WASHINGTON STATE UNIVERSITY

Department of Psychology and School of Electrical Engineering and Computer Science

Research Study Consent Form

Study Title: Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation

Researchers:

Maureen Schmitter-Edgecombe, PI 509-335-0170
Department of Psychology

Diane Cook, Co-PI 509-335-4985
Faculty, School of Electrical Engineering and Computer Science

Maggie Dines and Regan Jenkins, Laboratory Managers
509-335-4033 Department of Psychology

Sponsor: Department of Defense

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
- Study Purpose – The purpose of this study is to examine whether a personalized video-based training program can help people learn to use a digital tool.
- Major Activities of Subject Participation – You will be asked to participate in neurocognitive testing, a series of questionnaires at multiple time points, and to use the experimental digital tool regularly over the course of multiple months.
- Duration of Participation – The entire study will last for 6 months and require 13-22 hours of your time.
- Significant Risks – Risks include frustration and/or fatigue from completing study activities, and invasion of privacy due to being asked sensitive questions and sessions being audio/video recorded.
- Potential Intervention Benefits – The EMMA app training and intervention may provide participants with a tool to assist them with managing everyday activities.
- Alternative Procedures – You can decide to not participate in this study. If you join the study, you can change your mind later and quit at any time. You may refuse any question, test, or procedure.
- This is a pilot intervention study and should not be considered medical treatment.

You are being asked to take part in a research study carried out by *Drs. Maureen Schmitter-Edgecombe and Diane Cook*. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is this study about? The purpose of this study is to examine whether a personalized video-based training program can support older individuals in learning to use an experimental Electronic Memory and Management Aid application called EMMA. The EMMA app is intuitive and easy to use as it was designed in partnership with older individuals who had little experience with technology and were experiences memory problems. The EMMA app is installed on a mobile tablet and can also be accessed via a web-based browser. EMMA can assist individuals with organizing and scheduling daily activities, recording events that may need to be remembered, monitoring health information and recording performed activities.

You qualify because you are an older adult who reports experiencing some changes in your memory or thinking abilities, are able to provide your own informed consent, are able to complete the requirements of the study protocol and are interested in learning strategies to help with these difficulties. The study will enroll up to 50 older individuals reporting changes in memory and thinking abilities associated with age-related neurocognitive changes. If it proves to be effective, we believe this program will have important implications for supporting older adults' memory and everyday organization.

What will I be asked to do if I am in this study? If you decide to participate in this study, you will be randomly assigned to either one of two groups. Both groups will participate in the study for six months. You will be trained to use the EMMA app, which is an experimental digital tool, through a web-based training system that we developed, which is self-paced and adaptive. There are six training sessions which need to be completed within a four-week period. Each training session will last approximately 1-1.5 hours. The EMMA app was designed with help from individuals experiencing memory difficulties. It is easy to use even if you have no experience with technology. After training, you will continue to use the EMMA for the duration of the study. If needed we will loan you a tablet that contains the EMMA app, but the EMMA can easily be used on a personal tablet or computer. One group will learn to use the EMMA app largely independently, to help us understand how well we've designed the adaptive training program. The other group will receive some motivational support and usage feedback during the training.

We will also have you complete a brief set of cognitive tests at the beginning of the study. The tasks are designed to assess skills like attention, memory, and everyday problem-solving. The tasks will involve no discomfort to you. These tests will be administered remotely (i.e., over Zoom) and recorded to a secure server for scoring purposes. Many of the tasks are like "brain teasers". Examples of some of the tasks include remembering a list of words and creating designs using a set of rules. Most people enjoy testing, and we only ask that you put forth your best effort. These tests will take approximately 2 hours to complete. Breaks will be taken as necessary and at your request.

At the start of the study, you will complete a series of questionnaires about mood, quality of life, coping skills, memory, and functional abilities. These questionnaires will be completed again following the EMMA app training and once more at the end of the study. In addition, at the beginning and end of the study we will ask you to answer questions about everyday tasks and complete brief tasks of everyday living (e.g., call the lab at a specified time) in your everyday environment over the course of a three-week period. After you learn to use EMMA, you will also be asked to respond to questions about improving the EMMA app and web-based training and complete questionnaires about your satisfaction with the EMMA app and web-based training. During the first 4 weeks of the study, you will also receive a weekly call reminding to complete the training and receive technical support if required. Those in the motivation support group will also complete a brief exercise during those weekly calls which will take approximately 15 minutes.

Below is a table illustrating the tasks, timeline and requirements.

