Feasibility of a Dyadic Life Review Intervention for Older Patients with Advanced Cancer and Mild Cognitive Impairment (MCI) and their Caregivers

Patient and Caregiver Informed Consent Forms

NCT05200572

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PATIENT
CONSENT FORM

Feasibility of a Dyadic Life Review Intervention for Older Patients with Advanced Cancer and Mild Cognitive Impairment (MCI) and their Caregivers

Principal Investigator: Lee A. Kehoe, PhD, LMHC
Faculty Advisor: Supriya Mohile, MD

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this study is voluntary – It is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your medical care will not be changed in any way.
- You are being asked to take part in this study because you are 65 years and older and have Stage III or IV of any cancer type.
- The purpose of the study is to adapt and refine a life review intervention from an individual format to one that can be done with both a patient and a caregiver together.
- Life review intervention examines memories throughout your life that the study staff will prompt and explore with you and your caregiver
- Your participation in this study will last for about 14 weeks.
- Procedures will include completing surveys/questionnaires, 8 weekly session where you and your caregiver will review periods of your lives together, follow up surveys/questionnaires, and an interview.
- There are risks from participating in this study:
    - There is a possibility for emotional distress or fatigue.
    - Some questions cover sensitive topics that may make you feel sad.
    - The risk associated with this study also includes loss of privacy and confidentiality.

- You might not benefit from being in this research study. The potential benefit to you might be better insight and awareness into feelings about periods of life, a greater sense of connection to your caregiver, or feeling listened to by the study staff.

Purpose of Study: To test a life review intervention delivered to both patients and caregivers together, and the effects this has on relationships and emotional health.

Description of Study Procedures

After informed consent:
You and your care receiver will receive a "Firstbeat bodyguard 2" device to bring home with you. If you are unable to bring the device home after consent; study staff will mail the device to you with a return address mailer. This device is used to measure Heart Rate Variability (HRV). Heart rate variability measures changes in your heart rate that have occurred and has been shown to have connection to how people deal with psychological experiences such as stress or emotions. We are interested in exploring any connection between HRV and distress or emotions to help improve this intervention in the future. The device has two electrode ends, one end will attach to your upper right chest just below the shoulder bone; the other electrode end will attach to the left side of your rib cage area. A zoom session will be coordinated where study staff will walk you through the steps to wearing the device. Prior to beginning the life review sessions, you will be asked to wear the device for 20 minutes sitting in a quiet space alone with no distractions and breathing normally. You then can bring the device to your next clinic visit or mail back in the return address mailer.

Baseline:
The Baseline visit consist of the completion of the Baseline packet. This can be done in-person on the same day after completing this consent form, via telephone or Zoom at a coordinated time, or if you choose, through a survey link sent to a provided email.

The following procedures will be completed during the **Baseline Visit**:

- We will also ask you to fill out questionnaires on paper about your background, social support, relationships, stress, and emotions.

Intervention:

- You will receive a URMC confidential Zoom link at the coordinated intervention times each week.
- Each session will take approximately 1-1.5 hours.
- Each session, the interventionist will ask questions about certain periods of life from childhood to present.
- You will receive $40 for your time completing the informed consent and questionnaires before starting the intervention. You will then receive an additional $40 for completing the post-intervention questionnaires and interview, for a total of $80.

Post-Intervention:
A Post-Intervention packet will be provided on the last session or if elected, a survey link of the post-intervention questionnaires will be emailed to you. You can also choose to complete the post-intervention packet via telephone with the study team member and we will coordinate a time for this telephone call with your during the last session. You will have up to two weeks after the intervention to complete the post-intervention packet.

The following procedures will be completed during **Post-Intervention**:

- We will also ask you to fill out questionnaires on paper about your background, social support, relationships, stress, and emotions.
- At the last session you will be asked to schedule a post-intervention interview that can be done via URMC zoom conferencing within two weeks after completing the last life review session. This interview will be held separate from your caregiver. The interview will ask about your experiences during the study and intervention. This will be audio recorded. You can choose to have this audio recorded. The recording is optional.
- Study staff will mail the "Firstbeat bodyguard 2" device to you again with a return address mailer. You will have the exact same instructions as when you used this device before the life review sessions started. The device can then be mailed back with the return address mailer.

