UPMC
Western Psychiatric Institute and Clinic

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY
TITLE: Widowed Elders Lifestyle after Loss (WELL) Research Study

PRINCIPAL INVESTIGATOR:
Sarah T. Stahl, PhD
Assistant Professor of Psychiatry and Clinical & Translational Science
(412) 246-6003

CO-INVESTIGATORS:

Marie Anne Gebara, MD
Assistant Professor of Psychiatry
412-246-6024

Stephen Smagula, PhD
Assistant Professor of Psychiatry
(412) 246-6674

Bruce L. Rollman, MD, MPH
Director, Center for Behavioral Health
and Smart Technology, Professor
412-692-2659

Emilee Croswell, BA
Research Operations Coordinator
patelks3@upmc.edu

Thandi Lyew, BA
Research Coordinator
lyewt@upmc.edu

Ioana Neagoe, MS
Sr. Clinician
ian2@pitt.edu

Khusbu Patel, BS
Research Principal
patelks3@upmc.edu

Sejuty Minhaj. BS
Research Tech Clinical
minhajs2@upmc.edu

Alexandra Khani
Research Project Assistant
khanial@upmc.edu

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OVERVIEW: KEY INFORMATION

Your participation in this study is voluntary. Research studies only include people who choose to participate. Our staff will explain this study to you and will answer any questions you may have. *Please take your time to make your decision about participation.*

Study Purpose: The present study aims to examine the efficacy of a prevention intervention among older spousally-bereaved adults who are at risk for developing depression following the death of their spouse or life-partner. We hope to learn about health behaviors following the loss of individuals' spouse or life partner.

Study Duration: 5 visits over the course of 15 months: baseline (T1), month 1 (T1a), month 2 (T1b), post-intervention (or 3 months from baseline, T2), and then follow-up assessments at 3, 6, and 12 months post-intervention (T3, T4, T5).

Study Procedures:
You will be randomized to one of two groups. Both groups will wear actigraphy watches to monitor your rhythm of sleep and daytime activity. Both groups will receive written information about healthy lifestyle practices. The WELL intervention group will use a daily diary website to record daily sleep, meals, and activity. The WELL intervention group will also receive weekly phone calls from health coaches and will receive digital feedback via a lifestyle log website. Both groups will complete self-reported questionnaires throughout the 15-month study, as well as be assessed through diagnostic/clinical interviews. For this study, you may participate virtually, through videoconferencing calls or via phone. Some assessments may be completed by mail, if needed. Calls may be recorded to ensure fidelity to motivational health coaching.

Potential Risks or Discomforts:

- **Psychological discomfort** during the screening process and study procedures is possible. The screening questionnaire as well as baseline and follow up visits will cover sensitive topics including your spouse's cause of death and your physical illness, psychiatric history, and medical history. These topics may cause significant distress.
- **Breach of confidentiality (privacy)** is possible but not common. A breach of confidentiality would mean that information regarding subjects' mental- and physical health will be discovered by individuals outside of the study personnel, despite careful steps to protect confidentiality.
- **Physical discomfort associated with participation in physical activity.** As part of the intervention, participants are encouraged in engage in lifestyle practices including physical activities, such as walking, that have a small likelihood of physical risk.

Potential Benefits: There are no guarantees that you will receive any benefit from participating in this research study. You may benefit from the screening procedures that include a careful examination of your physical and mental health. The results of this study may help other older individuals cope with the loss of their spouse or partner. You may benefit from the satisfaction that derives from helping us understand older adults' health behaviors after losing a loved one.

Compensation: You will receive a total of $250 after completing all aspects of the study. You will receive $75 after completing the baseline assessment, actigraphy assessments, and the intervention. You will receive $40, $60, and $75 after completing the 3, 6, and 12-month post-intervention follow-up visits, respectively. All participants in our study will receive the same amount of compensation ($250) regardless of what condition or study group they are placed in, including those receiving the usual care condition (EUC), technology intervention (WELL), and those bereaved by COVID-19.

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Please take time to review this information carefully.

After you have finished, please talk to the researchers about the study concerning any questions you may have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

PURPOSE OF THIS STUDY

Why is this research being done?