	Total Time
Baseline Data Collection (weeks 1-4): Remote Assessment, Brief Everyday Living Tasks, Questionnaires	2-4 hours
Training: Clinician helps set up lesson 1. Completion of 6 web-based Training Lessons (weeks 5-8)	6 -10 hours
Brief training Check-ins (weeks 5-8)	1.5 - 2 hours
Post-training Data Collection (week 9): Questionnaires; Semi-structured interview	1-2 hours
Technology Support as needed (weeks 10-20)	.5 - 1 hour
Follow-up Data Collection (weeks 21-24): Remote Assessment, Brief Everyday Living Tasks, Questionnaires; Semi-structured interview	2-3 hours

Approximate total participation time: 13-22 hours

With your permission, we will also be asking a knowledgeable informant of your designation to complete a 30-minute interview at the start and end of your participation in this study. During this interview, we will ask the knowledgeable informant to provide information about their perceptions of your everyday memory performances on tasks of everyday living and experience with the EMMA app and web-based training. We will also be asking you to sign an authorization of release so that we can review medical records related to your health care use in the year prior to the study as well as the six months that you are involved in the study.

Are there any benefits to me if I am in this study?
The EMMA app training and intervention may provide participants with a tool to assist them with organizing and scheduling daily activities, recording events that may need to be remembered, monitoring health information and tracking performed activities.

Are there any risks to me if I am in this study?
The potential risks from taking part in this study are minimal. You may experience some invasion of privacy and discomfort associated with the tasks you are asked to complete in your home and with the video recording of the Zoom meeting. We will minimize the risks by asking you which tasks you are comfortable completing in your home. We will not share collected video of you completing the requested tasks with anyone outside of the project. The videos are being collected only for the accuracy of coding purposes and will be stored on a password protected computer in a secured lab or a password protected portable hard drive that will be kept in a secured lockbox and erased once coding and review is complete. Any personal information that you enter into the iPad outside of the EMMA app will not be stored on the secure server, as such there is a risk of data breach that WSU researchers cannot control.

Additionally, individuals who live in the same home as you may experience invasion of privacy should they enter the area where you are completing a Zoom meeting. To minimize this risk, we recommend that you complete the Zoom meetings in a private area of your home.

With regards to completion of the cognitive tests and questionnaires and learning to use the EMMA app through the web-based training system, you may become frustrated or find some of the tasks fatiguing. We will encourage you to take breaks from the testing to minimize this risk and you can ask to skip a task at any point. You can proceed through the training at your own pace, with several days to complete each lesson at your learning rate. You may also experience some invasion of privacy associated with answering sensitive questions. You may choose not to answer questions that you do not feel comfortable answering.

You may experience some frustration and inconvenience due to a disruption in your normal daily routine as a result of integrating a new tool into your daily life. If you become frustrated, you can choose the extent to which you use the EMMA in your daily life. It is also possible that

receiving feedback from the evaluation could be upsetting if the testing indicates that your current cognitive skills are below your expectations. If this is the case we will provide you with referrals to appropriate professionals in your area (e.g., neurologist, psychologist).

Furthermore, you will be asked questions pertaining to your mental health. It is your right as a participant to not respond to any question that you do not feel comfortable answering. If at any point during the study you endorse suicidal thoughts, plans, or intentions, the primary investigator will follow up with you and give you an appropriate referral if necessary. In compliance with the mandatory reporting law in Washington state, if any study personal gains information about: (1) you being in imminent danger to yourself or others or (2) abuse or neglect of any child or vulnerable adult, confidentially will be broken to ensure the safety of you and/or others.

Your participation in this study is voluntary. Refusal to consent to participation, or withdrawal of consent, is without penalty. While we have safeguards in place to protect confidential information, there is the potential risk of a breach in confidentiality. There may be some unexpected discomforts or risks in addition to those stated above, but every precaution will be taken to assure your personal safety and to minimize any discomforts.

Will my information be kept private? The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. Individuals or groups who may have access to the confidential data include the research team members and the designated Data Custodians in the Department of Psychology at WSU and the Voiland College of Engineering and Architecture. This includes access to research records by the WSU Institutional Review Board or the sponsor agency, which is the Department of Defense.

