clinic and the infusion center was to review the current medications of any patients entering their areas. Because these staff would know which patients were taking statins, it seemed reasonable to explore their willingness to place a label of any patient on statins in a study-provided notebook. With the nursing supervisor’s endorsement, the CRC arranged a training meeting for all Medical Assistants (MAs) in the clinic and the infusion center. A notebook was provided for each area that included a brief overview of the study, the key inclusion criteria and a list of statin medications. Blank pages were provided for labels to be placed. The MA’s, with the support of their managers, agreed to place the labels in the notebooks of any patient taking a statin medication. They also identified the best place to keep the notebook so they would remember to do this requested task. The CRC circulated daily to pick up labels and thank staff for their assistance. Visibility of the CRC served as a reminder that we really needed their help and valued their contribution.

This system proved to be an effective and efficient way for the CRC to identify potential study participants without adversely affecting the workflow of the clinic. The key step of finding the “needle in the haystack,” (i.e., patients taking statin medications) was accomplished, and the CRC could now do the more detailed work of reviewing the medical record to confirm eligibility and make contact with treating physicians and potential participants.

**The system was successful because:**

1. **Agreements and support came from the highest levels**
2. **Input was obtained through key people in the department to identify successful strategies**
3. **Planning included those who would actually do the work**
4. **The contribution of those doing the work was regularly acknowledged**

**Case study: Building a system outside your organization**

In conducting the statin study, our interest was to expand the pool of potential study participants by collaborating with the largest hospice/palliative care service in our area.

The Site PI had an established relationship with the hospice and personal relationships with the CEO, COO, and hospice medical director, with a long history of collaborating on research and serving as an “academic advisor” for the hospice. In planning for this study, it was important to explore the feasibility of collaborating and to ensure the partnership would meet both organizations’ objectives as well as those of the study. The hospice was interested in becoming a more research-focused organization so this partnership could help them achieve this goal. The statin study needed access to a pool of potential study participants with advanced, life-limiting illnesses, so collaboration with the hospice would be helpful to the University-based site.

The hospice medical director was interested in research collaboration and recognized that a common practice among hospices is to discontinue statin use when patients enroll in hospice services. Because this practice is not informed from evidence-based research, the medical director determined that all future patients enrolling in hospice would remain on their statin medication. The few exceptions were cases when a patient had musculoskeletal symptoms or when the statin was exacerbating gastrointestinal symptoms. In these cases, the statin was stopped and the referral was not passed on to the University CRC. The VP of operations and the VP of clinical practice shared this new practice and the collaborative research relationship with all hospice staff.

The VP of Operations determined that based on the existing collaborative partnership, that the HIPAA A form for potential study participants would be waived. This meant that hospice staff did not need to go through the challenging job of describing the study to hospice patients and obtaining permission for a research CRC to contact them. The CRC and VP of clinical operations developed a standard letter that was included in every newly enrolled patient’s chart. The letter advised the patient that the hospice was collaborating in the conduct of a research study with the university and if s/he met the study criteria, and his/her physician agreed, s/he may receive a call from a university researcher.

Based on the existing partnership between the University and the hospice, the CRC was given access to the electronic medical record system to review patient records and identify potential study participants. The VP of clinical operations arranged with the pharmacy services to send a secure email every other week to the CRC of any new patients enrolled in hospice who were taking a statin medication. Every other week the CRC travelled to the hospice and reviewed charts to identify potential study participants.

The VP of Clinical Practice and the CRC identified who would be included in communication to provide study updates and address any challenges with the developed processes.

When a study participant enrolled, the CRC sent an email to all managers, the medical director, team leader and the hospice patient’s nurse to let them know that their patient was now a study participant and whether they should continue vs. discontinue taking the statin medication(s). The hospice staff was tasked with making a note on the patient’s face page profile about their study participation and assignment. Every communication between the CRC and the hospice team provided an opportunity thank them for their invaluable support.

**The partnership with this organization was successful because:**

1. **Planning and development began at the highest levels**
2. **The goals and needs of each entity were explored and honored**
3. **Procedures were developed in partnership to facilitate case finding, communication and problem solving**
4. **Conduct of the research study did not impact the regular workflow of hospice staff**
5. **Acknowledgement of support and gratitude were expressed regularly**

# Section 5: Mental Preparation to do the job successfully

The roles and responsibilities of the CRC can be challenging. Thus preparing for the job is an important first step. Just as a baseball pitcher has to mentally prepare before a game, the CRC may find it useful to do a mental check in to gain clarity and focus.

1. Your thoughts and feelings about being a research recruiter
2. Why were/are you attracted to conducting research, particularly with this population?
3. Do you believe the research is important and worthy of study to advance health care knowledge?

Belief that certain populations are too ill, too burdened, or too frail can affect the recruiter’s willingness and confidence to offer the research opportunity to the target population.

1. Do you believe the study design offers a scientific way for to answer the research question? If not, in randomized control trials with a control group, the recruiter may feel that those assigned to the control group are being penalized or deprived of an intervention. This can affect the confidence of the recruiter in approaching potential participants.
2. What are your beliefs about approaching the target population for the study?
3. Because clinical research is important and advancing medical knowledge is a mission of many institutions, do you as a CRC believe you have the right to approach physicians, staff and potential participants without apologizing for “bothering” them?
4. Are you comfortable interacting with all kinds of people?
5. Do you feel that can you be “the face” of the study?
6. Do you feel empowered to “sell” the concept of the study with professional staff and ultimately to study participants?
7. Embracing the Concept of Selling: Traits of a Good Salesperson

Health professionals and researchers do not typically think of themselves as sales people. In fact, the very term “salesperson” may elicit a negative response and not be a role the CRC would embrace. But really, the roles and responsibilities of the CRC have a number of components that are sales-related. Moving beyond an initial reaction to the word, a CRC may want to ask him/herself:

1. Do you know your “product” extremely well so that you can talk about it in conversational terms? Can you/do you adapt your “pitch” to fit the customer? (See [Appendix H](#AppendixH) for suggested language).
2. Do you have the skills for active listening so that you can adjust the conversation to fit the person with whom you are speaking?
3. Do you think about research participation as providing opportunity and benefit?
4. When approaching and interacting with a potential participant, are you attentive, interactive, personable and focused?
5. Do you truly believe that the study for which you are recruiting is important and worthy of study?
6. Do you establish trust by responding opening and honestly to all questions?
7. Do you make the person being approached feel as if they are in control? Doing so will lower their guard so they can listen better to the “pitch.”
8. Are you comfortable closing the sale by asking “*Are you interested in*?” or “*Would you be willing to hear more?”* and establishing a follow up plan for future contact?
9. Do you honor the person whether or not they “buy” the product?
10. Maintaining Perspective
11. The CRC is giving the study participant a choice to participate or not in a research study. It is not a personal affront which choice is made.
12. You do the best job you can, describing the content of the study as honestly and personably as possible.
13. You are offering something that they may be interested in. You are inviting them to participate in the study.
14. You are giving them an opportunity to contribute to medical knowledge that may help others dealing with advanced life-limiting illness in the future.
15. You may be providing a way for them to find meaning in their struggle with illness and provide a legacy.

Take away messages:

1. You can’t sell something you don’t believe in.
2. You can’t be your own gatekeeper and decide for the potential study participant if the study would be good for them. Your role is to determine if the person meets the inclusion criteria and if yes, then it is your obligation to invite him/her to participate. If participation in the study isn’t offered, the protocol is not being conducted as designed, and the CRC could be depriving the potential study participant of a chance to participate in something that may help other people who are experiencing health challenges like s/he is facing.
3. If your research has been approved in your organization, then you, as a CRC, have a right to be there, approach physicians and potential participants, recruit people to participate in the study and collect follow up data. There is no need to apologize for doing the important job you were entrusted to do. Apologizing for bothering study participants, physicians and staff in fact devalues the research study.
4. Being prepared prior to interacting with a study participant, loved one, or clinician is essential. Knowing the research protocol in detail supports the CRC’s ability to respond confidently and correctly to questions, thereby building rapport and establishing trust. The interaction with the potential participant/family is not a dress rehearsal. Practicing your recruitment script through role plays with colleagues/friends/loved ones prior to the recruitment interaction is key.

Please see [Appendix G](#AppendixG) for a number of “stories” written from the perspective of the nurse recruiter.

Fundamental Beliefs and Values in Conducting Human Subject Research

Respect– At all times, and in every way, respecting the study participant and family members is paramount. Behaviors and attitudes that demonstrate respect include:

Understanding that the study participant is going through a lot, and may feel overwhelmed and conflicted.