The University of Pittsburgh is conducting a research study to learn about your health behaviors following the loss of your spouse or life partner. You may use a daily diary website to record your sleep, meals, and physical activity, share your information with a health coach, and learn new ways of reaching your health goals. You will also wear an actigraphy watch, which monitors your rhythm of sleep and daytime activity. This research study will help us understand how monitoring health behaviors may promote your health and wellbeing while coping with the loss of a spouse/life partner. Your participation in this study will last up to 15 months or until you notify the study team that you no longer wish to participate.

INFORMATION ABOUT STUDY PARTICIPANTS (PARTICIPANTS)

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time, even after signing this form. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your relationship with UPMC, the University of Pittsburgh, or Family Hospice and Palliative Care. Your information is kept completely confidential.

Who can take part in this study?

You may be eligible to participate in this study if:

- You are 60 years old or older
- You are fluent in English and with the capacity to understand the nature of the study and sign the written informed consent.
- You experienced the death of your spouse or partner within the last 12 months
- You experienced the death of your spouse or partner within the last 12 months due to COVID-19
- You are not taking new medication for depression or anxiety

How many people (participants) are expected to take part in this study?

250 participants who are recently bereaved.

INFORMATION ABOUT STUDY PARTICIPATION (PROCEDURES)

You were first interviewed by phone to see if you might qualify for the study. Once you have agreed to participate further, you will be asked to schedule a virtual or telephone visit for a baseline assessment. You will be assessed seven times throughout the entire study: baseline (T1), month 1 (T1a), month 2 (T1b), post-intervention (3 months from baseline, T2), and then at 3 (T3), 6 (T4), and 12 months post-intervention (T5).The baseline assessment will include reviewing this consent document, a clinical mood assessment, and several questionnaires. You will then be randomly assigned to participate in either the behavioral self-monitoring or enhanced care groups for 12 weeks. At the end of the 12 weeks, you will have a post intervention visit, as well as follow-up visits at 3, 6, and 12 months after the intervention period.

What will happen to me in this study? How much of my time will be needed to participate?

Baseline Procedures (T1):
Once you have completed a phone screening to see if you might qualify for the study, you will be invited to a baseline virtual or phone visit to confirm eligibility, where you will:

- be asked to sign this consent form after we review it with you,
- complete a clinical mood assessment (1 ½ hours),
- fill out self-report questionnaires about your medical and psychiatric history, cognitive function, mood, and health behaviors
- receive health tracking equipment for the study and technology use instructions

The baseline visit will take ~ 4 ***½*** hours and will involve a clinical interview (~1 ½ hours) and the completion of several questionnaires (~2 ½- 3 hours).

We will then mail you a packet that contains (1) a copy of this consent document, (2) an actigraph watch, (3) an actigraph diary, (4) pamphlets about healthy lifestyle choices, (5) a study calendar, (6) a payment card, and (7) and a small study gift. You will then begin to wear the actigraph watch for 1 week prior to entering the intervention period. Actigraphy watches measure your rhythm of sleep and daytime activity.

Intervention Period (0 – 12 weeks):
After the baseline assessment, you will participate in a 12-week intervention, where you will:

- Complete 4 written diaries about the actigraph watch (~5 minutes/day)
- Receive weekly phone calls from the study team (~5-30 minutes/week)
- Depending on group assignment, record 2 diaries/day (“Daily Diary” via a survey link, ~30 minutes/day) and view feedback about your daily rhythm) on a study website (“My Lifestyle Log”

Post Intervention Follow Up Visit: at ~ Week 12 (T2):
After the intervention period, you will schedule a virtual visit or phone call to complete the post intervention assessments. This visit will take ~2 hours and will involve completing:

- a clinical mood assessment
- self-report questionnaires about your health and wellbeing

Follow Up Visits: at 3, 6 & 12 months after the intervention (T3, T4, T5):
Each of these follow-up visits will take ~1 hours and will involve completing:

- a clinical mood assessment
- self-report questionnaires about your health and wellbeing

What procedures will be performed for research purposes?