Note: Information about your study participation and study results may be included in your electronic health record. If you have concerns about this, you should discuss this with the study team.

Number of Subjects: Approximately 40 pairs will be included in the study, 40 patients and 40 caregivers, for a total of 80 people.

Risks of Participation

Dyadic Life Review Interventions: The primary risks are emotional distress or fatigue and potential loss of privacy. Regarding distress and fatigue, you may think about stressors, negative life events, and caregiving burden/distress; you will receive support from the interventionist for such experiences.

Questionnaires and Interviews: Some questions may cause you to feel uncomfortable or upset. You may withdraw from a questionnaire or skip a question at any time for any reason and receive full reimbursement for that questionnaire; and, you may withdraw from the research study at any time without negative consequences.

Potential Loss of Confidentiality: The risk associated with this study also includes loss of privacy and confidentiality because we will collect data from your medical record. Protected health data will be kept in as confidential a manner as possible, but complete confidentiality cannot be assured.

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

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the URMC and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

If you agree to the zoom audio recording, the recordings will be transcribed (written out word for word). Even though first names will be used during the intervention or interview, any other additional information that can identify you will be deleted from the transcriptions of the audio-recordings. All study data will be stored in locked cabinets and electronic files will be stored using HIPAA-compliant storage solutions. Audio recordings will be kept for approximately 5 years then destroyed.

Benefits of Participation

You might not benefit from being in this research study. You may gain insight or awareness into yourself or your caregiver. You may benefit from the study by feeling more connected to your caregiver and feeling understood and listened to.

Costs

There will be no cost to you to participate in the study.

Payments

You will receive $40 for your time completing the informed consent and questionnaires before starting the intervention. You will then receive an additional $40 for completing the post-intervention questionnaires and interview, for a total of $80.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all information you provide to us in locked filing cabinets in a locked office; electronic data will be kept in a password-protected and secure database. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the URMC and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

- The study doctor will get your personal and medical information. For example:
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institute of Aging
- The Nation Cancer Institute

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time.

- You do this by sending written notice to the study doctor.
- Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study.

- Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Use of E-mail and Text Messaging in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record. Messages will be limited to appointment reminders.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

You are responsible for any fees charged by your carrier's service plan for text messaging. You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text". Your consent, and any request to stop email or text messaging, applies to this research study only.

Future Use of Health Information

Your health information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your health information are used or distributed. You will be given the option at the end of this consent form to decide if you would like your health information used for future research.

Reports about the results of the research done with your provided information will not be given to you or your doctor. These reports will not be put in your health record and will not have an effect on your care. The benefits of future research using your information include learning more about possibly adapting psychosocial interventions for older adults with cancer and their caregivers. No matter what you decide to do, it will not affect your care. If you decide now that your information can be kept for future research, you can change your mind at any time. There are not direct benefits to you.

Circumstances for Dismissal

You may be withdrawn from the study if you do not keep appointments for study visits or cannot complete study activities.

Commercial Profit
We will use your information for research only.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Contact Persons
For more information concerning this research study you may contact the Principal Investigator, Dr. Lee A. Kehoe at (585) 585-275-4625.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concern about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation
Participation in this study is voluntary and there is no penalty for nonparticipation. You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time.

Optional Storage and Future Use of Health Information; Audio Recording, and Contact Preference
This was discussed earlier in this document. Please circle your answer for each statement below.

STORAGE AND FUTURE USE OF HEALTH INFORMATION

May we use your stored health information for research related to developing psychosocial, mental health, and social support interventions for patients with cancer and caregivers?

Yes **No**

CONSENT TO FUTURE USE OF STORED HEALTH INFORMATION

May we share your health information with other researchers to study cancer and other research projects?

Yes **No**

CONSENT TO AUDIO RECORDING OF EXIT INTERVIEW

May we audio record the 8 weekly intervention sessions and your exit interview to learn about your experience with the intervention?

Yes No

CONSENT TO USE EMAIL/TEXT

May your study doctor, or someone from the study team, contact you using email for this study?

