OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 17966

Clinical Research Consent Summary

TITLE: Feru-guard (ferulic acid and Angelica archangelica extract) for behavioral symptoms in dementia

PRINCIPAL INVESTIGATORS: Sarah Goodlin, MD (503) 220-8262 ext.58585
Lynne Shinto, ND, MPH (503) 494-5035

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to learn more about the ways to improve or prevent decline in behavioral and psychological symptoms of dementia.
2. In this study, we will learn about a dietary supplement called "Feru-guard," a combination of ferulic acid and Angelica archangelica. **Feru-guard will be called "the study supplement" throughout this form.** We want to learn:
    a. If the study supplement is able to improve or prevent worsening of dementia-related behavioral and psychological symptoms, and
    b. if improvement of behavioral and psychological symptoms caused by the study supplement decreases caregiver-stress.
3. The study supplement is being developed by Glovia, Co. Ltd., and the company is paying for the research study.
4. We do not know if the study supplement works.
5. The study supplement has not been approved by the Food and Drug Administration (FDA).
6. The study supplement is 1 capsule taken by mouth 2 times a day with meals.
7. You will have a 50% chance of receiving the study supplement vs. a placebo. A placebo is a hard gel capsule that looks like the study supplement but has no real medicine in it. Neither you nor the researcher will not know which one you get.
8. If you join the study, you will receive the study supplement or placebo for 12 weeks. You will have 3 visits to OHSU. We check on your health at each onsite visit.
9. There are minimal risks involved in participating in the study.
10. If you agree to participate, samples and information collected during the study will be saved by the sponsor and principal investigators only for the purpose of this study.
11. Samples collected during the study will be used for genetic research.

CO1450

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Clinical Research Consent and Authorization Form

TITLE: Feru-guard (ferulic acid and Angelica archangelica extract) for behavioral symptoms in dementia

PRINCIPAL INVESTIGATORS:	Sarah Goodlin, MD	(503) 220-8262, ext.58585
	Lynne Shinto, ND, MPH	(503) 494-5035
CO-INVESTIGATORS:	Jason David	(503) 494-9240

FUNDED BY: Glovia, Co. Ltd.

SUPPORTED BY: Glovia, Co. Ltd.

CONFLICT OF INTEREST*:* None

PURPOSE:
You have been invited to be in this research study because you have been diagnosed with Alzheimer's disease, vascular dementia or mixed dementia and are 55 years old or older.

The purpose of this study is to test if the study supplement is able to help reduce common behavioral symptoms in dementia that may include depression, anxiety, irritability, and apathy. We are also interested in whether the study supplement is able to reduce caregiver stress by improving these symptoms.

The study supplement is a capsule that contains a proprietary combination of nutrients derived from plants. The main ingredients in the capsule are ferulic acid from rice bran and Angelica archangelica, which is a plant.

The use of the study supplement for behavioral symptoms in dementia is experimental. The study supplement is not approved by the U.S. Food and Drug Administration (FDA), because we do not know enough about it and how effective it is.

This study requires 3 visits to the clinic and will take 12-14 weeks to complete.

CO1450

As part of this study we will conduct genetic testing on your blood samples. Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. There is a gene that can affect the levels of fats (cholesterol) in your blood and fat levels may be

linked to dementia severity. Because the study will see if the study supplement changes fat levels in your blood, we will need to know what type of this gene you have.

Up to 70 adults will be in the study at Oregon Health & Science University.

PROCEDURES:

This study requires one screening visit to help identify people we believe are best suited to receive this type of therapy and meet eligibility requirements. The screening includes a clinical evaluation. If you meet entry criteria for participation, you will be invited to attend 2 more visits to OHSU over 12 weeks. Our study staff will also check in with you by phone once between visits to see how things are going and to ask about your health. You will have time with Dr. Goodlin, Dr. Shinto, or their study staff at each visit to have your questions answered.