Screening Procedures:

Baseline Visit (*~4 ½ hours*) – You will complete a clinical mood assessment with a trained clinician. During this evaluation, the clinician will ask you to provide information regarding any past or present psychiatric symptoms and any past or present medical or mental health conditions. You will be asked for contact information for yourself and your primary care provider(s). We will also administer questionnaires that will be used to assess demographic information, cognitive function, grief symptoms, circumstances of partners' death, severity of physical illnesses, sleep patterns, eating habits, physical activity, and social support. You will receive written education about healthy lifestyle choices including pamphlets from the *National Sleep Foundation*, the *US Department of Agriculture's Choose My Plate*, the *NIA's Age Page on Aging and Alcohol Abuse*, and the *NIH's Getting Fit for Life*. You will also be asked to choose a personal health goal on which to focus during the study; examples include: (a) engage in 150 minutes of moderate-intensity activity/week; (b) don't skip breakfast; and (c) get 7-8 hours of sleep per night.

You will be randomly assigned (like flipping a coin) to one of two conditions:

- 12-week WELL intervention group; or
- 12-week enhanced usual care group.

If you are assigned to the WELL intervention group, you will be trained to use the daily diary website and Lifestyle Log prior to starting the intervention. We will show you how to track your sleep, meals, and physical activity on the daily diary website. We will spend time with you to make sure you are comfortable using the daily diary to track your sleep, meals, and physical activity. You will also be provided with a written user manual for the daily diary website and actigraphy watch. You will receive digital feedback on your health goals and progress with our Lifestyle Log website. We will go over both websites with you and answer any questions you may have.

For this study, we will include a group of 100 participants who were bereaved by COVID-19 (or suspected COVID-19). These participants will undergo the same research procedures as the main study group. All participants complete 10 additional questionnaires (~20-30 minutes) during the baseline assessment that relate to the pandemic. These COVID-related questionnaires ask about constructs important to understanding the secondary health effects of COVID-19 including social isolation and support. This group of participants will be assigned to WELL or EUC groups and proceed through the study in the same way as the main study group.

At the end of the virtual/phone baseline visit, you will be asked to schedule your 3-month post-intervention visit (T2).

Intervention Procedures:

Actigraph watch & diary (*1-5 minutes/day*) – All participants will wear an Actigraph watch (like a Fitbit), on their non-dominant wrist for 1 week *prior to starting the intervention period*. You will wear the watch for the duration of the week, including during the night, but not while showering or swimming. The watch should not be immersed in water. Using a written watch diary, you will record when you take your watch off and on throughout the day. We will introduce you to the features of the Actiwatch during the virtual/phone baseline visit. After each completed week, you will mail the watch and the completed diary back to us in a pre-paid envelope provided to you by the study team. Contactless drop off will also be available by request.

Intervention Period (*12 weeks*) – You will participate in one of two groups:

- *WELL intervention:* Those who are assigned to the WELL intervention group will be asked to record their sleep, meals, and physical activity on a daily diary website. The daily diary website will be used twice daily for 12 weeks. This may take 5 to 20 minutes to complete each morning and each evening. We will ask you if you have a device like a desktop computer, laptop, or tablet to complete the daily diaries and view the Lifestyle Log. If necessary, we may provide a tablet during the intervention period, only for study use. On rare occasions, we may allow contactless pick up/drop off of study devices at our office in Bellefield Towers in Oakland. A staff member will provide you with instructions on receiving and returning devices. You may opt to receive an automated text or email reminder when it's time to complete a daily diary. This text or email will contain the daily diary link and Lifestyle Log link and passcode.

  You will also receive weekly phone calls from a trained health coach to discuss your daily routine of sleep, meals, physical activity, and personal health goals. Weekly video or phone calls will take anywhere from 15 to 60 minutes. These calls may be recorded to ensure that participants receive the intervention in a similar way. We will mail you 3 more actigraph watches to wear during this time. You will wear each watch for 1 week at a time, at weeks 4, 8, and 12 of the intervention. Using a written actigraph diary, you will record when you take your watch off and put it back on throughout the day. We will remind you when to begin wearing the watch and when to return it to us. You will return the watch to us in a pre-paid envelope. Please refer to the study manual (that we will mail you) for questions about using the websites and/or actigraph watch. You may also contact the study team for any questions or concerns about using the daily diary website, Lifestyle Log, actigraph watch, and/or your participation in the study.

