UNIVERSITY of ROCHESTER MEDICAL CENTER

EASTMAN DENTAL CENTER
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
STRONG MEMORIAL HOSPITAL
UNIVERSITY MEDICAL FACULTY GROUP

DEPARTMENT OF PSYCHIATRY

CONSENT FORM

Helping Older People Engage (HOPE)

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Sub-Investigators: April Buttaccio, MPH, Laurel Prothero, BS

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.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- 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 eligibility for and access to care through the Strong health system will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you reported being at least 60 years of age. You also indicated feeling like you lack companionship, feel left out, or feel isolated from others during the phone screening.

This study is being conducted by Dr. Kim Van Orden and the University of Rochester Medical Center.

Purpose of Study

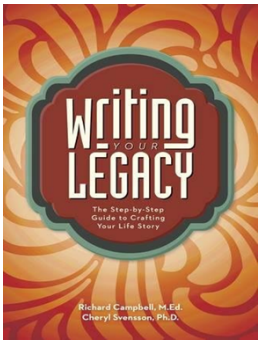
The purpose of this study is to understand the benefits of two activities—reflecting on one's past (called "life review") and volunteering in the community ("volunteering"). We are interested in learning how these activities may promote healthy aging. Specifically, we are interested in two aspects of healthy aging: social connectedness and well-being. Prior studies have shown us that volunteering is beneficial for physical and cognitive functioning (how well our bodies and minds work in our day to day lives). Prior studies have also shown us that life review is beneficial for mood and emotional health. This study asks the question: does looking back (life review) or giving back (volunteering) have the most benefits for *social connectedness and well-being*?

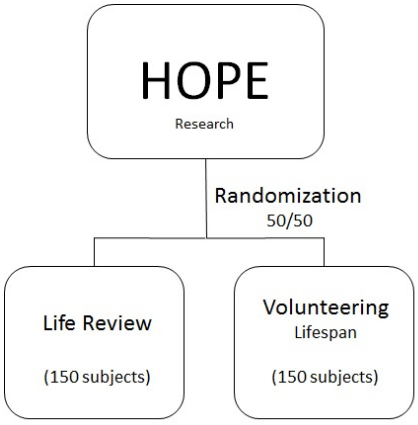
In this study, volunteering involves participating in a one-year volunteer program. Volunteers will participate in a flexible program with Lifespan that involves a menu of options including helping at senior centers, mentoring/tutoring, co-leading classes on skills such as fall prevention and many other options. Life review involves participating in a one-year reminiscence program that is self-guided (but with email and phone guidance and support). Completing life review involves flexible monthly reading and writing exercises that allow you to reflect on themes in your life. The exercises are designed to be enjoyable and do not require creative writing experience.

Description of Study Procedures

1. If you decide to participate in the study, you will be **interviewed** here in this office. The interview will take approximately two and a half hours. There are multiple-choice and open-ended questions about your physical health, emotional health and sense of well-being. The interview will help us determine if you are eligible for the remainder of the study.
    - Some of the questions in the interview ask about depression, anxiety, and suicidal thoughts. You do not need to feel depressed, anxious, or suicidal to be in the study.
    - You will be asked to complete tasks like remembering numbers and words.

2. After the interview, research staff will determine if you are eligible to continue in the study. A computer program will then **randomly** assign you to participate in the life review program or the volunteering program. Both programs last one year. The manner by which that assignment is made will be random, like the flip of a coin. The chances of being assigned to life review or volunteering are the same, fifty-fifty (50/50.) If research staff cannot provide your assignment at the first interview, you will be contacted within about a week to let you know if you are eligible and to which group you have been assigned.





Lifespan
take it on!

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- If you are randomly assigned to the **life review program**, you will:
    - Receive a life review program book (*Writing Your Legacy)* and instruction manual.
    - Be given an orientation to the program over the phone with our life review coach within about two weeks of when you are assigned to the program.
    - Read sections of the program book each month.
    - Participate in reflection writing exercises of about 2 pages in length twice a month, each addressing a different theme in your life (e.g., family, work, travel, etc.)
    - Email your writing to the life review coach each month to receive feedback and support. If you do not have internet access, there is an option of mailing your writing exercises to the coach.
    - Receive written feedback about your writing each month from the coach. The feedback will help you get the most out of life review. It is **not** a critique of your writing style.
    - The themes for the writing exercises are only suggestions. You do not have to write about anything that makes you feel uncomfortable.
    - The exercises were designed to promote reflection and new perspective, not dwelling on the past or feeling bitter.
    - After your final study visit (12 months), the life review coach will call you to review the life review program with you and answer any questions you may have.

- If you are randomly assigned to be a subject in the **volunteering program**, you will:
    - Volunteer with Lifespan for one year through RSVP (Retired & Senior Volunteer Program). We will give the RSVP volunteer coordinator your name and contact information. The RSVP volunteer coordinator will contact you within a week to introduce herself.
    - Complete a volunteer application and be approved by Lifespan prior to volunteering.
    - Consent to have Lifespan conduct a background check. Per Lifespan policy, volunteers must pass a background check prior to starting the program. Lifespan will notify the study team if you do not pass the background check. Lifespan will not disclose the reason(s) why, only that you did not pass the background check. If you do not pass, you will not be able to participate in the study. Lifespan will also review your driving record if you choose a volunteer assignment as a driver.
    - Meet with the RSVP volunteer coordinator within approximately two weeks of when you are assigned to the program to choose a volunteering activity.
    - Participate in weekly volunteer activities with Lifespan (the schedule is very flexible). Options are diverse. The volunteer coordinator's goal is to understand what you enjoy and what you are passionate about in matching you with a volunteer activity that has a *social component.* Examples range from one on one activities to co-leading group activities. The coordinator will help you figure out how you want to give back to your