Honoring the sanctity of the relationship between CRC and study participant.

Honesty in all interactions with study participants, loved ones, caregivers, and research team members.

Transparency of information shared with the study participant, including, but not limited to what to expect, what will occur, who will be involved, how long the study will last, and the risks and benefits.

Protection of personal health information and person’s well being (physical, emotional, spiritual, relational).

Inclusion – all people, regardless of their medical circumstances, should be given the opportunity to participate in research for which they are eligible. It is not up to the CRC, professional caregivers, or family members to decide if one should be included.

A sense of meaning, and offering an opportunity to create a legacy: making a difference for others in the future can come from being involved in research at this stage in one’s life.

Collaboration: Doing *with* not doing to.

Connection is created based on human-to-human interaction. The CRC cannot and should not stay emotionally detached, yet at the same time, needs to maintain professional boundaries and not get involved in providing medical care.

# Section 6: Approaching Potential Participants: Beginning the Dialogue

1. Recruiting by telephone

The first outreach to a prospective study participant or family member may be by telephone. The goal of such a contact is to establish a positive relationship, give a brief overview of the intent of the study and ultimately arrange a face-to-face meeting. The following tips may help the CRC achieve the goal of arranging a face-to-face meeting.

1. Keep the call short. The purpose / goal of this call is to set up a face-to-face meeting, not to fully explain the study on the phone.

*Rationale: You usually get one opportunity to introduce the study and offer the invitation. You want to make it count. Speaking in person will provide a better chance of being successful in enrolling the potential research participant.*

1. Use a warm, friendly telephone voice.

*Rationale: Building trust and rapport and minimizing resistance to hearing about the study are essential to scheduling a meeting.*

1. Establish that this is a good time for a discussion and let him/her know that your conversation could take 5 – 10 minutes.

*Rationale: Having the potential participant’s undivided attention to introduce the study enhances your likelihood of achieving the goal to schedule a more in depth discussion in person.*

1. Inform the potential participant that you have spoken with his/her physician and s/he is okay/ has no objection to you approaching him/her to discuss the study (if protocol requires/ is applicable).

*Rationale: Establishes that you have a legitimate right to approach them and that his/her physician is in “the loop” and is supportive of the research.*

1. Inform the potential participant that you have spoken with \_\_\_\_\_\_\_\_\_\_(family member) too and that s/he is okay with you calling her/him.

*Rationale: Being transparent by including family members into the discussion and acknowledging their involvement in making decisions and providing care builds trust.*

1. When referring to meeting with a person, you may want to use terms such as “I would like to talk with you…” or “I would like the opportunity to tell you about…” and then eventually “I would like to invite you to participate…” Words such as recruit or sign up may be off-putting to some.

*Rationale: People can be put off if they feel they are viewed as a guinea pig or a subject. Keep it friendly, approachable, and use neutral language.*

1. Reinforce to the person that s/he is in control and it is absolutely his/her choice to participate.

*Rationale: A cornerstone of all human subject research, it is imperative that every potential participant knows his/her rights and that s/he has the choice to participate, not participate, or end participation without any ramifications. This point cannot be stressed enough and you may find it helpful to periodically repeat it several times.*

1. Avoid getting caught up in answering a lot of questions on the phone. Suggested script: “Your questions are really important. It might be easier if you and I had a face-to-face conversation. Could we schedule a time when I could come to your home / meet you at the clinic and talk with you about it to see if you are at all interested? After you've had a chance to meet with me, you can decide whether this is something you would like to be a part of? “

Recap: Keep phone call short and only give brief explanation of study. The goal is to schedule an in-person visit.

1. Recruiting Face-to-Face

Potential study participants may be approached for face-to-face encounters in a variety of settings, such as hospitals, facilities (SNF/ALF/inpatient hospices) or homes. The following section offers practical strategies to support successful recruiting in these environments (see [Appendix H](#AppendixH) for a script on first approaching a potential participant as well):

### Potential Participants receiving care in a Hospital /Facility

1. Ensure that all preparatory work has been completed.

* Have you reviewed the medical record for initial screening of eligibility?
* Have you spoken with / received approval from their physician to approach the potential participant and invite him/her to participate in a research study?
* Do you have the right to approach the potential participant / patient (have HIPAA approval or a treatment relationship)?

1. Prior to entering the room, take note of the environment. Is it busy? Bustling? Loud? Are clinicians and, staff frequently going in and out of the person’s room?

* If there are a lot of distractions, you may want to postpone when you approach. You have one shot at this, and you want to stack the deck in your favor.

1. When first entering the room, go to the sink and wash your hands, and then approach the person’s bedside/chair and introduce yourself.

* Pay attention to your demeanor and presentation of self. Helpful phrase: “Remember, when working with study participants you are ‘doing’ with not ‘doing’ to.” This is a collaborative endeavor.
* Stand beside the bed/chair to avoid putting distance between you and the potential participant. The goal is to build trust and rapport. Also, you want to be easily heard.
* Alternative: ask to get a chair and sit next to the patient in bed or in a chair to be at his level.

1. Observe the study participant’s nonverbal cues. If appropriate, reach out and shake his/her hand, touch her/his arm or shoulder. Human touch, done in a respectful and non-invasive way can also establish trust.
2. Memorize an “introduction script” that you are comfortable with and can deliver in a conversational tone. It should only be about five sentences. The purpose is to introduce yourself and explain your role along with two or three sentences about the study:

* Suggested script: *“My name is Jane Smith and I'm a Research Coordinator here at Hospice of the World. Your doctor (Dr. \_\_\_\_\_\_\_\_) has given me permission to talk with you about a research project we are doing for people like you, who are dealing with an advanced life limiting illness. Would it be okay for me to tell you a little bit about the study?”*
* If the protocol requires physician approval prior to the CRC approaching potential research candidates, stating that you have done so when you first speak with the potential participant may help establish legitimacy. If s/he knows that the treating physician is comfortable with her/he being in the study, it may allay any underlying concern.
* If there are other family members in the room, acknowledge them and bring them into the conversation. A phrase such as *“It looks like you’ve got some important people in your life here with you too”* can break the ice and allow you to initiate introductions.
* Introduction scripts should be practiced in advance until you feel very comfortable with them. The study participant interaction should not be a dress rehearsal.

1. Once the potential participant has been approached and indicates a willingness to hear more about the study, you may want to ask permission to sit down. This continues to convey to the potential participant and loved ones (if present) that s/he is in control.
2. After providing a brief explanation of the study and the potential participant has given the okay to continue the dialogue, you may want to discuss and confirm the initial screening criteria. Although you may have already reviewed the medical record, it can be useful to confirm with the potential participant that they do meet all of the initial screening criteria.

### Potential Participants Receiving Care at home

People receiving home hospice or palliative care at home typically have family /friends who augment care provided by healthcare professionals. Because family members are often quite involved in the care, you may consider making them the first point of contact. Obtaining buy in of the family member(s) can be leveraged when the study is discussed with the potential participant.

1. In the home
2. Introduce yourself at the door and let him/her know why you are there. Provide a business card to further legitimize your role as a clinical research coordinator.

*Rationale: people receiving hospice and palliative services may have many staff providing care and may easily become confused on who is visiting and the reason for the visit.*

1. When first arriving at person’s home, acknowledge his/her generosity and thank him/her for letting you visit.

*Rationale: Ensuring that the potential participant and family know they are valued and that you are grateful for allowing you to come to their home and have this conversation shows that you want to establish a relationship based on respect.*

1. Make note of the environment. For example, if shoes are taken off at the door, ask if they would like you to remove your shoes.
2. Ask the potential study participant where they would like to talk. If she is in bed, let her/him know that you can talk to him/her in his/her bedroom or any location that is most comfortable.
3. Offer the study participant the opportunity to learn the details of the study. Regardless of the decision, thank him/her for his time and allowing you to come to their home.