This is a randomized study. Neither you nor the investigators can choose whether you get the study supplement or the placebo. The placebo is a capsule that looks like the study supplement but has no real medicine in it. You will have a 50% chance of receiving the study supplement. You and the investigators will not know which capsules you are taking. The study is done this way because knowing whether you are getting the study supplement can change the results of the study. If you start having serious side effects from the study supplement, the investigators can find out which you are taking to help you. Please ask the investigator if you have any questions at all about this kind of study.

Description of study visits (see Study Event Schedule below)

Screening (Visit 1): This visit will take about 2.0 hours.
The visit takes place at OHSU. A study coordinator will go over the consent form with you and your study partner to make sure that you understand what will happen when you participate in this study. You and your study partner will sign a consent form if you agree to participate in the study.

We will ask for information about your medical history and your age, highest education level attained (for example high school diploma or college degree), race and other characteristics about you that we call demographics. This is a long form and if you do not complete at this visit you can take it home and bring back the completed form at your next visit.

You will have a physical exam, including vital measures (for example, weight and blood pressure). We will ask you about any medications you are currently taking.

We will check your memory and thinking using standard tests, and we will ask your study partner questions about your memory and how you are doing in general. All of this information will tell us whether you are eligible to be in the study. If you qualify for the study at this screening visit the study coordinator will schedule a return visit within 14 days. If you do not qualify for the study we will compensate you for your time at this visit.

Baseline (Visit 2): This visit will take about 1.5 hours.
This visit will be at OHSU, within 14 days of the screening Visit 1. At the baseline Visit 2, we will learn more about your physical and mental function. We will test different aspects of your mental function, including concentration, memory, and problem solving, we will also ask you or your study partner to fill out a brief questionnaire about the foods you eat. We will check your vital signs and draw about two tablespoons of blood, to run laboratory tests that tell us about your

general health and about one gene that is associated how cholesterol is processed in your body that is associated with Alzheimer's disease. We will also ask your study partner some questions about their general well-being. We will record information about your medical conditions and any medications you are taking. At the Visit 2 we will give you a 12-week supply of either study supplement or placebo, we do not know which you have received.

Phone call (Visit 3): This visit will take about 30 minutes.
This visit will take place over the phone, about six weeks after Visit 2. The study Coordinator will call to ask you and your study partner about your general health, and if there are in changes in the medications you are taking. They will ask you how the study supplement is going. The study coordinator will then schedule your final study visit.

Week 12 (Visit 4): This visit will take about 2.5 hours.
This visit will take place at OHSU, and will be your last visit. You will have a physical and neurological exam. We will take your vital signs and draw about 2 tablespoons of blood to run laboratory tests that tell us about your general health. We will also ask you or your study partner to fill out a brief questionnaire about the foods you eat. We will measure your physical and mental function, including concentration, memory, and problem-solving. You will return any unused study medication. We will check to make sure you have been taking the study medication and ask you and your study partner about your general health since your last visit. We will also ask your study partner some questions about their general well-being. We will also ask you and your study partner if you know what study medication you were taking.

The following chart summarizes the activities that will occur over the course of this study:

Visit Number	Visit 1 Screen	Visit 2 Baseline	Visit 3 Week 6-Phone	Visit 4 Week 12
Trip to OHSU	X	X		X
Physical / Neurological exam	X			X
Vitals	X	X		X
Blood Draw		X		X
Mental Function Questionnaire	X	X		X
Food Questionnaire		X		X
Dispense Medication		X		
Health Check		X	X	X
Count Pills				X

If you have any questions regarding this study now or in the future, contact the site Principal Investigator Dr. Goodlin at (503) 220-8262 or the Study Coordinator Jason David at (503) 494-9240.

ACCESS TO YOUR TEST RESULTS:
We do not plan to share your research test results with you or your primary care provider. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and your primary care provider to inform you of test result. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory.

SUBJECT ACCESS TO GENETIC INFORMATION:
The research results of these studies will not be made available to you unless specifically requested because this research is in an early phase and the reliability of the results is unknown. No information may be disclosed to anyone other than you without your permission.