- *Enhanced Usual Care:* Those who are assigned to the enhanced usual care group will receive written information about grief and healthy lifestyle practices. You will also receive weekly phone calls from a member of the study team. The calls will take anywhere from 5 to 10 minutes each week. We will mail you 3 more actigraph watches to wear during this time. You will wear each watch for 1 week at a time, at weeks 4, 8, and 12 of the intervention. Using a written actigraph diary, you will record when you take your watch off and on throughout the day. We will remind you when to wear the watch and when to return it to us and provide a study timeline calendar. You will return the watches to us in a provided pre-paid envelope. Please refer to the manual (that we will mail you) for questions about using the watch. You may also contact the study team for any questions or concerns about your watch or your participation in the study.

Follow-Up Procedures:

Post Intervention Visit (T2) *(3 hours)* – After the 12-week intervention, you will schedule a virtual visit or phone call to assess grief symptoms, sleep patterns, meal choices, physical activity, and other lifestyle habits. A trained clinician will conduct a clinical mood assessment with you. After this visit, you will be asked to return the study equipment to the study team by prepaid mail envelope provided to you by the study team or contactless drop off.

Follow-Up Visits (at ~3, 6, and 12 months after the post-intervention visit*; 1 - 2 hours)* – You will be asked to complete virtual visits or phone calls, where we will conduct a clinical mood assessment at each visit. You will also complete questionnaires about mood, grief symptoms, sleep patterns, meal choice, and activities at 3, 6, and 12, months after the post-intervention follow up. The questionnaires will be used to assess wellbeing in the study. Follow up virtual visits or phone calls will take

approximately 1 to 2 hours. All study equipment should be returned to the study team via mail or contactless drop off by the end of the study.

Throughout the course of the study your care will always be supervised by a study psychologist or psychiatrist, in addition to the investigators and Medical Director of the Clinic. The Late-life Depression Clinic has a *24-hour answering service* with the study investigators and staff on-call. The phone number for the answering service is (412) 246-6006. If you are unable to research through the answering service, you may also contact the Emergency Room of Western Psychiatric Institute and Clinic at (412) 624-2100.

If you have participated in the RISE study, some of your identifiable data from RISE will be collected for this study, so that measures do not need to be repeated.

When will I complete my participation in the study?
The intervention period of the study is 3 months. The follow-up visits occur at 3, 6, 9, and 12 months after the intervention period. The total study time will be 15 months. You may opt to receive a summary of your assessment scores.

WELL QUALITATIVE (WELL-Q)

If eligible for WELL, you may also be invited to participate in a separate one-time interview that focuses on how bereaved adults live life without their loved one: the WELL-Q study.

Up to 20 participants may be invited to participate in this interview about their experiences and participation with the WELL study. These interviews will be conducted approximately 6 months after the intervention (T4 timepoint). You may be eligible to participate in an interview if you are placed in the study's intervention group.

If you are interested and selected, you will speak to the study team about your participation in WELL and your daily activities. Interested participants will be asked to provide verbal consent. If you choose to participate in WELL-Q, you will not have to undergo additional screening or baseline procedures. Participating in WELL-Q will have no effect on your participation in the main research study.

This interview will be recorded for the purposes of data analysis and quality control. All interviews are completely private and confidential. Only the study team will have access to these recordings.
You will be compensated $35 for this one-time interview via Vincent payment card.

INFORMATION ABOUT RISKS AND BENEFITS

What are the possible risks, side effects, and discomforts of this research study? What will the researchers do to protect me against these risks?

There is minimal risk involved in this study. No medications are included. You may become bored or tired while completing study activities. We will attempt to pace all study activities to fit your level of interest and energy.

The potential risks associated with participation in this study:

Psychological Discomfort during the Screening Process and Study Procedures: It is possible that you may experience elevated distress when thinking about the loss of their spouse. It is also possible

that you may also experience mild to moderate discomfort when answering screening questions, and in completing interview and self-monitoring assessments.

Physical Discomfort associated with Physical Activity: It is possible that you may experience mild to moderate physical discomfort associated with physical activity behaviors. As part of the intervention, participants are encouraged to engage in physical activities, such as walking, that have a small likelihood of physical risk.

Worsening Symptoms: The goal of this research is to determine if lifestyle interventions prevent or delay the onset of common mental disorders that accompany bereavement like depression, anxiety, and complicated grief. However, you may experience worsening symptoms of depression, anxiety, grief, and suicidality.

