The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization for spousal caregivers and noncaregiving adults

Study Title: The CARE Study: Caregiving for a Spouse with a Memory Disorder

Principal Investigator: Janice Kiecolt-Glaser, PhD

Sponsor: National Institute on Aging, National Institutes of Health

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study focuses on how the stresses of caring for a spouse or partner with a memory disorder affects the immune system (certain kinds of white blood cells that protect against infections and cancer), as well as risk for depression and anxiety problems. Participants will either be living with a spouse or partner who has a previously diagnosed memory disorder ("caregivers"), or they will take part as a "control" or noncaregiving participant, that is, a person who is married/partnered but who is NOT providing any care to an impaired family member. Data from caregivers and noncaregivers will be compared to see if there are differences related to the stresses of caregiving.

1. Why is this study being done?

To help scientist and physicians understand how longer-term stress affects the immune system.

2. How many people will take part in this study? 546

3. What will happen if I take part in this study?

At your first visit you will be interviewed, you will complete questionnaires, and you will have your blood drawn. About a year after your initial interview, you will have a second appointment, and a final appointment a year after that. At each of these annual appointments, blood samples will be again be drawn, and you will complete questionnaires and participate in interviews; these appointments will take 2-2.5 hours. Each of the procedures is described in more detail below.

At each of these annual visits 2.37 oz., or just over 1/4 cup of blood will be drawn from your arm to be used for immunological studies. The total amount that will be drawn across 2 years for the entire study will be 7.11 oz, or just under a cup, with at least 10 months between blood draws.

In the first interview you will be asked about depression and anxiety symptoms and health problems experienced over your lifetime; in subsequent years after the first visit, you will be asked about depression and anxiety symptoms and physical health problems experienced during the year since the last interview. The interviews will be audiotaped; the tapes will be stored online in a secure site, and will be erased once they have been transcribed (typed) and coded.

At each yearly appointment you will be asked to complete questionnaires with questions of a personal nature regarding your medications, health conditions, mood, feelings, health behaviors, personality, and your relationship with your partner.

At the end of each annual appointment, as part of standard procedures, you will be given a list of psychological counseling services should you wish to talk with someone at that time or in the future about any problems you're having.

You will be asked to perform simple physical performance tasks to assess frailty (weakness). To assess grip strength, you will be asked to squeeze a handheld device. You will also be asked to walk a 14-foot distance at your usual walking speed. Then, you will be asked to rise from a chair as quickly as possible with your arms across your chest.

Women who are pregnant or nursing cannot participate in this study. If you believe you may be pregnant, please inform the researchers.

We will request your spouse/partner's permission to access his/her medical records related to memory changes.

No medical report will be added to your medical records based on any part of research participation. Blood samples will not have identifying information such as name, initials, or address, only a code number. The blood samples will be stored with the same code number that is used on all the questionnaires and other forms that have been completed; the results of the testing will be kept confidential and will not be released. Names and other identifying information will be kept separate from the samples. Your name will not be in any publications or reports about this research; only group results, with no personal code number or other identifiers, will be reported.

4. How long will I be in the study?

You will have three appointments spread across two years. Each appointment will take 2 to 2.5 hours.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, 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 future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

With the blood draws you may experience bruising at the draw site, infection, pain, and fainting. Personal questions from the interviews and questionnaires may make you uncomfortable or could produce stress. Should you reveal suicidal intent, investigators are required to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk for harm to yourself or others. We are required by law to report child and/or adult abuse.

7. What benefits can I expect from being in the study?

There are no direct benefits you can expect from being in the study. However, your participation will help scientists and physicians understand the toll that stress takes on the body.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs for taking part. If you have to park for a study visit, we will cover the cost of your parking at the medical center.

10. Will I be paid for taking part in this study?

You will receive $60 for your time for your first visit, $65 for your second visit, and $70 for your third visit.

By law, payments to participants are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?

Your de-identified information might be shared with other researchers at the end of this study if requested. The researchers would not know your name, your address or phone number, or any other information that would identify you.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;

- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you. If a complete blood count is performed and we find abnormalities, we will notify you by a phone call or an email.

The National Institutes of Health (NIH) issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if NIH requests the information, or if the FDA tells us to release this information.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Please visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

II. Who may use and give out information about you?

- Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor; or
- owned by the sponsor.

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

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

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Janice Kiecolt-Glaser PhD at 614-293-3499, Institute for Behavioral Medicine Research, Ohio State University College of Medicine, 460 Medical Center Dr, Room 130, Columbus, Ohio 43210-1257

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Manager, The Ohio State University Medical Center, Suite E2140, 600 Ackerman Road, Columbus, Ohio 43202

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Janice Kiecolt-Glaser PhD at 614-293-3499.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	Signature of participant

	AM/PM
Date and time	
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time