*Rationale: Because participation in research is voluntary, it is critical that a potential participant and her loved ones feel respected and valued, and that they are freely giving of their time.*

1. Recruiting in health delivery systems outside your health delivery system

When recruiting in a skilled nursing facility / assisted living facility (SNF/ALF) or hospice that is unaffiliated with your health delivery system, you may experience additional steps or hurdles that will need to be considered:

* Difficulty in accessing and reviewing the medical record. This may be due to factors such as HIPAA concerns, incomplete records, gatekeepers, and SNF/ALF policies. Potential participants and loved ones may need to give the facility written permission to share information with you.
* Difficulty getting adequate information over the phone – the recruiter may need to go to the SNF/ALF to talk about the study with the decision makers (e.g., medical director, charge nurse) to establish formal procedures for interacting with facility residents.
* If the protocol includes cognitively impaired research participants, an extra layer of complexity may be added, due to the need to determine and confirm the name and contact information of the patient’s legally authorized representative.
* Think in terms of establishing a partnership. Identify key decision makers, establish formal systems and develop strategies to educate staff. These steps can facilitate obtaining information and support good will. While establishing formal systems may take time initially, the investment will support the conduct of the current study and potentially future studies over the duration of the study and across multiple participants.
* Establishing systems should not be seen as a barrier to conducting research, but a step in the process to successful recruiting, consenting and collecting follow-up data.

**Case study of recruiting in a facility outside of your organization**

The CRC received a call from an outside palliative care service about a person residing in an assisted living facility (ALF) who appeared to meet study qualifications. After reviewing the person’s palliative care record, the CRC contacted the attending physician for approval to approach the person / legally authorized representative (LAR) to discuss the study. The LAR was in agreement about offering her loved one the study, so the CRC and the LAR met at the ALF. The CRC confirmed that the potential participant was cognitively impaired. The CRC and the POA reviewed the study, obtained consent and collected baseline data. After the participant was enrolled, the CRC and POA met with the Director of Nursing and the Facilities Director to let them know that their resident was enrolled in a research study. The CRC provided them with an overview of the study and let them know the randomization assignment. A copy of this material was provided to the ALF and the staff indicated it would be placed in the resident’s medical record. The LAR signed a statement letting the facility know that she was in agreement with the CRC obtaining health information about her loved one in person or via telephone. The CRC was given the phone number of the nursing director for future contacts.

This example illustrates the numbers of people involved in setting up a system:

* Palliative care service
* Attending physician
* Legally Authorized Representative (LAR)
* Study Participant
* Director of Nursing
* Facilities Director
* CRC

Clear and thoughtful communication with each party resulted in building the system to support ongoing collaboration to meet the study objectives.

# Section 7: Consenting the Potential Study Participant: It’s a Process, not a Piece of Paper

Informed consent is the cornerstone of clinical research. As the title of this section indicates, consent is not merely a form that is signed and filed away in the medical record, but rather it is a process that requires thoroughness and transparency.

Institutional Review Boards often have templates for required consent form components, including language requirements for certain phrases/topics. Some sections may require minimal explanation, while others will require a fair amount of detail. IRB requirements may result in a lengthy consent form (e.g., 10 pages). Potential participants might find this rather daunting, particularly those not familiar with clinical research.

Once the study has been introduced and the potential participant agrees to learn more, the consenting process begins.

Because participants do not often remember all the study details, you may want to develop a handout highlighting the key messages:

* The result of participating is that others may benefit from what we learn
* Participation is voluntary
* If applicable, highlight the ways in which the study is not an extra burden to the patient (e.g., no clinic visits, no labs or blood draws)
* Randomization is like the flip of a coin or drawing from a hat
* Participants have the right to withdraw at any time

The following tips can help the CRC offer consent in a manner that ensures that the potential participant is fully informed and supports success.

Tips:

* Know the consent form so well that you can explain the study in detail, maintaining eye contact at all times.
* Practice consenting with others prior to approaching and enrolling your first study participants.
* Plan to take time with the potential participant in reviewing the consent. Let her/him know that the process could take 15 to 20 minutes depending on the study details.
* Confirm that it is okay to continue with the consent process. If not a good time, schedule a time to return in the near future.
* Pay attention to body language. If you sense distraction, irritability, fatigue, offer to return at a more convenient time.
* Offer the potential participant a copy of the consent form to follow along, or just listen as you review the form. Let her/him know that if they decide to participate, s/he will get a copy of the consent form.
* Use the consent form with the potential participant to prompt you as you cover each of the topics / areas.
* Explain exactly what will happen if s/he chooses to participate in the study so they will know what to expect – no surprises.
* What s/he will have to do / not have to do (e.g., no office visits, no labs, telephone follow up only)
* Lay out the expectations for follow up visits (e.g., after today, I will call you once a week for the first month, and then twice a month after that….)
* Address questions as they come up. This may mean that the consent process may not follow the consent form in the order written.
* Acknowledge questions positively. *“That is a really important question…”*
* Solicit additional questions to ensure that the potential participant is fully informed.
* If there are loved ones present, ensure that their questions also are addressed.
* Give the person time to review the consent form after you have verbally explained the study.
* Invite the potential participant to reiterate his/her understanding of the research study and what they understand will happen if s/he decides to participate.
* Suggested script: *“So that I know I have done a good job of explaining the study, can you tell me what you believe will happen if you decide to participate in this study?”*
* Reiterate that participation is voluntary and s/he should not feel pressured by anyone to participate (including your doctor, loved ones, me [CRC]). It is always your choice.
* Some consent forms incorporate HIPPA privacy regulations as part of the consent form, adding to the overall length. Consider verbally breaking the discussion into two distinct areas*: “The first part of the form talks about the study details. The second part addresses privacy issues.”*  We recommend reviewing questions related to the study itself before talking about the privacy regulations.
* Suggested script for introducing the privacy regulations: *“Your privacy and respecting you rights with regard to the research study is important to us, so I would like to review these regulations with you.”*
* The last section of a consent form (directly before the participant’s signature) summarizes the study and the agreement. By signing the consent form, the participant is entering into a contract with you (as a representative of the research study). You may want to read that section word for word.
* Once the participant has signed the consent form, provide her/him with a copy complete with signatures.
* Thank him/her for his/her time.
* Thank him/her for his/her willingness to participate in a project that is intended to help other people like themselves in the future.
* Obtain any required baseline data as outlined in the protocol. If participant appears tired, offer to return later to obtain required information.
* Reiterate what will happen next: “*I will come back in one hour to collect some information about your overall health*” or *“I will call you in one week…”*

Take away messages:

1. The consent process takes time. Plan for it and negotiate with the potential participant to increase your likelihood of success.
2. Cover all areas of the consent to ensure the potential participant is fully informed.
3. Participation in research studies is voluntary. Offering the consent in a manner that is collaborative and invites partnership can increase the likelihood of success.
4. Thanking participant for his/her time and participation in an endeavor designed to help others like them enhances the likelihood that s/he will view his/her participation as valued and worthwhile.

# Section 8: Collecting Follow up Data: Making the Most of your Investment

Enrolling and consenting participants into research studies is a critical first step. However, without accurate and complete baseline and follow up data, the research question(s) cannot be answered. The goal of every follow up visit should be to collect all the data from every participant at every time point. The following suggestions can support this process:

1. Beginning of visit / phone call
2. Begin every call / interaction with a reintroduction of yourself and context of why you are calling. *“Hello, this is \_\_\_\_\_\_\_\_\_\_\_\_, and I am \_\_\_\_\_\_\_\_\_\_\_\_\_ with the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ study. “*

*Rationale: People with advanced illnesses typically have a number of people who contact them, so providing a framework for the discussion tends to orient them and put them at ease.*

1. Immediately determine through asking (and observation of non-verbal behavior if in person) if it is a good time to talk. Let her/him know the expected length of the call/visit.

*Rationale: This reaffirms that the study participant is in control. S/he determines when and if s/he wants to answer the research questions and if it is an okay time to talk.*

1. Data Collection
2. Let her/him know the amount of time the call /discussion is likely to take.

*Rationale: Letting study participant know how long the questionnaires will last could be a determinant in her/him deciding whether to answer questions now, or negotiate a better time. It is better for both the recruiter and the participant to not feel rushed or otherwise distracted.*

1. Pay attention to verbal and /or non-verbal cues. If voice tone of the participant changes, or if the participant makes comments such as “Are we almost done?” you may want to offer to call back or visit at another time.

*Rationale: It is more important to maintain the relationship with the participant than push too hard to get all the data at any one point in time. The goal is to keep the person enrolled and collect all follow up data for the duration of the study.*

1. Acknowledge participant’s voice, what you are hearing: *“You sound tired. Has something changed in your world?”*

*Rationale: Participants will often share what is happening. Once s/he has talked about his situation, s/he may be willing to respond to some research questions.*

1. Potential script should you start off with some resistance: *“Are you willing to answer at least some of the questions for me?* “ If s/he agrees, you could then say *“Great, but please tell me when you don't want to do anymore. If you want to answer all my questions, that would be great. But you don't have to.”*
2. When interacting with the participant, be fully present, listen carefully, and acknowledge each conversation’s nuances.