RISKS AND DISCOMFORTS:
You may have some side effects we do not expect because we are still learning about Feru-guard.

The daily dose of Feru-guard is 3 grams. There are some mild side effects known to be associated with Feru-guard including stomach upset, constipation, or diarrhea.

The placebo consists of a common starch-based food additive (maltodextrin), and possible side effects include allergic reactions, unexplained weight gain, bloating and flatulence.

We do not know how Feru-guard interacts with different medications, so investigators will carefully review all the drugs you are taking before giving you a study supplement. You must not be in the study if you are taking warfarin (Coumadin) or some other anticoagulants because two of the ingredients in Feru-guard are known to have anticoagulant properties. We do not know how anticoagulant drugs interact with the study supplement and do not want to increase any risk of bleeding. It is okay to be in the study if you take aspirin or other anti-inflammatory drugs like Advil or Aleve. The study monitors for increased bleeding at in-clinic visits for safety. If any other health care provider prescribes any new drug(s) for you while you are in the study, please tell the investigator before taking the new drug. You could also have the provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter drugs while you are in the study unless you first check with the investigator. If you notice any new symptoms after starting the study supplement, you should notify a study coordinator or Dr. Goodlin.

We will draw blood from your arm. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

Some of the questions we ask you (for example, questions about your mood) may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you find a counselor.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and Federal law, there is still a small chance that you could be harmed if a release occurred.

BENEFITS:
You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:
You may choose not to be in this study. Your participation is completely voluntary.

CONFIDENTIALITY:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Research records linked with personal information will be coded with a unique identification number to insure confidentiality and will contain no personal identifiers. Only the investigators and people involved in the conduct of the study will be authorized to link the code to you.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The study funder, Glovia Co. Ltd., and the funder's representatives
- The Office for Human Research Protections, a federal agency that oversees research involving humans.
- The Data and Safety Monitoring Board that independently monitors safety throughout the study.

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

COMMERCIAL DEVELOPMENT:
Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

COSTS:
There will be no cost to you or your insurance company to participate in this study.

The research study will pay for costs associated with study visits, study supplement, laboratory tests, and questionnaires (including envelope postage). You will receive $20.00 for each completed visit. If you withdraw or are removed from the study, you will be paid for the visits you complete. We may request your social security number in order to process any payments for participation.

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. We may request your social security number in order to process any payments for participation.

LIABILITY:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Goodlin at (503) 220-8262 ext.58585.

If you are injured or harmed by the study supplement, or study procedures you will be treated. Your medical treatment will be provided at no cost to you or your insurance company if the injury is directly caused by the study supplement, or study procedures and would not have been expected from the standard treatment for your condition, progression of your condition or other reasons. Any medical treatment you need for the standard treatment for your condition, progression of your condition, or other reasons will be billed to you or your insurance.

OHSU and the funder do not offer any other financial compensation if you are injured or harmed as a result of participating in this research. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Sarah Goodlin at (503) 220-8262 ext. 58585 or the study coordinator Jason David at (503) 494-9240.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information.

If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Lynne Shinto, ND, MPH
3181 SW Sam Jackson Park Rd, CR120
Portland, Oregon 97239
Email: shintol@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your stored blood samples, questionnaires, and other clinical and medical information used for the study but the material will not be destroyed and we will continue to use it for research.

You may be removed from the study for any of the following reasons: if the investigator stops the study, if the sponsor stops the study, if you develop serious side effects, if your health condition prevents you from continuing the study. If you stop being part of this study, the investigator or one of the staff members will talk to you about any medical issues regarding the stopping of your participation. If you choose to stop participation in the study before the end you will be requested to complete a treatment discontinuation visit for safety reasons. This evaluation will include the procedures normally performed at visit 4.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Signature	Subject Printed Name	Date
Person Obtaining Consent Signature	Person Obtaining Consent Printed Name	Date

Authorized Representative for Research (Study Partner) Signature	Authorized Representative for Research (Study Partner) Print	Date

Authorized Representative's Relationship to Subject