

Aim-3: Alzheimer's Disease and Related Dementias Prevention Messaging to Increase Smoking Cessation Attempts in Older Adult Smokers

Informed Consent Procedures

Principal Investigator:

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Study Sponsor:

DHHS, PHS, NATIONAL INSTITUTES OF HEALTH

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Contact Information:

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IRB Approval:

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Aim 3 Study Oral Consent Procedures

After completing the Phone Screen, study staff will use the Study Information Sheet (see uploaded Study Information Sheet) to discuss study procedures and all elements of informed consent including:

- Study sponsor
- Invitation/Summary
- Study purpose
- Study participation, including assessments, schedule of study contacts, and treatment overview
- Risks, Benefits, and Costs
- Payment for participation
- How to revoke authorization
- Confidentiality
- How to contact study staff

Information to be used or disclosed will include your demographic information, recordings, or questionnaires and surveys and may be used by study staff, the UW Institutional Review Board which oversees the study, the UW Center for Tobacco Research and Intervention, and the Clinical Sciences Research and Development Data Monitoring Committee.

Individually identifiable health information disclosed pursuant to the authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

Any questions so far? NO YES _____ Answer questions

We just reviewed some of the risks of the study. Can you tell me what one risk might be?
[Teach back method to confirm decision making capacity. If patient unable to respond, review potential risks and ensure understanding.]

Thank you. Taking part in this study treatment is voluntary. This means that you decide if you want to take part in the study you can stop at any time. Your choice will not affect your relationships with UW Madison, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. By agreeing to be in this study, you are not giving up any legal rights. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

I'm about to ask if you give your consent to be in the study and to let us collect and use your health information for study purposes. If you decide to take part in the study, I will send you a written summary of all the information we discussed about this study. It will include contact information for the study team and instructions for what to do if you decide you want to leave the

study, have any questions about your rights as a research participant, or have any complaints you cannot resolve with the research team.

Do you have any questions about the study? NO YES _____ Answer questions

DO YOU CONSENT TO PARTICIPATE IN THE STUDY AND ALLOW FOR THE USE OF YOUR HEALTH INFORMATION? YES NO

YES → Continue

NO → Thank you for your time.

Great! I'm so glad you've decided to join the study! We'll send you a welcome letter in the mail. This will have a summary of what we just talked about and additional information about the study. It will also give you the phone number of our research partners at UW Madison.

If participant wants to get contact numbers now, provide these over the phone:

Project Principal Investigator: 608-265-4797 (questions about study)

Confidential Research Compliance Line: 1-833-652-2506 (complaints about study or team)

We are requesting your email and text messaging number for a couple of reasons. First, we can email you a summary of the information we just discussed, or we can send it in the mail. We also would like to email you reminders about study calls, and provide additional study information via email. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email messages. You should avoid sending sensitive, detailed personal information by email. Email messages should also not be used to convey information of an urgent nature. Please tell me which of these statements about messages are true for you:

Would you like me to email or mail you the summary of what we just discussed?

_____ Mail
_____ Email (what is your email address? _____)

Email

_____ Yes, you may use email to contact me for this study.

_____ No, I do not want to be contacted by email.