UF | Institutional Review Board
UNIVERSITY of FLORIDA

# INFORMED CONSENT FORM
***to Participate in Research, and***

# AUTHORIZATION
***to Collect, Use, and Disclose Protected Health Information (PHI)***

## INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

## GENERAL INFORMATION ABOUT THIS STUDY

**1. Name of Participant ("Study Subject")**

_____

**2. What is the Title of this research study?**

Does dietary supplementation with curcumin maintain or improve physical and cognitive function in aging adults at increased risk for disability? (SPICE Study)

**3. Who do you call if you have questions about this research study?**

Principal Investigator: Steve Anton, Ph.D. Department of Aging and Geriatric Research (Telephone 352-273-7514 Dr. Robert Mankowski at 352-2945055 or 407-818-7308-413-0592 (24-hour cell phone number).

Other research staff: Study Coordinator (Telephone 352-273-9212)

## 4. Who is paying for this research study?

The sponsor of this study is The University of Florida Claude D. Pepper Older Americans Independence Center (funded by the National Institutes of Health)

## 5. Why is this research study being done?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

**a) In general, what is the purpose of the research, how long will you be involved?**
The purpose of this research study is to test whether curcumin (a part of turmeric - spice used in Middle Eastern and Asian cooking), taken as a daily dietary supplement, maintains or improves thinking processes (cognition) and physical function in older adults, particularly those who are at risk of functional decline. You will be in this study for approximately 4 months.

**b) What is involved with your participation, and what are the procedures to be followed in the research?**
Participants are assigned by chance to take either curcumin or a “placebo” (identical pill without curcumin or “sugar pill”) for 3 months, and changes in measures of physical and cognitive abilities, and blood markers of inflammation are compared between the two groups.

**c) What are the likely risks or discomforts to you?**
The risks are minimal as the study "medication" is a dietary supplement readily available over the counter and currently in use as a supplement to prevent and/or control osteoarthritis at doses similar to or higher than those used in this study. This product received GRAS (Generally Recognized as Safe) status in 2009.

Blood draw, questionnaires, physical performance tests are a usual part of daily life and health examinations and considered minimal risk.

**d) What are the likely benefits to you or to others from the research?**
It is possible that participants assigned to receive curcumin may have some general health benefits, such as improvement in arthritis, but this is not for sure. Its use as a dietary supplement could help others preserve mental and physical abilities as they grow older and prolong independence.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**
The option if you do not want to participate in this study is to do nothing.

*Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study*

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.

## WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

### 6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Participation in this study is not a part of your regular clinical care. Your clinical care will not be affected by the participation in this research.

### 7. What will be done only because you are in this research study?

This study involves a Baseline visit followed by 3 monthly visits with approximate time of 2 hours for each visit.

**At the Baseline visit:**

- The Study Coordinator will review this Informed Consent document with you and answer any questions you have about the study. You will be asked to sign this Informed Consent and given a copy for your records.
- Approximately 60 mL (about 2 tablespoons) of blood will be drawn. This will be used to study a variety of substances in the blood that may relate to inflammation and to make sure that it is safe for you to participate in this study. Your vital signs (blood pressure, pulse), weight, and waist circumference will be measured.
- You will be asked to perform a walking test over about 400 yards to determine your normal walking speed. You may use a cane for this test but not a walker or other assistive device. You will be asked to repeat the short battery of physical function tests from your second Screening visit. You will have tests of the strength of your leg muscles and of the grip strength in the hand you use the most.

- You will be asked to complete several questionnaires that ask about your thoughts, feelings, activities of daily life, if you have any pain and a few questions about your diet.
- You will be asked to complete a few assignments on paper and on computer that test your memory, thinking process and concentration.
- If you decide to take part in this study, you will be randomly assigned, much like the flip of a coin, to receive either curcumin or placebo as a dietary supplement. This means:
    - A placebo is a substance that looks like and is given in the same way as an experimental supplement but contains no active ingredient, for example , a “sugar pill;”
    - A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits or be exposed to the risks of the curcumin, if there are any (any risks or benefits are described below).
    - You will have a 1 in 2 chance of receiving curcumin and a 1 in 2 chance of receiving placebo. In the remainder of the Consent Form, both the curcumin and the placebo will be called the “study supplement.”
    - You and the investigator and his team who doing the study will not know whether you are receiving placebo or curcumin, but that information is available if it is needed.
- You will be given a month’s supply of the study supplement with clear instructions for how to take it.
- You will receive a telephone call from your Study Coordinator about 2 weeks after your visit to ask about any side effects or health problems you have experienced since the Baseline visit.

