College of Nursing
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

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Study Title: Personalized Experiences to Inform Improved Communication for Minorities with Life Limiting Illness

Unique Protocol ID: 17-1885

COMIRB
APPROVED
For Use
15-Nov-2017
14-Nov-2018

Principal Investigator: **Heather Coats, PhD, APRN-BC**
COMIRB No: **17-1885**
Version Date: **11.14.17**

Study Title: **Personalized experiences to inform improved communication for minorities with Life Limiting Illness**

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?

We are collecting stories from patients who are dealing with illness. We want to hear how your illness has impacted your emotions, your relationships and your spirituality. From the gathering of your story, we want to them take your story and add it to your electronic medical record for your clinicians to learn more about how your illness affects you. The goal of using your story is to help improve communication between you and your clinician.

Other people in this study

Up to 24 patients will participate in the study.

What happens if I join this study?

- If you join the study, first your story and medical record data will be collected by an interview with a member of the research team.
- This interview will be voice recorded (audio only) and should take less than two hours of your time. Your story will then transcribed by the research team within 48 hours.
- Next, you will have the opportunity to meet with the research team member a second time to review your transcribed story. At this time, you will be allowed to make changes to your story prior to your story being entered into your medical record.

- Last, in follow-up, you will then be contacted for a second interview to get your feedback about being in the study.

- This second interview will also be voice recorded (audio only) and should take less than an hour of your time.

- You will be in the study for no more than three months to allow for the above three meetings to take place: 1) the first interview, 2) the second meeting to review your story 3) the follow-up interview

What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

- You could become tired during the 60-120 minutes interview process. If you experience this, you can take rest periods or if necessary reschedule a return visit to complete the interview.

- You could feel some uncomfortable emotions due to the sensitive topics of discussion around your illness, your emotional state, your relationships, and your spirituality. If you experience this, you can stop the interview, reschedule for return visit to complete interview, or choose not to participate in the study.

- You could feel pressured to participate in the proposed project. To decrease the risk of this, the researcher will arrange with you, a private time with only a research members and yourself present for the interview. Once in this private setting, the researcher or research team members will remind you that participation is voluntary and that you may stop the interview at any time without any penalty or prejudice.

- **Identity will be protected:** Although there is a very rare risk that your identity could be known, the researcher will maintain confidentiality by removing all identifiers from the study materials. Only the researcher and the research team members will have access to the identities of the participants.

- Due to the preliminary nature to the study, the study may include others 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 ways to improve communication between patients and clinicians. There are no known benefits for the participants.

Are there alternative treatments?

There are no alternative treatments as part of this study. You may choose not to participant without penalty or loss to which you are otherwise entitled.

Who is paying for this study?

- This research is being paid for by National Institutes of Health/National Institute of Nursing Research.

Will I be paid for being in the study?

You will be paid $50 gift card after each interview visit in this study. This will add up to $100.00 dollars in gift cards if you complete both interviews for the requirement of your time to be a participant in the study. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

You will not need to pay for any part of being a participant in the study.

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 choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The principal investigator may decide to stop your participation without your permission if the study research team thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time

Who do I call if I have questions?

The researcher carrying out this study is Heather Coats, PhD, APRN-BC. You may ask any questions you have now. If you have questions later, you may call Heather Coats, PhD, APRN-BC at 303-724-3740. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Heather Coats, APRN-BC with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) 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 Colorado Denver
- University of Colorado 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 UCD and its affiliate hospitals may not be covered by this obligation.

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.

Heather Coats, PhD, APRN-BC
University of Colorado, College of Nursing
Mail Stop C288
13120 E. 19th Avenue
Aurora, CO 80045
Heather.coats@ucdenver.edu
Office Phone: 303-724-3740

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study principal investigator and the rest of the research study team.
- National Institutes of Health/National Institute of Nursing Research 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 research 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.
- Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the Colorado state police or other agency. Also, if we get a court order to turn over your study records, we will have to do that.
- Safeguards for protecting your confidentiality will include:
  - At time of enrollment, the study's principal investigator will assign you a number that is non-identifiable to any of your personal information. Once assigned, this number will then be used to de-identify the remainder of participants' personal information and each participant's interview transcripts.

- Only de-identified audio and written transcripts of interviews will be available for the remainder of the research team for analysis and interpretation processes. Only the principal investigator and the research team will have access to your identified personal information.
- All of the study data will be stored electronically on password-protected servers, folders and files, and only principal investigator and the research team will have access to these study-related electronic files identifiers to personal identifiers for the enrolled patients.
- The digital audio files and transcripts of the interviews will be reviewed and edited to remove all identifying information (such as names, places, or specific unique details of the patient or nurse by the principal investigator. Original recordings and all transcript files will be destroyed when the final usable set of transcripts is complete, also no later than the end of the study period.
- 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
- Research Visit and Research Test records
- Other: Your shared story

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find ways to improve communication between patients and clinicians. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data 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 collected from you.
- If data are in a form that identifies you, UCD 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.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Agreement to be in this study and use my data

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 understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

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COMIRB No: **17-1885**
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Study Title: **Personalized experiences to inform improved communication for minorities with Life Limiting Illness**

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?

This study plans to learn more about storytelling as a communication intervention for patients with life-limiting illness (LLI). Storytelling can pull together the complex experiences of patients with LLI in relation to cultural meanings of illness, which has been shown to improve quality of life and to decrease suffering. The goal of this project is to help improve communication between you and your patient. You are being asked to participate in this study because you are a nurse responsible for caring for a patient who has been diagnosed with a life-limiting illness.

Other people in this study

Up to 18 nurses will participate in the study.

What happens if I join this study?

If you join this study, as part of your patient's care, you will be asked to read their story after it has been added to their electronic health record. You will also be asked to provide feedback on your experience reading your patient's story and whether it provided useful information.

This feedback information will be collected in two ways.

1. An interview will be collected by a member of the research team on how you used the patient story in your care of your patient. This interview will be audio recorded and should take less than two hours of your time.
2. Second, you may also choose to participate in usability testing of the workflow processes that evaluates ease of use, relevance and appeal, efficiency and subjective satisfaction. This data will be collected via debriefing the technical aspects of the use of the story in your daily practice routine by completing a

system usability questionnaire and providing user feedback. This debrief and questionnaire collection will take less than an hour of your time.

Your participation will last approximately one month.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

Risk of breach of confidentiality

1. Although there is a very rare risk that your identity could be known, the researcher will maintain confidentiality by removing all identifiers from the study materials. Only the researcher and the research team members will have access to the identities of the participants.

Risk of discomfort

1. You could feel some uncomfortable emotions due to the sensitive topics of discussion around your patient's illness and your emotional state. If you experience this, you can stop the interview, reschedule for return visit to complete interview, or choose not to participate in the study.

Due to the preliminary nature to the study, the study may include others 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 ways to improve communication between patients and clinicians. There are no known benefits for the participants.

Who is paying for this study?

This research is being sponsored for by National Institutes of Health/National Institute of Nursing Research.

Will I be paid for being in the study?

You will be paid a $50 gift card for the interview session and an additional $50 gift card if you choose to participate in the debrief session and questionnaire feedback. This may add up to $100 for both data collection times. If you leave the study early, or if we have to take you out of the study, you will be paid only for the sessions you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

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 choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

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Agreement to be in this study and use my data

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 understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____