*Rationale: It can be tempting to rush through the questions, particularly those that are hard to ask and answer. When the data collection visit is rushed, one runs the risk that the participant will just tell you what they think you want to hear or what will make the interview end sooner.*

*If the study participant is irritable or uncomfortable, the CRC may experience something such as “Fine, everything is just fine” or “Let’s just get this done.” Give person the option of stopping – address what you are observing directly. “Is this becoming too wearisome for you?”*

1. Whenever possible, have the same person conduct the initial and all follow up visits. Data collection interactions should feel safe and valued.

*Rationale: This continuity fosters rapport and trust with the participant. People provide richer, fuller data (particularly subjective data) when they trust you, feel like they “know” you, and feel respected.*

1. Remember your role – you are to follow the protocol and conduct research the same way, every time, for every participant. Your role is not to diagnose, treat or medically intervene.”
2. When gathering functional status, have some “back pocket” questions that you ask to get an accurate report on their level. See [Appendix I](#AppendixI) for some sample probing questions that can be used when inquiring about a person’s functional status.

**Tip for fielding clinical questions during a study participant interaction**

In the course of your interactions with study participants, it is likely that information will be shared, or questions will be asked that are not related to the research study. For example, *“I have had a rash on my inner thigh for the past three days. What do you think it means?”* or *“I have been so nauseated lately I haven’t eaten anything in two days.*

Although it is tempting to provide advice or verbalize your observation, you may have to walk the fine line of not becoming emotionally involved while still being compassionate and caring.

The CRC can and should acknowledge the study participant’s struggles / concerns expressed during the interview. “It sounds like you have had a really rough time in the last two weeks. I am so sorry you are dealing with this.”

Then redirect him/her to his/her health care provider to address the concern / symptom. “I think you are dealing with something that you should discuss with your oncology nurse. When we are done with this phone visit, will you call the clinic and tell them what you just shared with me?”

You show compassion and caring, and maintain that human connection but you don’t get involved in care provision. Conversely, you don’t dismiss their concern although you have collected the data for that time point.

1. End of visit
2. At the end of each visit / phone call, let the participant know what to expect for the next visit. For example: *“I will call you in a week. It will take no more than 10 minutes.”*
3. Give a general timeframe when you will be calling for follow up appointments / calls rather than setting a specific time and date.

*Rationale: Scheduling a phone appointment may seem like a good idea for managing participant expectations, but you run the risk of needing to apologize if you miss the meeting (due to being with another participant, illness, other issue). This could potentially break down some trust and rapport that you have worked hard to build. By not setting up a firm time, you minimize the potential of disappointing the participant or appearing that you are not organized.*

1. Sincerely thank him/her for participating. Example: *“Thank you for your willingness to answer the research questions and for sharing your experiences so that in the future we can help people like you, who are dealing with an advanced illness.”*

*Rationale: It is one more way to ensure they feel respected and valued as a person. S/he is not merely a “subject” in a study with the CRC just going through the motions of collecting data.*

1. Other Considerations

If the participant has a scheduled appointment with your clinic / hospital that falls in the time period of a follow up visit, you may want to consider contacting him/her at their visit (or asking if you can meet her/him).

Example: Oncology patient is getting an infusion. CRC sees upcoming schedule for this study participant and swings by the infusion center. *“Hi \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name of participant)! I saw you were here so I just wanted to check in with you to see how you're doing. Are you feeling up to answering some research questions?”*

*Rationale: Human connection is best made and maintained by face-to-face interaction. Our experience is that the study participant often is glad for the company and the distraction.*

Take away messages:

1. Complete and accurate data collection of follow up data is necessary for meaningful findings to be drawn and recommendations for clinical practice to be disseminated.
2. Respecting the participant’s choice about when s/he is willing to respond to research questions increases the likelihood of collecting the needed data. Thanking participants for his/her time answering research questions and for participating in the study reinforces that s/he is valued.
3. Be flexible in how and when you connect with the study participant.

Appendix A: Sample CRC Job Description

UNIVERSITY OF MAKE BELIEVE

**Clinical Research Coordinator (CRC)**

**Department of Medicine**

Position Number**: 123456**

**Nature of Work**

Conduct research study under the direction of the Principal Investigator. Direct contact with a population experiencing advanced illness.

**Professional Field**

Clinical research involving direct patient contact.

**Supervision Received**

The PI of the study will be the direct supervisor.

**Supervision Exercised**

None.

**Examples of Work Performed**

In a collaborative team environment, recruit, screen, consent, enroll, randomize and collect data on study participants following research study protocol. Coordinate the clinical trial under the supervision of the PI, including the scheduling of potential participants, tracking patient participation and drop out, assisting with annual IRB package submissions, and entering and verifying study data. Position requires face-to-face and telephone interviewing of patients who are experiencing advanced illness; experience and degree of comfort with people at end of life is necessary. Position also will communicate with participant’s primary physician. Comfortable communicating with physicians is necessary. May need to establish recruiting relationships with organizations outside the University, communicate with community physicians and recruit/conduct visits in participant homes.

**Knowledge, Skills, and Abilities**

Previous experience collecting clinical research data on human subjects, with a sound foundation in research methodology. Proficient in MS Office (Outlook, Word, Excel, and Access). Comfortable with medical terminology. Ideal candidate is capable of juggling competing tasks, prioritizing work, thinking on her/his feet, and can identify issues and problems as well as identify possible solutions. Flexible approach to getting the work completed is valuable.

**Minimum Requirements**

Bachelor’s degree and two years of clinical research experience. Nursing background and/or CRC certification (either ACRP or SoCRA) preferred.

**Salary Range**

$\_\_\_\_\_\_\_\_\_\_\_\_\_ FTE, depending on experience.

Source of Funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Does this position have fiscal responsibility?**

No

**Approval:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PI or Department Chair Date

Jane Smith, MD, MSPH

Appendix B: Sample Consent Form for CRC Interview

**Valid for Use Through:**

**Study Title: *COGNITION CHANGES WHEN GETTING CHEMOTHERAPY FOR BREAST CANCER***

**Principal Investigator: Jane Smith, MD, MPH**

**IRB No: 13-1100**

**Version Date: May 1, 2013**

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

**Why is this study being done?**

You are being asked to participate in a research study of the effects of chemotherapy on abilities such as concentration, memory and problem solving. These are also known as cognitive abilities. You are being asked to take part in this study because you fit into one of the following two groups: 1) You are a female 45 years of age or older and will undergo chemotherapy for breast cancer; 2) You are a female 45 years of age or older and you do not have cancer, have never undergone chemotherapy, and are being asked to be a control subject.

A total of 300 persons will be recruited for this study (150 women with breast cancer and 150 women who are cancer-free control subjects.

**What happens if I join this study?**

If you agree to take part in this study, there will be no change in your care. We will, however, ask you to undergo testing of your memory, concentration, and thinking, and have blood drawn so we can obtain information on the amount of certain proteins in your blood that are associated with inflammation and diabetes. We also may ask you to undergo an MRI scan (which is the use of magnetic field and radio waves to examine the tissues of the body) to look for any signs of inflammation in your brain. If you are asked to have an MRI we would like to repeat the MRI scan on two more occasions. These tests are unrelated to any standard care that you may be receiving, and are solely a part of this research study. This is not a treatment study.

We would like to test you three different times, approximately six to nine months apart. On each visit we will conduct a number of physical and cognitive tests. The tests of thinking deal with reasoning, concentration, learning, short-term memory, and problem solving. The physical tests include basic physical acts such as walking, getting up from a chair, and reaching over the head. We will ask about your mood, your ability to perform everyday tasks, and your quality of life in general. The same set of tests will be given on each of the three visits. The testing will take about three hours on each occasion. They will be done in your home or an office and do not require hospitalization. We will give you the opportunity to take frequent breaks on the days you are being tested, and will schedule the sessions at a time that is convenient for you.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include slight pain when drawing blood. During each data collection session, approximately one to two teaspoons of blood will be removed twice by putting a needle into your vein. This is the standard method used to obtain blood for tests. A bruise may form at the site. A total of seven teaspoons will be taken for research purposes over the course of this study.