**<u>At the Monthly Visits (Months 1 and 2)</u>**

- The Study Coordinator will ask you about any changes in medications, symptoms, illnesses, Emergency Room visits, or hospitalizations you have experienced since your previous visit.
- Your vital signs (blood pressure, pulse), weight, and waist circumference will be measured.
- Approximately 30 mL (about 1 tablespoon) of blood will be drawn. This will be used to make sure the study supplement is not affecting your blood chemicals.

- You will be asked to perform a walking test over about 400 yards to determine your normal walking speed. You may use a cane for this test but not a walker or other assistive device. You will be asked to repeat the short battery of physical function tests from your second Screening visit.
- You will be given a month's supply of the study supplement with clear instructions for how to take it and a new pill diary
- You will receive a telephone call from your Study Coordinator about 2 weeks after your visit to ask about any side effects or health problems you have experienced since the previous visit.

**At the Month 3 Visit (final study visit):**

You will be asked to repeat many of the tests performed at the Baseline visit to provide a comparison with the baseline results.

- The Study Coordinator will ask you about any changes in medications, symptoms, illnesses, Emergency Room visits, or hospitalizations you have experienced since your previous visit.
- Your vital signs (blood pressure, pulse), weight, height and waist circumference will be measured.
- Approximately 60 mL (about 2 tablespoons) of blood will be drawn. This will be used to study a variety of substances in the blood that may relate to inflammation and to make sure the study supplement has not affected your blood chemicals.
- You will be asked to perform a walking test over about 400 yards to determine your normal walking speed. You may use a cane for this test but not a walker or other assistive device. You will have tests of the strength of your leg muscles and of the grip strength in the hand you use the most.
- You will be asked to complete several questionnaires that ask about your thoughts, feelings, and activities of daily life.
- You will be asked to complete a few assignments on paper and on computer that test your memory, thinking process and concentration.
- You will be asked to give your pill diary from the previous month to the Study Coordinator and to return your bottle of study supplements with any remaining pills.

Telephone Follow-up: You will receive a telephone call about 3-4 weeks after the Month 3 visit to ask about your health and review any problems you have had since stopping the study supplements.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

**If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form**

**8. How long will you be in this research study?**

You will be in the study for about 4 months.

**9. How many people are expected to take part in this research study?**

We are planning to screen 500 people and expect that about 24 persons complete the study.

## WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

**10. What are the possible discomforts and risks from taking part in this research study?**

Risks associated with the study supplement. Curcumin is a component that is extracted from a spice called turmeric root. Turmeric has been used in cooking (e.g., curry), as dietary supplements, and to treat inflammatory conditions in the Middle East and India for centuries. Curcumin is available commercially through most health food stores and is generally considered safe at the doses used in this study.

The most common side effects of curcumin (occurring in more than 10 out of 100 persons taking the supplement) are gastrointestinal (stomach) and include mild nausea, vomiting, diarrhea, acid reflux (heartburn), and bloating. These occur more often at high doses of curcumin and resolve with stopping the supplement. In a large study comparing curcumin to ibuprofen to treat arthritis, about 10 – 12% of participants taking curcumin experienced abdominal discomfort or distension, acid stomach (dyspepsia) or loose stools. These side effects occurred to the same extent in participants taking ibuprofen.

Some studies in animals have suggested that curcumin may change the way your body processes other medications. However, this effect has not been reported in humans.

To minimize these risks, Study coordinators will review your medications and note any changes at each monthly visit. They will also ask about side effects that you may have experienced. In addition, blood tests will be performed at monthly visits to make sure there are no changes in blood chemicals related to the study supplement. You will be notified of any changes in blood chemicals, and, if they may be related to the study supplement, you will be asked to stop the supplement until your next visit.

Risks associated with the blood draw. The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. To minimize these risks, study staff are trained to draw blood properly and use measures to prevent complications.

Risks associated with blood pressure measurement. The risks of placing a blood pressure cuff on a participant's arms are that it may cause pinching or slight bruising. To minimize these risks, study staff are trained to measure blood pressure appropriately.