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community. There are numerous volunteering options and you will work with Lifespan staff to decide what activities you are most interested in and feel comfortable with. All of the volunteer activities are social – either in groups or one-on-one (e.g., *not* solitary activities like computer work). Activities may take place at Lifespan and locations in the community. You are not expected to volunteer in a setting that makes you uncomfortable. However, for some of us, the social aspect of volunteering may be somewhat challenging at first and push us slightly out of our comfort zones. For many of us, achieving manageable challenges can be rewarding. You are in control of the experience and you are not expected to do anything you are uncomfortable with.
    - Receive on-going training and support by the RSVP Volunteer Coordinator at Lifespan.
    - Receive a small partial reimbursement for travel related to volunteering.
    - Have the opportunity to participate in volunteer support groups and educational opportunities each month through Lifespan.
    - Complete monthly timesheets about the number of hours spent volunteering and the activities you participated in.

- We ask that all subjects do not start any other new long-term volunteer activities during the 12 months of study participation (one-time only activities are allowed). You can continue current volunteer activities.

- All subjects will receive the scheduled follow-up interviews by the research team. These interviews will be conducted at these time points: 3 months after beginning the program (surveys done online or by mail/in-person if preferred), 6 months after beginning the program (in-person), 9 months after beginning the program (surveys done online or by mail/in-person if preferred), and 12 months after beginning the program (in-person).

Number of Subjects

Approximately 300 subjects will take part in this study. 150 will participate in the life review program and 150 will participate in the volunteering program.

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Duration of the Study

Your participation in the study will last up to 12 months. The table below outlines the duration of the study and study procedures.

Study Procedures	Baseline Visit	3 Month Surveys (Online or mail/in-person)	6 Month Visit (In-person)	9 Month Surveys (Online or mail/in-person)	Final 12 Month Visit (in-person)
Consent	✓				
In person Interview	✓		✓		✓
Surveys completed online or by mail		✓		✓	
Volunteering or Life Review Assignments	Throughout the 12 months of study participation				

Risks of Participation

There are a few risks of participating in the interviews.

1. The questions in the interview could cause emotional stress due to the personal nature of the material. For example, you will be asked about your emotional health and that may bring up difficult memories or feelings. All the questionnaires and tasks have been used in previous research with older adults and no lasting negative effects are expected from the evaluations. You are free to not answer any question(s) for any reason at any time.

2. The questions in the interview could cause fatigue due to the length of the interview. You are free to stop the interview and resume later if you become fatigued.

3. Some of the interview questions ask about depression and suicide. If we become concerned about your safety (or the safety of others) and/or your responses indicate a high level of depression, we will notify Dr. Van Orden or Dr. Conwell (or their associate) for recommendations. One action they may take is to notify your primary care provider. In addition, the researchers are required to report information regarding potential child abuse or neglect reported by you.

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There are a few risks of participating in the life review program:

1. You may feel emotionally stressed due to the personal nature of the topics considered and shared during the program. You are free to skip any exercises or topics you do not feel comfortable with. You will only share material with the coach that you feel comfortable sharing.

2. You may feel fatigued after completing the reading and writing exercises. You are welcome to complete the exercises across multiple sittings.

There are a few risks of participating in the volunteering program:

1. You may feel nervous about participating in a new program and meeting new people. (We hope this is beneficial over the long run, though it can be uncomfortable at first).

2. You may feel fatigue after volunteering. You are free to end activities early if needed or re-schedule if you are not feeling well or are tired.

Remember: for both programs, you are not expected to do anything you are not comfortable with. You are free to stop either program at any point.

As a means of reducing the risk of emotional stress in this study, we may communicate with your primary care doctor via medical record to ensure the study is a good fit for you. We will not document this in your medical record.

Transmitting your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you from being in this study might be increased well-being.

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Sponsor Support

The University of Rochester is receiving funding from The National Institute on Aging for conducting this research study.

Costs

There will be no cost to you to participate in this study. The programs and all program materials will be provided to you free of charge.

Payments

You will be paid $50 for the initial in-person interview. If you are eligible for the remainder of the study, you will be paid $10 for each of the two survey follow-ups at 3 and 9 months after you begin participating in the study. You will receive $35 for the 6 and 12-month in-person interviews. Thus, you could receive up to $140 total. This payment is by check, which can take 4-6 weeks. You will not be paid for your participation in either program.

Conditions for the Use of E-mail

The researcher cannot guarantee but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and researcher must consent to the following conditions:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

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 have trained all of our study interviewers in confidentiality procedures. We will enter and store the information you share with us using coded identification labels. Your named file is stored in a locked filing cabinet in a locked office, kept separate from your coded file. We will maintain project computers in secure locations with restricted access by enforced password protection. Sometimes, however,

researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask study staff 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
- Timesheet data from Lifespan
- If you failed the background check performed through Lifespan
- Past or present medical records or e-records to make sure the study is a good fit for you

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 Health
- Lifespan

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 right

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 be permission be valid?

This permission will last indefinitely.

May I cancel my permission to use and disclose information?

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?

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?

There is a risk that your information will be given to others without your permission.

A description of this clinical trial will be available on http://www.ClinicalTrials.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 website at any time.

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 research information 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. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Contact Persons

For questions related to your participation, contact the research coordinators at 585-273-1811. For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Kim Van Orden at 585-275-5176.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642-8315, 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 concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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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.

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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

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