Any information that is obtained from this study that can be identified will remain confidential. Any information used for scientific publication will be used without disclosure of personally identifying data. Research findings will be reported for groups of participants or for individuals who have been assigned a research code that is not personally identifying. Anonymized group data may also be shared with other research teams upon request. All data will be coded and entered into a computer database without reference to name. Data entered online will be secured in a HIPAA compliant manner. The original data will be kept in locked offices. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. Once identifiers have been removed, we will not ask your consent for the use or sharing of your data in additional research. The data for this study will be kept for a minimum of 5 years following publication of the last study to result from this research project.

EMMA is a tablet and web-based app. The information that you enter into the EMMA app will be transmitted and stored using Amazon Web Services (AWS). This is a third party service. The security of AWS has been carefully reviewed and approved by WSU Information Security Services. Data will be continuously captured by the EMMA app. Data elements will include all data that you log into EMMA and activity-use. Use of the EMMA app and the apps varying components will be tracked and transferred to a de-identified database for analysis. Similarly, your progress through the web-based training, including all of your responses, will be tracked and transferred to a de-identified database for analysis.

The EMMA app has the capability to make use of the iPAD speech-to-text software. Apple's speech recognition process involves capturing audio of the user's voice and Apple's servers process and translate that information into text. If you choose to allow this feature, Apple retains access to your spoken information.

The EMMA app has the capability to use the camera on your iPad to take pictures. Pictures you take are stored locally to the iPad in the Photos app. If you transfer devices, your pictures will no longer be available. Similarly, we do not store photos, so if you redownload the application your photos would no longer be linked to the app.

Are there any costs or payments for being in this study? There will be no costs to you for taking part in this study. You will be compensated up to $200 in cash for participating in this study. You will receive $25.00 for completion of the first testing session and then for every month of participation in the study (5) up to $125.00. For completion of the final testing session, you will receive $50.00. All funds will be dispersed as a lump-sum at the completion of participation. You will also receive a brief report detailing your performance on the cognitive tests relative to others your age. Should you want to continue using the EMMA app, we will help you get the app installed on a tablet of your own, but any tablet we have loaned will need to be returned.

Who can I talk to if I have questions? If you have questions about this study or the information in this form, please contact the researcher Dr. Maureen Schmitter-Edgecombe: Johnson Tower 312, Pullman, WA 99163, schmitter-e@wsu.edu, 509-335-4033. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neil 427, PO Box 643143, Pullman, WA 99164-3143.

What are my rights as a research study volunteer? Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may also choose not to answer specific questions or to stop participating at any time.

What does my signature on this consent form mean?
Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- **Statement of Consent**

I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

☐ **YES,** I give my permission to be videotaped while completing tasks during testing sessions for data scoring purposes. I understand that this recording will not contain my name. The videotapes will be erased after the data is scored.

☐ **YES,** I give my permission for the researchers to contact _____ at _____. This individual is my _____ (please indicate individuals relationship to you). I understand that the above named person will be contacted by the researchers to see if they would like to be my study partner. I understand that the above named person will be asked if they would be willing to answer questions related to their perceptions of my everyday memory and problem solving abilities, my performances on tasks of everyday living and my experience with the EMMA app. I also understand that the information provided by _____ will remain confidential.

Statement of Person Obtaining Informed Consent
I have carefully explained to the person taking part in the study what he or she can expect. I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation.

I also certify that they:

- Speaks the language used to explain this research

- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

_____ _____

Signature of Person Obtaining Consent Date

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*** Participant Copy ***

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Additionally, individuals who live in the same home as you may experience invasion of privacy should they enter the area where you are completing a Zoom meeting. To minimize this risk, we recommend that you complete the Zoom meetings in a private area of your home.

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Furthermore, you will be asked questions pertaining to your mental health. It is your right as a participant to not respond to any question that you do not feel comfortable answering. If at any point during the study you endorse suicidal thoughts, plans, or intentions, the primary investigator will follow up with you and give you an appropriate referral if necessary. In compliance with the mandatory reporting law in Washington state, if any study personal gains information about: (1) you being in imminent danger to yourself or others or (2) abuse or neglect of any child or vulnerable adult, confidentially will be broken to ensure the safety of you and/or others.

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Will my information be kept private? The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. Individuals or groups who may have access to the confidential data include the research team members and the designated Data Custodians in the Department of Psychology at WSU and the Voiland College of Engineering and Architecture. This includes access to research records by the WSU Institutional Review Board or the sponsor agency, which is the Department of Defense.