Yes No

May your study doctor, or someone from the study team, contact you using text messaging for this study?

Yes No

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent:

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date

UNIVERSITY of ROCHESTER MEDICAL CENTER

CAREGIVER
CONSENT FORM

Feasibility of a Dyadic Life Review Intervention for Older Patients with Advanced Cancer and Mild Cognitive Impairment (MCI) and their Caregivers

Principal Investigator: Lee A. Kehoe, PhD, LMHC
Faculty Advisor: Supriya Mohile, MD

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this study is voluntary – It is your choice.
- If you join this study, you can change your mind and stop at any time.
- You are being asked to take part in this study because you are 50 years of age or older and were identified as a caregiver to a patient with cancer
- The purpose of the study is to adapt and refine a life review intervention from an individual format to one that can be done with both a patient and a caregiver together.
- Life review intervention examines memories throughout your life that the study staff will prompt and explore with you and your care receiver
- Your participation in this study will last for about 14 weeks.
- Procedures will include completing surveys/questionnaires, 8 weekly session where you and your care receiver will review periods of your lives together, follow up surveys/questionnaires, and an interview.
- There are risks from participating in this study:
    - The risk associated with this study includes loss of privacy and confidentiality.
    - There is a possibility for emotional distress or fatigue.
    - Some questions cover sensitive topics that may make you feel sad

- You might not benefit from being in this research study. The potential benefit to you might be better insight and awareness into feelings about periods of life, a greater sense of connection to your care receiver, or feeling listened to by the study staff.

Purpose of Study: To test a life review intervention delivered to both patients and caregivers together, and the effects this has on relationships and emotional health.

Description of Study Procedures

After consent:
You and your care receiver will receive a "Firstbeat bodyguard 2" device to bring home with you. If you are unable to bring the device home after consent; study staff will mail the device to you with a return address mailer. This device is used to measure Heart Rate Variability (HRV). Heart rate variability measures changes in your heart rate that have occurred and has been shown to have connection to how people deal with psychological experiences such as stress or emotions. We are interested in exploring any connection between HRV and distress or emotions to help improve this intervention in the future. The device has two electrode ends, one end will attach to your upper right chest just below the shoulder bone; the other electrode end will attach to the left side of your rib cage area. A zoom session will be coordinated where study staff will walk you through the steps to wearing the device. Prior to beginning the life review sessions, you will be asked to wear the device for 20 minutes sitting in a quiet space alone with no distractions and breathing normally. You then can bring the device to your next clinic visit or mail back in the return address mailer.

Baseline:
The Baseline visit consist of the completion of the Baseline packet. This can be done in-person on the same day as the Screening visit, via telephone or Zoom at a coordinated time, or if you choose, through a survey link sent to a provided email.

The following procedures will be completed during the **Baseline Visit**:
- We will also ask you to fill out questionnaires on paper about your background, social support, relationships, stress, and emotions.

Intervention:
- You will receive a URMC confidential Zoom link at the coordinated intervention times each week.
- Each session will take approximately 1-1.5 hours.
- Each session, the interventionist will ask questions about certain periods of life from childhood to present.
- You will receive $40 for your time completing the informed consent and questionnaires before starting the intervention. You will then receive an additional $40 for completing the post-intervention questionnaires and interview, for a total of $80.

Post-Intervention:

A Post-Intervention packet will be provided on the last session or if elected, a survey link of the post-intervention questionnaires will be emailed to you. You can also choose to complete the post-intervention packet via telephone with the study team member and we will coordinate a time for this telephone call with your during the last session. You will have up to two weeks after the intervention to complete the post-intervention packet.

The following procedures will be completed during **Post-Intervention**:

- We will also ask you to fill out questionnaires on paper about your background, social support, relationships, stress, and emotions.
- At the last session you will be asked to schedule a post-intervention interview that can be done via URMC zoom conferencing within two weeks after completing the last session. This interview will be held separate from your caregiver. The interview will ask about your experiences during the study and intervention. This will be audio recorded. You can choose to have this audio recorded. The recording is optional.
- Study staff will mail the "Firstbeat bodyguard 2" device to you again with a return address mailer. You will have the exact same instructions as when you used this device before the life review sessions started. The device can then be mailed back with the return address mailer.