Your blood will undergo molecular testing. All subjects, including control subjects, must be tested for the presence of what are known as inflammatory molecules. Two of these are know as interleukins, one is called a tumor necrosis factor, and another is called C-reactive protein, or CRP. These are naturally occurring proteins, produced by your body’s immune system, and they cause inflammation. We are interested in learning whether inflammation might be involved in the cognitive problems, fatigue, and depression often seen in women who are receiving chemotherapy for breast cancer. We will also look for the presence of hemoglobin A1c, which is a test of how well your body regulates your blood sugar level. The data collected in this study are of course confidential, and individual data will be discussed only with you.

Magnetic Resonance Imaging (MRI) involves lying very still within a long tube surrounded by a powerful magnet. The body is then exposed to changing magnetic fields. There are no known risks to the types of magnetic fields and radio wave used in these studies, but there is always a possible unknown risk to this or any test. Rarely (one in thousands of exams) a sunburn-like skin burn may occur over a small area of the body. We take special precautions for this not to occur. In addition, you must lie still in a small space, and some people may experience claustrophobia.

The risks involved in answering the mood and quality of life surveys include a possible feeling of anxiety about answering questions that you would rather not talk about or that may make you uncomfortable. Other than that, there is no risk to you from the cognitive testing; if you feel fatigues or need a break, you will have the opportunity to take a break. The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about cancer chemotherapy (the treatment of cancer by using drugs). This study is not designed to treat any illness or to improve your health. Also, there are risks as mentioned in the Discomforts and Risks section above.

Who is paying for this study?

This research is being paid for by the National Institutes of Health.

Will I be paid for being in the study? Will I have to pay for anything?

You will be paid $35 per interview (a total of three over a 15-month period), and $15 per session for the two blood draws. If you are asked to undergo a magnetic resonance imaging (MRI) scan, you will be paid $50 for each of these. Participants who do not have MRI will receive a total of $150 over the course of the study for their participation. Participants who do undergo MRI will receive an additional $150 for all three MRI scans.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, you doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled.

If you chose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause your harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

The University of Make Believe has no plan to pay for a physical or psychological injury. If you are injured or hurt during this study, you may call Jane Smith, MD, MPH at 444-555-6666.

Who do I call if I have questions?

The researcher carrying out this study is Jane Smith, MD, MPH. You may ask any questions you have now. If you have questions later, you may call Dr. Smith at 444-555-6666, or Jim Smith, a co-investigator, at 444-555-6667. You will be given a copy of this form to keep.

You can also call the Multiple Institutional Review Board (IRB). You can call them at 444-555-6677.

Who will see my research information?

The University of Make Believe and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

* University of Make Believe
* University of Make Believe Hospital
* The Children’s Hospital of Make Believe
* Veterans Affairs Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Make Believe and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study’s Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jane Smith, MD, MPH, 1122 N. First Ave, Anytown, PL, 00998

Others who have a legal right to see that information may look at both the research records that identify you and the consent form signed by you.

* Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
* People at the University’s Institutional Review Board (IRB)
* The study doctor and the rest of the study team.
* NIH, who is the company paying for this research study.
* Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

* Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
* Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
* Research Visit and Research Test records
* Psychological tests
* Billing or financial information

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University of Make Believe and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

* The data, or the tissue, blood, or other specimens are given by you to the investigators for this research and so no longer belong to you.
* Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you.
* If data, tissue, blood, or other specimens are in a form that identifies you, University of Make Believe or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
* Any product or idea created by the researchers working on this study will not belong to you.
* There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature: Date:

Print Name:

Consent form explained by: Date:

Print Name:

|  |
| --- |
| Appendix C: Sample Protocol to Give to CRC Prior to Hiring Interview |



|  |  |
| --- | --- |
| Title | Mechanisms of family caregiver resilience: Role of emotion reactivity and regulation |
| Protocol Number | 13-1111 |
| Type and Phase |  |
| Sponsor | Department of Medicine |
| Principal Investigator | Jane Smith, MD, MSPH |
| Lead Statistician | Dawn Juan, PhD |
| PCRC Contact | Bob Dole |
| Protocol Version  Release Date | 1 |
| Revision History | n/a |

**Statement of Confidentiality**

|  |
| --- |
| The information contained in this document is privileged and confidential. Any distribution, copying or disclosure is strictly prohibited unless federal regulations or state law requires such disclosure. Persons to whom the information in this document is disclosed must be made known that the information is confidential and may not be further disclosed by them. |

*\*These guidelines have been informed by:*

Chan AW, Tetzlaff JM, Gøtzsche PC, Mann H, Berlin JA, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleza-Jeric K, Laupacis A, Moher D (2013). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. British Medical Journal: 1-42.

|  |  |
| --- | --- |
| **Administrative information** |  |
| Title | Mechanisms of family caregiver resilience: Role of emotion reactivity and regulation |
| Trial registration | Not applicable. |
| Protocol version | Version 1.0 |
| Funding | Department of Medicine |
| **Introduction** |  |
| Conduct in the PCRC | When caring for a loved one with an advanced illness such as cancer, family members often supplement the clinical care provided by oncologists, palliative care, and/or hospice. The stress involved in caring for a loved one is understandable and even expected. How people cope with stress in this situation is not as well known or documented. Some people seem better able to take care of themselves than others. In this pilot study, we will learn more about how family caregivers deal with stress, which will inform our R01 submission to ask more specific research questions on how to best intervene and support family caregivers in the future. |
| Background and Rationale | This study will be gathering pilot data for a future R01 application.  Family caregivers of loved ones living with cancer may provide care for many months or even years and this amount of stress may be associated with significant morbidity. There is benefit in identifying those at risk who may benefit from intervention. There is benefit in understanding what makes people resilient and how we can build resilience in people – learning from those who do well to intervene with those who don’t do well.  For purposes of this study, “family caregiver” is broadly defined to include any individual identified by the patient as being involved with their care, excluding professional health care providers.  Using the real-world psychosocial stress of being a family caregiver for a person with cancer who is enrolling in a phase 1 trial, we will explore the relationships among age, emotional regulation ability (ERA), physiologic responses to stress, and perceived responses to this psychosocial stressor.  The planned study is cross-sectional, with the goal of describing variation in response among this population. Based on the findings from this pilot study, we will seek extramural funding (and submit a separate COMIRB application) for a future longitudinal study across transition points that are hypothesized to either increase or decrease psychosocial stress (e.g. treatment non-response, regular scan reviews, long term care admission, hospice enrollment, hospitalization, emergency department visits, death) among family caregivers of persons enrolled in oncology phase 1 trials. |
|  | Not applicable |
| Objectives | **Research Question:**   1. What are the current experiences of family caregivers of oncology Phase I trial participants?   **Sub-Questions:**   1. What moderates the link between stress and outcomes? 2. What protective factors emerge across the lifespan? 3. What biological factors might be on the causal pathway between stress and outcome (mediators)?   Our hypothesis is that there are people who have developed coping skills to manage the stress involved in caring for a loved one with cancer. We would like to learn more about those strategies to inform and further the science and care provision to those with advanced illnesses and the people who care for them. |
| Study design | This study consists of a one-time survey which will be administered to family caregivers of oncology Phase I trial candidates during the candidate’s regularly scheduled visits to the Phase I clinic at the University of Make Believe Comprehensive Cancer Center. The candidates will be screened for eligibility and interest and introduced to the study during the patient’s screening visit and the survey will be administered during the patient’s first day of their first course of treatment (Course 1, Day 1).  **Screening Visit**   * The research assistant or nurse practitioner will approach potentially eligible family caregivers while they wait for the patient’s first screening clinic appointment. They will be screened for eligibility and interest and then presented with an introduction to the study in the form of a flyer (Appendix A – Study Introduction Flyer).   **Course 1, Day 1 Visit – Survey**   * At the patient’s clinic visit for Course-1, Day-1 caregivers will be approached again by the research assistant or nurse practitioner. * They will be provided again with a brief introduction to the study in the form of a flyer (Appendix A – Study Introduction Flyer). * At this interaction, the potential participants will be re-screened for eligibility and interest if they are being approached by a different clinic representative. * If eligible and amenable, they will be given the self-administered survey, which consists of demographic questions and psychosocial measures (Appendix B – Survey). * If participants elect to complete the survey they will be able to return it into a large repository of other completed surveys so as to minimize ways to identify them. * All responses will remain completely unidentifiable.   The participant’s choice to complete or not complete the survey will have no effect on the treatment the patient is receiving. |
| **Methods: Participants, interventions, and outcomes** |  |
| Study setting | All participant recruitment and data collection will occur in the Phase I clinic at the University of Make Believe Comprehensive Cancer Center. |
| Eligibility criteria | All participants must be able to read and understand English, at least 18 years old and not older than 89 and able to complete the study instruments independently. The upper limit of 89 years of age is placed due to a desire for these pilot data to remain anonymous, per the requirements of exempt IRB review. |
| Interventions | This is a non-intervention study. |
|  | Not applicable. |
|  | Not applicable. |
| Outcomes | Not applicable. |
| Participant timeline | See Section 8 above. |
| Sample size | 250 study participants. |
| Recruitment | The initial plan is to approach cancer patients at their first visit to the cancer center. This assumes they will be accompanied by a loved one / caregiver. If this assumption proves to be wrong, we will expand the recruitment time frame to include any visit at which the patient is accompanied by a loved one who cares for her/him. |
| **Methods: Assignment of interventions (for controlled trials)** |  |
| Sequence generation | Not applicable. |
| Allocation concealment | Not applicable. |
| Implementation | Not applicable. |
| Blinding (masking) | Not applicable. |
|  | Not applicable. |
| **Methods: Data collection, management, and analysis** |  |
| Data collection methods | When participants complete the survey they will return it into a large repository of other completed surveys. All responses will remain completely unidentifiable.  The data will then be transcribed by a research assistant and entered into REDCap. |
|  | As this is a one-time survey, there are no retention plans or strategies. |
| Data management | The following steps will be taken to protect against loss of confidentiality. First, all study personnel and investigators will be required to participate in mandatory and ongoing educational programs concerning research ethics. These programs are available through the IRB. One of these programs must be completed by all members of the investigative team prior to IRB approval of the proposed work. Second, all data will be collected with strict attention to HIPAA guidelines and stored using HIPAA-compliant data management systems, allowing only password restricted access to limited designated key study personnel. Only aggregate results for the population studied will be released; no individual patient data will be released from the database. Third, the data collected are anonymous, so there are no PHI on the data collection forms. Finally, all data collection forms will be in a locked file cabinet. |
| Statistical methods | All of data from surveys will be entered into REDCap electronic data capture tools hosted at UCD. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies.  Data Analysis will entail evaluations of the frequencies of responses and scoring breakdowns, using SPSS 18 / PASW 18.  This data analysis will inform a future fundable grant application which will be designed to provide a psychosocial intervention to this population of caregivers for oncology phase I trial patients.  The research assistant will track the number of participants who were screened for participation and if they decline to participate, will track their reasons for declining in order to assess feasibility for future prospective studies. |
|  | Not applicable. |
|  | Not applicable. |
| **Methods: Monitoring** |  |
| Data Monitoring Committee (DMC) | Not applicable. |
|  | Not applicable. |
| Harms | Not applicable. |
| Auditing | Not applicable. |
| **Ethics and dissemination** |  |
| Research ethics approval | This protocol will be submitted to the University of Make Believe’s Institutional Review Board. We are requesting exemption. |
| Protocol amendments | Once the protocol has been approved, any changes to the protocol must be communicated by the Principal Investigator (PI) to the funding agency.  Each Site PI will need to submit an amendment to the local IRB for review and approval prior to implementing the change. Clearly highlighted changes must be included in the amendment.  It is also the PI’s responsibility to report any unanticipated problems with the study to the IRB. |
| Consent or assent | The research assistant or nurse practitioner in the Phase I cancer clinic will obtain informed consent. |
| Confidentiality | When participants complete the survey they will return it into a large repository of other completed surveys. All responses will remain completely unidentifiable. |
| Declaration of interests | There are no financial and other competing interests for principal investigator. |
| Access to data | Provide a description of who will have access to the final trial dataset, and any contractual agreements that limit such access for investigators. |
| Ancillary and post-trial care | Outline plans, if any, for ancillary and post-trial care, and for compensating those who suffer harm from trial participation. |
| Dissemination policy | Describe plans for investigators and sponsors to communicate trial results to participants, healthcare professionals, the public, and other relevant groups, including any publication restrictions. |
| **Appendices** |  |
|  | Data collection form |