Any information that is obtained from this study that can be identified will remain confidential. Any information used for scientific publication will be used without disclosure of personally identifying data. Research findings will be reported for groups of participants or for individuals who have been assigned a research code that is not personally identifying. Anonymized group data may also be shared with other research teams upon request. All data will be coded and entered into a computer database without reference to name. Data entered online will be secured in a HIPAA compliant manner. The original data will be kept in locked offices. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. Once identifiers have been removed, we will not ask your consent for the use or sharing of your data in additional research. The data for this study will be kept for a minimum of 5 years following publication of the last study to result from this research project.

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Are there any costs or payments for being in this study? There will be no costs to you for taking part in this study. You will be compensated up to $200 in cash for participating in this study. You will receive $25.00 for completion of the first testing session and then for every month of participation in the study (5) up to $125.00. For completion of the final testing session, you will receive $50.00. All funds will be dispersed as a lump-sum at the completion of participation. You will also receive a brief report detailing your performance on the cognitive tests relative to others your age. Should you want to continue using the EMMA app, we will help you get the app installed on a tablet of your own, but any tablet we have loaned will need to be returned.

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What does my signature on this consent form mean?
Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- **Statement of Consent**

I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

☐ **YES,** I give my permission to be videotaped while completing tasks during testing sessions for data scoring purposes. I understand that this recording will not contain my name. The videotapes will be erased after the data is scored.

☐ **YES,** I give my permission for the researchers to contact _____ at _____. This individual is my _____ (please indicate individuals relationship to you). I understand that the above named person will be contacted by the researchers to see if they would like to be my study partner. I understand that the above named person will be asked if they would be willing to answer questions related to their perceptions of my everyday memory and problem solving abilities, my performances on tasks of everyday living and my experience with the EMMA app. I also understand that the information provided by _____ will remain confidential.

Statement of Person Obtaining Informed Consent
I have carefully explained to the person taking part in the study what he or she can expect. I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation.

I also certify that they:

- Speaks the language used to explain this research

- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Printed

Human Research Protection Program (HRPP) - Office of Research Assurances
PO Box 643143 Neil Hall 427 Pullman, WA 99164-3143
Telephone: (509)335-7646 Email: irb@wsu.edu Web site: www.irb.wsu.edu

Principal Investigator:	Maureen Schmitter-Edgecombe
Study Title:	Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation
IRB #:	

HIPAA AUTHORIZATION FORM

By signing bellow, you agree to the to the following:
By law, researchers must protect the privacy of health information about you. In this form the word "you" means both the person who takes part in the research and the person who gives permission for another person to be in the research. Researchers may use, create, or share your health information for research only if you let them. This form describes what researchers will do with your information. Please read it carefully. If you agree with it, please sign your name at the bottom. You will get a copy of this form after you have signed it.

If you sign this form, information will be shared with the people who conduct the research. In this form, all these people together are called "researchers." Their names will appear on the research consent form that you sign.

The researchers will use the health information only for the purposes named in this form as described below:

1. **What "health information" includes:**
   - All information about you that is collected during the research study. This might include the results of tests or exams that become part of the study records; diaries and questionnaires that you might be asked to fill out as part of the study and other records from the study.
   - All health information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures and your medical history.

2. **What the researchers may do with health information:**
   - The researchers may use and create health information about you for the study.
   - They may also share your health information with certain people and groups. These may include:
     - The sponsor of the study and its representatives

- Government agencies, review boards, and others who watch over the safety, effectiveness, and conduct of the research.
- Other researchers when a review board approves the sharing of the health information.
- Your health insurer if they are paying for care provided as part of the research study.
- Others, if the law requires.

- **The listed sponsors are identified as:**
  - Department of Defense
  - **ORSO#**AWD002175
  - **Grant title:** A Digital Memory Notebook to Support Everyday Functioning, Decrease Caregiver Burden and Track Health Status
  - **PI name on grant:** Maureen Schmitter-Edgecombe, Diane Cook

3. Removing your name from health information:

- The researchers may remove your name (and other information that could identify you) from your health information. No one would know the information was yours.
- If your name is removed, the information may be used, created, and shared by the researchers and sponsor as the law allows. (This includes other research purposes.) This form would no longer limit the way the researchers use, create, and share the information.