Number of Subjects: Approximately 40 pairs will be included in the study, 40 patients and 40 caregivers, for a total of 80 people.

Risks of Participation

Dyadic Life Review Interventions: The primary risks are emotional distress or fatigue and potential loss of privacy. Regarding distress and fatigue, you may think about stressors, negative life events, and caregiving burden/distress; you will receive support from the interventionist for such experiences.

Questionnaires and Interviews: Some questions may cause you to feel uncomfortable or upset. You may withdraw from a questionnaire or skip a question at any time for any reason and receive full reimbursement for that questionnaire; and, you may withdraw from the research study at any time without negative consequences.

Potential Loss of Confidentiality: The risk associated with this study also includes loss of privacy and confidentiality. Protected health data will be kept in as confidential a manner as possible, but complete confidentiality cannot be assured.

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

If you agree to the zoom audio recording, the recordings will be transcribed (written out word for word). Even though first names will be used during the intervention or interview, any other

additional information that can identify you will be deleted from the transcriptions of the audio-recordings. All study data will be stored in locked cabinets and electronic files will be stored using HIPAA-compliant storage solutions. Audio recordings will be kept for approximately 5 years then destroyed.

Benefits of Participation

You might not benefit from being in this research study. You may gain insight or awareness into yourself or your caregiver. You may benefit from the study by feeling more connected to your caregiver and feeling understood and listened to.

Costs

There will be no cost to you to participate in the study.

Payments

You will receive $40 for your time completing the informed consent and questionnaires before starting the intervention. You will then receive an additional $40 for completing the post-intervention questionnaires and interview, for a total of $80.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all information you provide to us in locked filing cabinets in a locked office; electronic data will be kept in a password-protected and secure database. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the URMC and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institute of Aging
- The National Institute of Cancer

Why will this information be used and/or given to others?
- To do the research
- To study the results
- To see if the research was done correctly
- If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my data?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your data at any time.
- You do this by sending written notice to the study doctor.
- Upon receiving the written notice, the study team will no longer use or disclose your health
- information and you will not be able to stay in this study.
- Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new data identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my data protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Use of E-mail for Communication in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record. Messages will be limited to appointment reminders.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand

this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

You are responsible for any fees charged by your carrier's service plan for text messaging. You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text". Your consent, and any request to stop email or text messaging, applies to this research study only.

Future Use of Data

Your data might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your data are used or distributed. You will be given the option at the end of this consent form to decide if you would like your data used for future research.

Reports about the results of the research done with your data will not be given to you or your doctor. These reports will not be put in your health record and will not have an effect on your care. The benefits of future research using your data include learning more about possibly adapting psychosocial interventions for older adults with cancer and their caregivers. No matter what you decide to do, it will not affect your care. If you decide now that your data can be kept for future research, you can change your mind at any time. There are not direct benefits to you.

Circumstances for Dismissal

You may be withdrawn from the study if you do not keep appointments for study visits or cannot complete study activities.

Commercial Profit

We will use your information for research only.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Contact Persons

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Voluntary Participation

Participation in this study is voluntary and there is no penalty for nonparticipation. You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time.

Optional Storage and Future Use of Health Information; Audio Recording, and Contact Preference

This was discussed earlier in this document. Please circle your answer for each statement below.

STORAGE AND FUTURE USE OF DATA

May we use your stored data for research related to developing psychosocial, mental health, and social support interventions for patients with cancer and caregivers?

Yes **No**

CONSENT TO FUTURE USE OF DATA

May we share your data with other researchers to study cancer and other research projects?

Yes **No**

CONSENT TO AUDIO RECORDING OF EXIT INTERVIEW

May we audio record the 8 weekly intervention sessions and your exit interview to learn about your experience with the intervention?

Yes **No**

CONSENT TO USE EMAIL/TEXT

May your study doctor, or someone from the study team, contact you using email for this study?

Yes **No**

May your study doctor, or someone from the study team, contact you using text messaging for this study?

Yes **No**

SIGNATURE/DATES

- After reading and discussing the information in this consent form you should understand:
- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent:

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date