Appendix D: Sample PCRC Clinical Research Coordinator Interview Questions

Candidate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of interview: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Interviewer(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Tell me three things about yourself/your skill set that uniquely qualify you for this position.
2. Tell me about your experience(s) working on a federal grant (Probe: type, scope, role, multi-site, analytic work etc.).
3. What is it about this job that is most appealing to you? Least appealing?
4. What type of working environment do you prefer? (Probe: self-motivated, doesn’t need a lot of supervision, organized, manages time well)
5. Tell me about a time that you had to gather a lot of information from different sources and organize it. What did you like about it? What was hard about it?
6. Describe a situation where you had to deflect an escalating situation and how you handled it.
7. What type(s) of prior exposure have you had in being around people receiving palliative and/or end-of-life care?
8. Tell me a little bit about your experience with grief – dealing with your own grief, others’ grief etc.
9. How do you reduce stress in your life? What do you do to relax? Debrief?
10. Request candidate conduct an informed consent process on you (assuming you gave them the fictitious consent form a week in advance and explained that this would be part of the interview).
11. What are your long and short-term goals?

**Protocol Review (sent to candidate one week prior to interview with the following questions):**

1. After reading the protocol, what questions came to mind?
2. What, if anything, is missing or unclear?
3. What questions /comments would you pose to the author(s) of the protocol to improve it?
4. In three or four sentences describe, what is this protocol about? How would you explain this study to a potential research participant?
5. What concerns, if any, do you have in operationalizing / implementing the protocol in a clinical setting?

Appendix E: CRC Checklist of Materials and Supplies

**A. For initial interaction / possible consent, and baseline data collection time point**

1. Bag/ trapper keeper for all supplies
2. Pens
3. Clipboard
4. Business cards
5. Tracking worksheet/notepad to document potential participant name, MRN, room number, and attending MD
6. IRB approved recruiting materials:

* Participant handout
* Clinician handout/ study overview

1. List of rounding MDs for various services with contact phone/page numbers by day of week
2. Study Forms:

* Eligibility
* Consent
* Baseline
* Follow up visit

**B. For study participant follow up visit/phone call**

1. Tracking sheet of participant ID number, initials, dates of visits and type of visit due
2. List of enrolled participants with

* Study ID number and initials
* Contact phone number (s)
* Name of family member(s)/ facility/ staff
* Randomization assignment

1. List of medications as noted on prior follow up visit for each participant
2. Case report forms:

* Follow up visit forms
* End of study forms for deaths, non-compliance with randomization assignment and drop out of study

Appendix F: Typical Monday in a University setting: CRC tasks for the statin continuation trial

1. Oncology clinic and inpatient setting: obtain a list of potential patients who meet the initial screening criteria (on a statin). This may come from email review of medical records, physician referral, labels of patients’ names made available or other mechanisms established by the site.
2. Review this subset of charts.
3. Attend morning rounds/meetings to identify additional patients from services such as oncology, acute elderly or palliative care service.
4. Page hospital physicians to get OK to consider possible patients.
5. If unable to talk with MD face to face or by phone, send an e-mail to the attending physician with the patient's name and their ID number, letting them know you have reviewed the medical record and the person may qualify for Dr. \_\_\_\_\_\_\_\_\_\_\_’s study on statin discontinuation.
6. Add the questions when speaking or e-mailing “would you be surprised if this patient died in the next year?” if “no, would not be surprised,” the patient may be eligible. Ask the questions regarding cardiovascular history, contraindications to coming off or staying on a statin medication.
7. When criteria confirmed and MD agrees patient may be approached, confirm that you will talk with the patient and get back to MD if the patient agrees to study participation.
8. When the patient is enrolled in the study, CRC phones/emails the doctor: “Dr. \_\_\_\_\_\_\_\_, your patient ID # did enroll in the statin study and has been randomized to (discontinue or continue) statin medications. If randomized to discontinue, request they write an order to D/C statin medication. If randomized to continue statin medication, no need to write an order. Ask MD to make a note in patient’s medical record regarding study enrollment and randomized assignment. Some sites may also request IRB protocol number to include in note.
9. Advise MD that patient has been notified of randomization assignment. Document that physician contact was made by adding a note in the research record.

Appendix G: Stories from a nurse recruiter for the statin continuation vs. discontinuation study

**Tackling the statin study**

As an experienced nurse research recruiter I feel intimidated by the “statin study.” There are so many ways that patients do not qualify. The population is very sick. Some of the inclusion criteria are based on my judgment. This study will require that I gain the trust of the research team, physicians who I hope will refer potential participants to me, and the participants themselves along with their families if I am to succeed. I will need to draw on all of my experience as home health nurse, hospice liaison and project manager. I am also a daughter who has experienced the death of both parents. I hope I don’t fail.