4. How the researchers protect health information:

- The listed researchers will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.
- **The listed researchers are identified as:**

Name:	WSU Email:
Reanne Chilton	reanne.cunningham@wsu.edu
Margaret Dines	margaret.dines@wsu.edu
Regan Jenkins	regan.jenkins@wsu.edu
Callan Lujan	callan.lujan@wsu.edu
Brooke Beech	brooke.beech@wsu.edu
Catherine Luna	catherine.luna@wsu.edu
Maureen Schmitter-Edgecombe	schmitter-e@wsu.edu
Diane Cook	djcook@wsu.edu
Bryan Minor	bminor@wsu.edu
Jason Minor	jason.a.minor@wsu.edu
Brian Thomas	Bthomas1@wsu.edu
Samina Rahman	Samina.rahman@wsu.edu
Jamie Li	xingzi.li@wsu.edu
Chance Desmet	chance.desmet@wsu.edu
Carolyn Pagan	carolyn.pagan@wsu.edu
Nicole Whitely	nicole.whiteley@wsu.edu
Keira Monaghan	keira.monaghan@wsu.edu

5. **After the researchers learn health information:**
   - The limits in this form come from a federal law called the Health Insurance Portability and Accountability Act. This law applies to your doctors and other health care providers.
   - Once the researchers get your health information, this law may no longer apply. However, other privacy protections will still apply.

6. **Storing your health information:**
   - Your health information may be added to a database or data repository. This permission will end when the database or data repository is destroyed.
   - You do not have to sign this permission ("authorization") form. If you do not, you may not be allowed to join the study. You may change your mind and take back your permission at any time.
   - **To take back your permission, contact the study manager (name, contact method):**
     - Margaret Dines email: margaret.dines@wsu.edu
     - Regan Jenkins email: regan.jenkins@wsu.edu
     - Lab Phone: (509)335-4033
   - If you do this, you may no longer be allowed to be in the study. The researchers will keep any information in the study record they already collected.
   - Your authorization will expire when the goals of the study have been met.
   - **The listed research goals are identified as:**
     - Examine how older adults who are noticing changes in their memory or thinking abilities learn to use a personalized video-based training program to maintain routines and independence.
     - Utilize a web-based training system to teach participants to use the app.
     - Use EMMA to assist individuals with organizing and scheduling daily activities, recording events that may need to be remembered, monitoring health information and recording performed activities.
   - During the study, you will not be allowed to see your health information that the researchers may place in your medical record. After the study is finished, you may see this information.

7. **Signature:**
    - If I have not already received a copy of the Privacy Notice, I may request one. If I have any questions or concerns about my privacy rights, I should contact the WSU IRB at: irb@wsu.edu.
    - I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.
    - I agree to the use, creation, and sharing of my health information for purposes of this research study

Research subject/legal representative name:

Relationship to subject:

Date:

Signature (required): _____

PI name: Maureen Schmitter-Edgecombe
Date:
Signature (required): _____

AUTHORIZATION FOR RELEASE OF CONFIDENTIAL INFORMATION

from the research project entitled
Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation
Washington State University, Department of Psychology
P.O. Box 644820, Pullman, WA 99164-4820
(509) 335-4033

The data obtained about your cognitive abilities as a result of your participation in the research project entitled "**Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation**" is confidential. This data will not be given to anyone without your written permission or that of your conservator. I understand, however, that my records may be reviewed or copied by the Washington State University Institutional Review Board or by other regulatory agencies. These agencies might review my records to check the information collected in this study, to check how the study was conducted or for other uses allowed by law. Although federal and state laws require the study doctor to protect the privacy of my records, I understand that absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. Please complete the information below if you would like to have the data about your cognitive performances that was obtained as part of this research project released or discussed with another health care professional.

Last Name _____ First Name _____ M.I. ____

These records should be discussed with or sent to the address(es) and person(s) indicated below:

_____

_____

_____

_____

I give permission to the **Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation** research project at Washington State University to release information from my research records to the person(s) specified above. I understand that the release will become effective on the day I sign it. I understand that I can cancel this release at any time, except to the extent that it has already been acted upon, by notifying the research project in writing.

Signature _____ Date _____
Participant or Participant's Legal Representative

This project was reviewed and approved by the Washington State University Institutional Review Board. The Principal Investigator of this project is Dr. Maureen Schmitter-Edgecombe who is a Professor in the Department of Psychology at Washington State University, Pullman.

WSU IRB #19498-006
Approved: 1/12/2023

AUTHORIZATION FOR RELEASE OF CONFIDENTIAL INFORMATION to

Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation

Washington State University, Department of Psychology
P.O. Box 644820, Pullman, WA 99164-4820
(509) 335-4033

To: _____

Clinic or Physician Currently Holding Records

_____

Street Address City State Zip

Please release from my records the information listed below to Dr. Maureen Schmitter-Edgecombe the Principal Investigator of the "**Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation"** research project at Washington State University (WSU), P.O. Box 64420, Pullman, WA, 99164-4820. This project was reviewed and approved by the WSU Institutional Review Board. I understand that all requested medical records might be reviewed or copied by the WSU Institutional Review Board or by other regulatory agencies. These agencies might review my records to check the information collected in this study, to check how the study was conducted or for other uses allowed by law. Although federal and state laws require the study doctor to protect the privacy of my records, I understand that absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. I also understand that I can cancel this release at any time by notifying you in writing.