Risks associated with cognitive (thinking) function tests. There is a risk that you will find memory and concentration tests stressful. You might feel tired or sad because it may be difficult to remember things that you are asked to remember.

To lessen these risks, research staff will explain what to do during the tests. You may skip any question you do not wish to answer. There is no right or wrong answer on these tests, and test scores by themselves do not mean that you have a problem with your memory or mental abilities. You may ask for a short rest if you become tired.

Risks associated with physical performance tests. There is a risk of losing your balance and falling associated with the physical performance-based testing (e.g., the ¼ mile walk test, balance tests, rising from a chair) and participation in physical activity. Falling also places you at risk for a bone fracture. There is also a risk of soreness in muscles or of injury to muscles or tendons/ligaments.

To lessen these risks, you will be safely escorted to chairs located along the walking course should you become unsteady. A Study Coordinator will follow you at a close distance during the walking tests and will be at your side during all the physical tests, should you need assistance.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you.

If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

**11a. What are the potential benefits to you for taking part in this research study?**

Various health benefits have been attributed to curcumin; however, most of these are not scientifically established. So it is possible that participants assigned to receive curcumin may have some general health benefits, such as improvement in arthritis, but this is not for sure.

**11b. How could others possibly benefit from this study?**

If curcumin is effective in slowing or improving functional decline in older persons, its use as a dietary supplement could help preserve mental and physical abilities as we grow older and prolong our independence.

**11c. How could the researchers benefit from this study?**

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

**12. What other choices do you have if you do not want to be in this study?**

The option if you do not want to participate in this study is to do nothing. If you do not want to take part in this study, tell the Principal Investigator or research staff and do not sign this Informed Consent Form

**13a. Can you withdraw from this study?**

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

**13b. If you withdraw, can information about you still be used and/or collected?**

If you withdraw from this study, no further information will be collected. However, information that has already been collected, became a part of this study and is required to retain the study integrity.

**13c. Can the Principal Investigator withdraw you from this study?**

You may be withdrawn from the study without your consent for the following reasons:

- If the Principal Investigator or study physician decide that your participation in the study could be harmful to you
- If you develop a medical condition or need treatment not allowed in the study
- If you do not follow study instructions
- If the study is canceled
- For other administrative reason

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**14. If you choose to take part in this research study, will it cost you anything?**

**Study Drugs**

Curcumin Supplement will be provided at no cost to you while you are participating in this study.

**Study Services**

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Anton at 352-273-7514 or a study coordinator Ms. Elaine Norat at 352-273-9212.

**Items/Services Not Paid for by the Sponsor**

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

**15. Will you be paid for taking part in this study?**

You will receive $50 for completion of the Baseline visit, $25 for completion of each monthly visit (Months 1 and 2), and $50 for completion of the Month 3 visit. Thus the greatest amount you can receive for participation in this study is $150.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

**16. What if you are injured because of the study?**

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Bhanuprasad Sandesara at 352-273-9212 or 412-607-3914 (24-hour cell) if you experience an injury or have questions about any discomforts that you experience while participating in this study.

**17. How will your health information be collected, used and shared?**

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name
- Contact information
- Date of Birth
- Social Security Number (for compensation purposes)
- Information about your past and current medical history
- Medications you are taking
- Results of the tests of physical function
- Information from the questionnaires about your habits, perceptions, pain, some dietary habits and usual activities
- Results of the tests of how you think and process information
- Results from the laboratory studies

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

**18. For what study-related purposes will your protected health information be collected, used, and shared with others?**

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purposes:

- To test whether curcumin, taken as a dietary supplement, maintains or improves cognitive and physical function in aging adults;
- To test whether curcumin's effects on physical and mental function are related to effects on inflammation; and
- To help in planning other studies testing curcumin's effects on aging.

This information will be stored in locked filing cabinets. Once this information is collected, it becomes part of the research record for this study.

**19. Who will be allowed to collect, use, and share your protected health information?**

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

**20. Once collected or used, who may your protected health information be shared with?**

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies that are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order.

It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

**21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?**

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

## SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

| Signature of Person Obtaining Consent and Authorization | Date |
|---|---|

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

| Signature of Person Consenting and Authorizing | Date |
|---|---|