**Coming to terms with my role**

I ponder the question: What is a recruiter for a research study? After much consideration I realize I am a salesperson. Yes, a highly skilled salesperson whose role is to “sell” the opportunity to participate in a research study to people with advanced illness that will further knowledge and help people like them in the future. The thought of being a salesperson does not sit well with me. After all, I’m a health professional. After I get past the emotional images I become more comfortable with my role as salesperson. The people who are most successful in sales know their product well, can articulate the various facets of their product with confidence and are very savvy at reading their customers. They know what to say and when. They have great listening skills. They also know that people are most likely to buy from people they like. They develop excellent interpersonal skills. Yes, I guess I am a highly skilled salesperson who will hopefully be successful at recruiting people to participate in something bigger than them. In this context I gain more respect for myself and for my role. My job description never mentions the words salesperson. I wonder why.

**Using the word “die”**

The language used for the study eligibility criteria is intriguing to me. I will need to consult with physicians about whether they believe their patient / potential study participant will “pass away” in the next year. That is what is written on the case report form. Are the words “pass away” an indication of our own discomfort with the words death or dying? Having worked in hospice I’m used to hearing and talking about death and dying. Often when I call physicians, to seek their permission to approach their patients I use the cold hard words “death” and “dying.” As they contemplate the patient’s condition, they reflect the same language back to me that I use. “No, I wouldn’t be surprised if they were to die in the next year.” One of the baseline questionnaires uses the word “die.” I’m perplexed why the case report forms don’t use the same language for interacting with our professional colleagues.

**On being comfortable with the target population**

I know this study is directed to people with advanced life-limiting illness. When I introduce the study to potential study participants, I don’t shy away from saying those words and using good eye contact while I say them. My belief is that if potential participants don’t know they have an advanced life-limiting illness it is not likely they will enroll in a study directed to this population. By putting their status on the table and speaking comfortably and honestly about this, I develop trust.

**Reviewing eligibility criteria with a physician**

After previewing a potential participant’s medical chart, I call his physician to obtain permission to approach him. The attending physician contemplates whether he would be surprised if this patient were to die in the next year. “It is a tough question” he says. “If the patient has the help and support he needs he probably will make it and not die in the next year.” I ask the doctor what he believes is the likelihood this patient will get that kind of support. After all, this patient recently spent two days on the floor prior to being found and transferred to the hospital. The doctor verbalizes that he is less sure about the likelihood of survival. I remind him that the question is really would you be surprised if this patient were to die in the next year.” It is not a prognosis. It’s an assessment. After a little more dialogue he settles on his belief that “No, I would not be surprised if this patient died in the next year.” He gives me permission to talk to the patient but cautions me “please don’t be hanging any crepe.” I reassure him that I will not do that. He comments that now that he thinks about it, this patient may be better off without statin medication. I clarify the nature of the study and that the patient could be assigned to either stay on or come off statins if he chooses to enroll. I thank him for giving me the opportunity to talk to his patient and confirm that I will call him if the patient agrees to participate in the study. After approaching, screening, and enrolling his patient, I call the physician back to inform him which randomization arm his patient was assigned. I also tell him that I used the words “advanced life-limiting illness” and that the patient did not react negatively at all to hearing these words. The physician volunteers “maybe nurses do a better job in having these conversations than doctors do.“

**Stories from patient / potential study participant encounters**

**Participant A**

He is in pain in the hospital. Once he gets some relief I return to his room and tell him about the study. I put aside my doubts that maybe he is too ill. I need to honor the protocol and the stated eligibility criteria. He meets the criteria. After I explain the study to him, he agrees to participate. I receive a phone call from his wife that evening letting me know how upset they are and how unreasonable it was for me to put their loved one through this. They demand a meeting the next day. They let me know that I will be meeting with the wife and the son who is a police officer. I feel intimidated. The palliative care nurse has shared that she has experienced the intimidation of the family as well. We meet the next morning. Their body language says they are ready for attack. I introduce myself and learn their names. Before they can vent their anger, I apologize for any additional distress that I have caused them in the face of what they are already experiencing with a loved one dealing with advanced illness. They respect this and their body language relaxes. The son (police officer) begins to question me in a manner consistent with his profession. I can only be honest and validate that the study is indeed for people like his father. I review the study objectives. After talking about the various aspects, the son says ”we will leave everything on hold” for now. I clarify what “on hold” means and learn that the patient will stay on the study with assignment to stop statins for now. They will contact me “next week” to confirm.

Take away: It is hard to recruit really sick patients, but my job is to honor the protocol. Every potential study participant is a person who often has family members with needs and concerns for their sick loved one. Perhaps family members should be included in discussions about research study participation, so their support can be obtained early in the process. This should be considered for all participants, cognitively intact and those with a legally authorized representative who makes medical decisions on their behalf.

**Participant B**

She is in an assisted living facility. She decided last week that she was not going to get out of bed any more. Hospice was called in. She is in bed and sleeping when I arrive. I arouse her. We discuss the study. She meets the eligibility criteria even though she gets some of the Short Portable Mental Status Questionnaire (SPMSQ) wrong. She is able to reiterate the study purpose and repeats back what will happen if she enrolls. She signs the consent even though her handwriting is very shaky. The baseline questionnaires wear her out, but we get through them. She deteriorates rapidly over the next week. According to the medical staff, she is barely able to be aroused at times. I begin to question myself. Did I enroll her in error? Someone who declines that quickly…were they really a qualified study candidate in the first place? I visit her the next week and am relieved that she has “perked up” some. She is still only at 20% on the AKPS scale. We are able to complete all the questions for the follow up visit and I feel reassured that maybe I did not enroll her in error. She dies 6 weeks after study enrollment. I tell myself that I have to trust the process.

Take away: This study is designed to target people who are dealing with an advanced illness. Their conditions can change quickly. I need to trust the study inclusion criteria.

**Participant C**

He has not been on hospice long when I meet him and his wife in their home. After a long discussion about the study, the patient says he would like to participate. The wife does not want to rock the boat by changing any medications, so would prefer he not enroll. Suddenly I feel like we are a triangle and I am coming between the husband and wife. I try to elicit her concerns but she looks at her husband and says “it’s up to you.” Her tone sends the message that she does not support the idea of participating in the research. She can’t really articulate her concerns. Her body language is closed with arms folded across her body. He decides that in spite of his wife, he will participate in the study. We complete the consent and baseline questions. Within a month of enrolling, the wife calls and asks that I not call him anymore to ask the questions because it is too much for him. I am allowed to obtain information from his hospice nurse.

Take away: Study participants and families may not always be in agreement. The participant does have the capacity and right to decide. Just because there may be evidence of conflict does not mean that I should not offer the participant the opportunity to participate.

**Participant D**

He is hospitalized and acutely ill from respiratory complications. He has a tracheostomy so understanding his speech is difficult. Nevertheless, he is able to communicate with me sufficiently so that I can understand him. He agrees to participate in the study. Conducting the quality of life questionnaire is a challenge. He reaches for the Kleenex box as I ask if he is depressed, sad, fears the future, how he feels about his whole life. I wonder if have the right to put him through this in the face of all the physical challenges he is experiencing.

Take away: Evaluating the effect of statin continuation vs. discontinuation on quality of life is a study outcome. It is not up to me to decide if I have the right to administer certain questions or not. It is my responsibility to conduct the study protocol as defined. I can be empathetic and supportive and let him take his time to process each question even though it may be emotionally painful.

**Participant E**

I meet him in the oncology outpatient clinic. He has had a laryngectomy. He communicates with a writing board and the loving support of his wife. He is interested in the study as he writes “to help others.” I wait for him to write answers. I don’t want to be impatient to get to the answers because this is how he has to communicate, and it does take time. We establish a warm and trusting relationship. Several weeks after enrollment this patient experiences anaphylactic shock and full cardiac arrest from a new chemotherapy drug. While he is in ICU making a recovery his wife calls to tell me about his experience. I learn from her that he was the one who told her that she needed to call the research nurse to let her know what had happened to him. I visit him in the hospital to conduct a follow up visit. The wife calls me a few days later to tell me that my visit meant so much to him.

Take away: research subjects are people dealing with challenging issues. My ability to establish positive relationships enhances the likelihood that I will get as much research data on every participant as possible. My approach and relationship building validate that each participant is engaged in a worthwhile endeavor and that I value them as people as well as a study participants.