_____

Last Name First Name M.I. Previous Name (if any) Date of Birth

_____

Permanent Street Address City State Zip Phone

I am participating in a randomized controlled study older that is evaluating use of a digital memory notebook for assisting individuals experiencing memory impairment. Could you please send the following information to the Principal Investigator of the "**Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation"** research project.

1. Records regarding my health care utilization between the following dates _____ and _____.

Signature _____ Date _____
Participant or Participant's Legal Representative

Photocopy reproduction of this request shall be for all intents and purposes as valid as the original. You may retain this form in your files.

WSU IRB #19498-006
Approved: 1/12/2023

Washington State University

Participant Honorarium Form

This document is to confirm that I,

*(**First name**) _____ (**Middle initial**) _____ *(**Last name**)_____

(**WSU ID** if applicable)_____

*(**Home address**) _____

*(**Email**) _____

have received an honorarium in the amount of $_____

for my participation in the project titled: *"**Electronic Memory and Management Aid (EMMA) Web-based Training Evaluation" IRB#19784-001**, on *(**Date**) _____

_____ _____

*Signature of participant/recipient *Date received

_____ _____

Signature of experimenter dispersing the honorarium Date dispersed

** Indicates required field*

WASHINGTON STATE UNIVERSITY

College of Arts and Sciences, Department of Psychology and School of Electrical Engineering and Computer Science

Research Study Consent Form

Study Title: Ecological Momentary Assessment (EMA) of Cognition and Context

Researchers:

Maureen Schmitter-Edgecombe, PI 509-335-0170
Department of Psychology

Diane Cook, Co-PI 509-335-4985
Faculty, School of Electrical Engineering and Computer Science

Maggie Dines and Regan Jenkins, Laboratory Managers 509-335-4033
Department of Psychology

Sponsor: National Institute of Aging

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
- Study Purpose – The purpose of this study is to investigate patterns of older adults' everyday cognitive performance and factors like fatigue, mental sharpness and distractors that may influence everyday cognition.
- Major Activities of Subject Participation – You will be asked to wear a smartwatch during the day for a total of two weeks and answer questions on the smartwatch pertaining to your current state of being and take a short cognitive test.
- Duration of Participation – A total of two weeks over the course of six months. Completion of the smartwatch prompts will require about two hours total of your time each week.
- Significant Risks – Risks include frustration and/or fatigue with answering smartwatch prompts, and invasion of privacy due to being asked sensitive questions.
- Potential Benefits – Participants may learn about self-monitoring their internal state and environment.
- Alternative Procedures – You can decide to not participant in this study. If you join the study, you can change your mind later and quit at any time. You may refuse to answer any question or cognitive test.

What you should know?
You are being asked to take part in a research study carried out by Drs. *Maureen Schmitter-Edgecombe and Diane Cook*. As a participant in the "Electronic Memory and Management Aid (EMMA) Web-Based Training Evaluation," you are eligible to take part in this additional research opportunity. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. Your decision to take part in this additional research opportunity will not impact your participation in the "EMMA Web-Based Training Evaluation" study. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is the purpose of this study?
The purpose of this study is to enhance knowledge of older adults' everyday cognition and to investigate potential influences on everyday cognition, such as fatigue, mental sharpness and environmental distractors. Data will be collected via smartwatches. The data will be used to identify individual and group patterns of everyday cognition and to determine internal and external contextual factors (e.g., feelings of mental sharpness, time of day) that may influence the cognitive performance patterns. The data will also be used to inform real-time intervention development.

You qualify because you are an older adult who reports experiencing some changes in your memory or thinking abilities, are able to provide your own informed consent, and are currently enrolled in the Electronic Memory and Management Aid (EMMA) Web-Based Training Evaluation. The smartwatch queries and response options are all designed in English, requiring participants to be English-speaking. The study will enroll up to 50 older individuals reporting changes in memory and thinking abilities associated with age-related neurocognitive changes. We believe this smartwatch data will have important implications for assessing and supporting older adults' memory and everyday cognition.