Breach of Confidentiality: It is possible that information regarding your mental and physical health will be discovered by individuals outside of study personnel, despite careful steps to protect confidentiality. Maintaining strict security on information provided by participants will minimize risks to confidentiality. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. Maintaining strict security on information provided by participants will minimize risks to confidentiality. With your permission, the study team may also send reminders and answer general questions about the study through text message. Text messages are not encrypted or secure during their transmission and could be intercepted by unauthorized third parties.

The researchers will try to minimize these risks by:

Psychological Discomfort during the Screening Process and Study Procedures: You can end participation at any time if participating in this study leads to significant distress. You may also refuse to answer any questions that make you uncomfortable. Interviews will be carried out by study staff and supervised by Drs. Stahl and Gebara. If study questionnaires or study protocol elicit distress, you will be instructed to contact the PI, who will assist with questions and concerns.

Physical Discomfort associated with Physical Activity: You will not be asked to perform any behaviors that could result in physical harm. You are also discouraged from participating in any physical activity that makes you feel uncomfortable or that could result in physical harm.

Worsening Symptoms: At any point during the study, participation can be stopped if depression severity increases or if suicidality is observed or reported. If you show evidence of major depression, anxiety, complicated grief, or increased suicide risk, you will be referred out of the study for appropriate clinical care by your PCP with mental health specialist back-up as needed from Dr. Marie Anne Gebara. The clinical status of all participants will be reviewed weekly by the members of the study team and Drs. Stahl and Gebara. Given that bereavement increases the risk of mortality from a range of causes including suicide, we will assess suicide risk at each timepoint. If at any point participation is associated with new or worsening of suicidal ideation, you will be referred to your primary care physician and/or a mental health professional for further evaluation and treatment. Additional safety measures include access to a 24/7 answering service for clinical emergencies with geriatric psychiatry as back-up.

Breach of Confidentiality: As with all research, there is a chance that confidentiality could be compromised. It is possible that information regarding your mental and physical health will be discovered by individuals outside of study personnel, despite careful steps to protect confidentiality. Maintaining strict security on information provided by participants will minimize risks to confidentiality.

Study data will be kept strictly confidential and participants' identities will not be revealed in any publication. All participants will have identification numbers that will be used on forms and for data storage purposes. The study team will have locked files linking participants' names and identification numbers. All information will be kept in locked files and access to these materials will be limited to study personnel. Computer databases and tablet data are protected by several procedures, including password protection of subject data and a firewall around the entire Research Computing Network at the University of Pittsburgh. With your permission, the study team may also send reminders and answer general questions about the study through text message. Text messages are not encrypted or secure during their transmission, and could be intercepted by unauthorized third parties.

What are the potential benefits from taking part in this research study?

There are no guarantees that you will receive any benefit from participating in this research study. You may benefit from the screening procedures that include a careful examination of your physical and mental health. You may also benefit from monitoring and managing your health via the daily diary and sharing results with the research staff or your PCP. You may also benefit from becoming aware of your physical activity, diet, and sleep behaviors. The results of this study may help other older individuals cope with the loss of their spouse or partner. You may benefit from satisfaction you may derive from helping us understand older adults' health behaviors after spousal loss.

ENDING THE STUDY

Your participation is voluntary. You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you decide to leave the study before it is finished, please tell one of the study staff members listed on the first page of this form.

Your participation may be discontinued if you are unable to complete any of the study procedures, unless engaging in an activity (such as physical activity) would be unsafe for you to do. If you decide to withdraw or you are withdrawn from the study, the information you have provided in response to our questions, as well as the daily diary data, will continue to be stored and used by the research team.

If you have questions about this research study, you may contact the investigators listed at the beginning of this consent form. If you have questions about your rights as a research subject, please contact the Human Participants Protection Advocate at the University of Pittsburgh IRB Office, 1-866-212-2668.

Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate (e.g. you show evidence of major depression)
- Your condition changes and you need treatment that is not allowed while you are taking part in the study (e.g. increased suicidal risk).
- You do not follow instructions from the researchers
- The study is suspended or canceled.

FINANCIAL INFORMATION

Who will pay for the costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. Neither you, nor your insurance provider will be charged for the costs performed only for the purposes of this research study. You will be charged in the usual manner for any procedures performed as part of your standard medical care (care you would receive even if you were not participating in this research study).

Will I be paid if I take part in this research study?