**Participant F**

He is a World War II vet. I had agreed to meet him at his home to discuss the research study. Before we even begin to talk about the study, he walks me over to his wedding picture with his sweet Jenny who also is present at the visit. They have been married for 60 plus years and she is the light of his life. I also see his WWII pictures. He was in the army. I believe he is telling me that he is a person first and foremost, not just a hospice patient who might be a potential research study participant. He eagerly agrees to participate in the study. The only physical problem he will admit to is that he has sore knees. Trying to get an accurate picture of his physical health and mental health is challenging. For him, as long as he has Jenny, he has no worries and no troubles even though he is on hospice with end stage renal disease.

Take away: The McGill Quality of Life scale and Edmonton Symptom Assessment System scales have no right or wrong answers. Answers are whatever the participant believes them to be. My job is to present each question clearly and ask the study participant to answer each question as honestly as s/he can.

**Participant G**

When I first enter this participant’s home, I find myself thinking “I hope he doesn’t sign up for the study.” He has a raspy voice, and has a nasty habit of horking up phlegm every few minutes. He has waste cans filled with tissues everywhere and his house is a mess. He takes a long time to answer every question. He becomes impatient with me if I repeat a question. “Why can’t you just be quiet and let me think?” Then he asks to have the question repeated. He has met all the study criteria so I know he qualifies to be in the study. I just wish I didn’t have to deal with him. This enrollment home visit takes such a long time. I am ready to leave. He says, “Now you have taken all this information from me. I want you to just sit and talk with me now.” Half an hour later I learn that he is from the Deep South. He says if he didn’t have forgiveness in his heart, that for a white woman arriving at his door he could blow my head off. I am not afraid. I have been a home health nurse and have experienced many situations. I learn about his upbringing, and adopted family here. He respects that fact that I have taken time to get to know and understand him. He apologizes several times for being rude to me. Follow up visits never go quickly.

Take away: Research study participants are varied and different. They are all worthy of respect. Some visits take a long time. I have to be accepting and ready to deal with whatever confronts me.

**Participant H**

I will be meeting him in the oncology outpatient clinic. His doctor has notified me in advance that he is a high profile government official. My initial reaction is to consider “Is there anything I need to do differently?” After all, this is a highly intelligent man with status. I quickly refocus my thoughts and realize that I do not need to do anything differently. He is a person dealing with an advanced life-limiting illness and his loved ones are supporting him through the process. He is just like every other study participant that is considered for study inclusion.

Take away: Regardless of status, the research study is intended for all people with an advanced life-limiting illness who meet study criteria. My role is to offer them the opportunity to participate.

Appendix H: Suggested Language / Hip Pocket Phrases for Various Participant Interactions

**When approaching a potential participant**

Hello, are you \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (participant’s name)? My name is \_\_\_\_\_\_\_\_\_\_\_\_ and I am a research coordinator with Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (institution). *[Shake hands if deemed appropriate.] Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has given me permission to come talk with you about* a research study that we are doing for people like you who are dealing with an advanced illness. Could I have a few minutes of your time to tell you about the study (project)?

Is this a good time for you?

If “no,” agree on a time to return.

If “yes,” then follow these steps:

1. Sit in a chair at eye level and close to the potential study participant
2. Invite family members/ loved ones to listen as well if potential study participant desires
3. Provide a brief summary of the study and ask if they are interested in hearing more of the details
4. If they express interest, tell them you will need about 30 minutes of time to talk about the eligibility requirements and review the study consent form in detail
5. Confirm that this is a good time for them. If so, proceed. If not, arrange a time to return.
6. Explain and obtain eligibility screening questions
7. If all screening criteria are met, continue to explain the study using the consent form. *Suggestion: Offer the study participant the opportunity to follow along on a copy of the consent form or just listen as you explain.*
8. Speak slowly, clearly and in a voice tone that study participant can hear.
9. Review each section of the consent form highlighting transitions to maintain interest and keep participant engaged in the conversation.
10. Maintain eye contact.
11. Provide the opportunity to ask questions.
12. If applicable per the protocol, inform person that his/her physician is knowledgeable about the study and agrees that the potential participant should be invited to participate.
13. Reinforce that participation is a choice and there are no negative consequences for deciding not to participate.
14. Allow time for the person to make a decision and, if needed, agree to return after study participant has discussed with loved ones or care provider(s).
15. Obtain consent and signature on consent form for those who choose to participate.
16. Thank person for his/her willingness to participate.
17. Arrange a time to complete baseline data collection and explain randomization process.
18. For potential study participants that decline to participate, thank her/him for his/her time.
19. Reassure person that there are no negative consequences for deciding not to participate in the research study.

**Strategies when potential participant does not meet all eligibility criteria**

1. Scenario 1: After reviewing study eligibility criteria, potential participant has too high functional ability based on AKPS assessment:

Suggested Script:

*“It looks like you are functioning at a level that is a little too high to be a participant in this study.  The study involves people who are not doing quite as well as you are doing right now.  I hope that you continue to do well.  Would it be okay for me to check back with you in 2-3 months to see if anything has changed in your functional ability?   If you have had some decline we can discuss your interest in being a part of this study at that time.   Thanks so much for your time, and again I wish you well in the coming months.”*

1. Scenario 2: Eligibility criteria exclude cognitively impaired persons and nothing in medical record noted any cognitive functioning difficulties, so potential participant was approached. It was not until the CRC began to interact with the person that it was clear s/he had some cognitive deficits.

Suggested Script:

*Mr(s). \_\_\_\_\_\_\_\_, thank you so much for letting me talk with you about the statin study. Your physician, Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has given me permission to talk with you and see if you are interested. Before I go into the study details I’d like to ask you a few questions about your overall functioning and your memory. Would that be okay? After completing the mental status questionnaire, the potential participant incorrectly answers six questions, meeting the criteria of having cognitive impairment.*

*Recruiter: “Mr(s). \_\_\_\_\_\_\_\_\_\_ it looks like you are having some difficulties with your memory.” Recruiter pauses and gives potential participant time to think about this and respond.*

*After a pause, the potential participant might say something such as, “yes, I guess I have noticed that I’m a little more forgetful this past year and it is harder to remember things.”*

*Recruiter: Mr(s).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ we are not going to review the details of the study. Being in this study requires that you be able to remember things when I call you on the telephone. Based on how your memory was when I asked you the questions, it looks like your memory is not quite good enough for you to participate in the study.*

*Give participant an opportunity to respond, and then say “Thank you so much for your time and best of luck to you in the coming months.”*

**Other Usable quotes / Hip Pocket Phrases**

When Introducing of self and study

* 1. You are being *invited* to be in this research study.
  2. Deciding whether or not to be in a research study is your choice. You should feel good about participating and know that the choice to participate or not is right for you.
  3. Explanation of HIPAA – “*We want to make sure we are honoring your privacy and to make sure we are doing ethical research, so this research can be used for the future.”*
  4. Serious health condition (as opposed to illness, advanced illness, cancer, etc.)
  5. Study participant rather than “research subject” or “patient.”
  6. Research study as opposed to “project” or “trial.”

Working with fatigued or restless person

1. *“Are you just too weary right now? Do you need a break?”*
2. *“I have some research questions to ask”* (as opposed to I have interview questions or I would like to conduct an interview)

Studies involving drug cessation (e.g., statin trial)

1. “*As you get sicker and develop more symptoms, we as health care professionals are really good at giving you more and more medications to handle the situations you are dealing with. The reason this research is being done is we want to know if people with an advanced illness should be given a drug that is typically given for preventative purposes as opposed to treat a health condition you are currently dealing experiencing.”*

Appendix I: Suggested Language To Accurately Assess Functional Status

Obtaining functional status information, particularly over the phone, can be challenging because people tend to self-report that they are doing better functionally unless clarification is sought. Here are some probing questions you could consider using.

* + 1. Do you generally spend more or less than half a day in bed?
    2. If you spend more than half a day in the bed:
       1. How many times a day do you get out of the bed? How long are you out of the bed?
       2. Do you require extensive care from nurses or health care professionals?
    3. If you spend less than half a day in bed:
       1. Do you require assistance with normal daily activities? For example:
          - Are you able to work outside the home? If yes, what kind of work do you do?
          - What type of work are you able to do around the house?
          - Do you prepare your own meals?
          - Are you able to bathe yourself?
          - Are you able to dress yourself?
          - Are you able to climb a flight of stairs without getting winded?
          - Do you do your own grocery shopping?
          - Do you require a lot of assistance and frequent medical care because of your symptoms or illness?