What will I be asked to do if I am in this study?
If you decide to take part in the study, you will wear a smartwatch (Apple Watch) during waking hours for a one-week period. You will be asked to charge the smartwatch at night when you are sleeping. During this period, you will be asked to respond to prompts four times per day. These prompts will require you to answer a set of questions. You can ignore the prompts if you do not desire to answer them. After one week, you will be

asked to place the watches and chargers in the prepaid mail package and mail the watches back to the WSU Neuropsychology and Aging Laboratory (in some cases the watches may be picked up). The second week of data collection will begin when you complete the follow-up cognitive testing session approximately six months after the baseline cognitive testing session. Once again, you will be asked to respond to the watch prompts four times per day for one week, and then mail the watches and charger back (or have them picked up) at the end of the week. If you are living within reasonable driving distance, materials can be dropped off and picked up from your home by lab personnel.

We will use an app on the smartwatch to administer and collect data for the watch prompts. For each prompt, you will complete a brief cognitive n-back test (45 sec) and answer questions about your current self and external environment. For most questions, you will be given a list of answers to choose from. You will choose your response by tapping it on the screen. These prompt sets will be administered four times per day through text cues on the smartwatch and should take less than five minutes to complete each time.

The watches will continuously collect sensor data as you perform your daily routines. Sensor data includes accelerometer (measures movement), gyroscope (measures rotation), GPS (gives approximate location of the watch), magnetometer (measures magnetic waves which helps determine location of the watch), and heart rate. The watch identifier, the sensor data, and your responses will be encrypted and sent using secure transmission to our server where they will be stored in our database. Your research study identifier will be assigned to a watch identifier during the initial meeting. This information will be securely stored on a password protected computer. The data from the smartwatches may be combined with clinical data collected as part of the parent study.

Are there any benefits to me if I am in this study?
While there is no direct benefit to participating in this research study, you may learn more about self-monitoring your internal state and the environment.

Are there any risks to me if I am in this study?
The potential risks from taking part in this study are minimal. You may experience some discomfort associated with wearing the smartwatch. Potential risks include: invasion of privacy, breach of confidentiality, and psychological discomfort. Regarding invasion of privacy, you do not have to respond to any questions that you feel uncomfortable answering. The risk of a breach in confidentiality is minimized by providing an ID number that will be entered in the place of your name while encrypting all data and by keeping confidential information on secure

servers (in a secure location for physical data). Regarding distress, discomfort and frustration, you may also stop participating in the study at any time, choose not to complete a smart watch EMA question, or not to wear the smart watch for the full data collection duration.

We will not share collected data and video of you completing the requested tasks with anyone outside of the project. Your participation in this study is voluntary. Refusal to consent to participation, or withdrawal of consent, is without penalty. While we have safeguards in place to protect confidential information, there is the potential risk of a breach in confidentiality. In the event of a data breach, research staff will contact and inform you of what data may have been compromised. Staff will also offer information on resources available to you if you have concerns about the breach. There may be some unexpected discomforts or risks in addition to those stated above, but every precaution will be taken to assure your personal safety and to minimize any discomforts. If you become frustrated or uncomfortable with the smart watch, you may discontinue the study or take a break from data collection. You are free to stop participation at any point.

Will my information be kept private?

The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings.

Any information that is obtained from this study that can be identified will remain confidential. Any information used for scientific publication will be used without disclosure of personally identifying data. Research findings will be reported for groups of participants or for individuals who have been assigned a research code that is not personally identifying. Anonymized group data may also be shared with other research teams upon request. All data will be coded and entered into a computer database without reference to name. Data entered online will be secured in a HIPAA compliant manner. The original data will be kept in locked offices. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. Once identifiers have been removed, we will not ask your consent for the use or sharing of your data in additional research. The data for this study will be kept for a minimum of 5 years following publication of the last study to result from this research project.

Under certain circumstances, information that identifies you may be released for internal and external reviews of this project. Individuals or groups who may have access to the confidential data include the research team members and the designated Data Custodians

in the Department of Psychology at WSU and the Voiland College of Engineering and Architecture. This includes access to research records by the WSU Institutional Review Board or the sponsor agency, which is the National Institute of Aging.