You may receive up to a total of $250 after completing all visits of the study. Payments will be staggered. You will receive $75 after completing the baseline assessment, actigraphy assessments, intervention, and post-intervention assessment. You will receive $40 after completing the 3-month follow-up assessment. You will receive $60 after completing the 6-month follow-up assessment. You will receive $75 after completing the 12-month follow-up assessment. The Vincent debit card system will be used for payments. You will receive a water bottle in your study start up packet as a small thank you gift. We will either reimburse up to $20 for transportation to the clinic, or validate parking, for contactless pickup and/or drop off of study equipment.

Because you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Your information (even if identifiers are removed) may be used for commercial profit; however, you will not retain any property rights, nor will you share in any money that the that the investigators, the University of Pittsburgh, or outside agencies may receive.

CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

How will the researchers protect my privacy?

Any information about you obtained from or for this research study will be kept as confidential (private) as possible. As a participant, you will be assigned an identification number. This number, instead of your name, will be used in all records. Research records will be kept in a separate research file that does not include names, registration numbers or other information that is likely to allow someone other than the researchers to link the information to you. We will not allow anyone to see your record, other than people who have a right to see it. These records will be stored in locked or password-protected files in a limited-access office. You will not be identified in any reports on this study. You will not be identified by name in any publication of the research results. All information gathered from you will be encrypted and entered into a secure database and stored on secure servers at the University Center for Social and Urban Research at the University of Pittsburgh.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

It is possible that authorized representatives from The Late-life Depression Prevention & Treatment Center, University of Pittsburgh Office of Research Protections, or the National Institute of Mental Health may review your data for the purpose of monitoring the conduct and safety of this study. Per

University of Pittsburgh policy, research records will be maintained for at least 7 years after study completion.

Your research information may be shared with investigators conducting other research. This information may be identifiable. For example, in very unusual cases, your research records may be released in response to an order from a court of law. Also, if we learn that you or someone with whom you are involved is in danger of potential harm, we will need to inform the appropriate agencies, as required by Pennsylvania law.

What information about me could be seen by the researchers or by other people?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study. Your primary care provider may be informed of your participation in the study *if medically necessary*. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care if medically necessary, including:

- Hospital/doctor's office records, including test results (MRI, urine tests, diagnoses, age, past medical history, results of any tissue biopsies or blood tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Demographic and billing information
- Other information

This authorization is valid for an indefinite period. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team. You will not be notified of any individual research results.
We will also use websites such as REDCap and GitHub to help us analyze the data we receive in this study. The data we use for analysis contains no identifiable information.
A description of this clinical trial will be posted on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results of the study, once available. You can search this website at any time.

As long as your information is kept within UPMC, it is protected by UPMC's privacy policies. For more information about these policies, ask for a copy of the UMPC "Notice of Privacy Practices". This information is also available on the web at: http://www.upmc.com/patients-visitors/privacy-info/Pages/notice-of-privacy-practice.aspx.

NATIONAL DATA ARCHIVE

Data from this study will be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before. During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA.

Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data

must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, the National Institutes of Health will issue a Certificate of Confidentiality to all studies it funds in which sensitive information are acquired and stored for research analysis. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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 written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

VOLUNTARY CONSENT

- The above information has been explained to me and all my current questions have been answered.
- I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during this study, and any such future questions, concerns or complaints will be answered by Dr. Stahl or a qualified member of her research team.
- I understand that there is little risk involved in this study. No medications are included. You may become bored or tired while completing study activities. We will attempt to pace all study activities to fit your level of interest and energy.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time. My decision to participate will not affect your relationship with UPMC, the University of Pittsburgh, or Family Hospice and Palliative Care.
- We may try to contact your primary care physician or other mental health specialist to share information from the study to ensure that you are receiving the best possible care.
- I understand that I may contact the Human Participants Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations if the research team is unavailable.
- By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team, if medically necessary. A copy of this consent form will be provided to me.

_____ _____

Participant's Signature **Printed Name of Participant**

_____

Date

MENTAL HEALTH SPECIALIST CONTACT INFORMATION (Optional):

I authorize the study team to contact the following person regarding my status during my participation in this study:

Name of Provider: _____

Phone number: _____

Email (if applicable): _____

PRIMARY CARE PHYSICIAN CONTACT INFORMATION:

I authorize the study team to contact the following person regarding my status during my participation in this study:

Name of Primary Care Physician: _____

Phone number: _____

Email (if applicable): _____

INVESTIGATOR CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date