The app used for this research makes use of Apple's location services. This information is collected by Apple as part of the mobile device system. The devices we use for the study will not have any identifiers and we will use the highest privacy settings possible to limit the amount of data that is collected by the company. While we have safeguards in place to protect the confidential nature of the information we gather from you, there is the potential risk of a breach in confidentiality. If a breach occurs, location information collected from the device could potentially lead to an approximate identification of you. You can find Apple's privacy policy here: https://www.apple.com/legal/privacy/en-ww/

Are there any costs or payments for being in this study?
There will be no costs to you for taking part in this study. If you opt to participate in this smartwatch study, you will receive $30 for wearing the smartwatch at time 1 and another $30 for wearing the watch at time 2. This $60 compensation, which will be awarded at study completion, is in addition to the compensation offered in the "EMMA Web-Based Training Evaluation" study.

Who can I talk to if I have questions?
If you have questions about this study or the information in this form, please contact the principal investigator: Dr. Maureen Schmitter-Edgecombe, schmitter-e@wsu.edu, 509-335-4033. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.

What does my signature on this consent form mean?
Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- You are giving your voluntary consent to take part in the study.

Statement of Consent (Please initial below to indicate agreement or disagreement)

Yes, I agree	**No, I disagree**	
_____	_____	I give my permission to be videotaped while completing tasks during the parent testing sessions for data scoring purposes. I understand that this recording will not contain my name. The videotapes will be erased after the data is scored.

I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect. I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation. I also certify that they:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

***** Participant Copy *****

WASHINGTON STATE UNIVERSITY

College of Arts and Sciences, Department of Psychology and School of Electrical Engineering and Computer Science

Research Study Consent Form

Study Title: Ecological Momentary Assessment (EMA) of Cognition and Context

Researchers:

Maureen Schmitter-Edgecombe, PI 509-335-0170
Department of Psychology

Diane Cook, Co-PI 509-335-4985
Faculty, School of Electrical Engineering and Computer Science

Maggie Dines and Regan Jenkins, Laboratory Managers 509-335-4033
Department of Psychology

Sponsor: National Institute of Aging

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
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- Major Activities of Subject Participation – You will be asked to wear a smartwatch during the day for a total of two weeks and answer questions on the smartwatch pertaining to your current state of being and take a short cognitive test.
- Duration of Participation – A total of two weeks over the course of six months. Completion of the smartwatch prompts will require about two hours total of your time each week.
- Significant Risks – Risks include frustration and/or fatigue with answering smartwatch prompts, and invasion of privacy due to being asked sensitive questions.
- Potential Benefits – Participants may learn about self-monitoring their internal state and environment.
- Alternative Procedures – You can decide to not participant in this study. If you join the study, you can change your mind later and quit at any time. You may refuse to answer any question or cognitive test.

What you should know?
You are being asked to take part in a research study carried out by Drs. *Maureen Schmitter-Edgecombe and Diane Cook*. As a participant in the "Electronic Memory and Management Aid (EMMA) Web-Based Training Evaluation," you are eligible to take part in this additional research opportunity. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. Your decision to take part in this additional research opportunity will not impact your participation in the "EMMA Web-Based Training Evaluation" study. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

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servers (in a secure location for physical data). Regarding distress, discomfort and frustration, you may also stop participating in the study at any time, choose not to complete a smart watch EMA question, or not to wear the smart watch for the full data collection duration.

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in the Department of Psychology at WSU and the Voiland College of Engineering and Architecture. This includes access to research records by the WSU Institutional Review Board or the sponsor agency, which is the National Institute of Aging.

The app used for this research makes use of Apple's location services. This information is collected by Apple as part of the mobile device system. The devices we use for the study will not have any identifiers and we will use the highest privacy settings possible to limit the amount of data that is collected by the company. While we have safeguards in place to protect the confidential nature of the information we gather from you, there is the potential risk of a breach in confidentiality. If a breach occurs, location information collected from the device could potentially lead to an approximate identification of you. You can find Apple's privacy policy here: https://www.apple.com/legal/privacy/en-ww/

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Statement of Consent (Please initial below to indicate agreement or disagreement)

Yes, I agree	**No, I disagree**	
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I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect. I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation. I also certify that they:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Washington State University

Participant Honorarium Form

This document is to confirm that I,

*(**First name**) _____ (**Middle initial**) _____ *(**Last name**)_____

(**WSU ID** if applicable)_____

*(**Home address**) _____

*(**Email**) _____

have received an honorarium in the amount of $_____

for my participation in the project titled: *"***Ecological Momentary Assessment (EMA) of Cognition and Context" IRB#19498-006**, on *(**Date**) _____

_____ _____

*Signature of participant/recipient *Date received

_____ _____

Signature of experimenter dispersing the honorarium Date dispersed

** Indicates required field*