CT.GOV Cover page

Study Title: A phased clinical trial of dietary supplemental kava: kava pharmacokinetics

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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: _____

## GENERAL INFORMATION ABOUT THIS STUDY

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

   _____

2. **What is the Title of this research study (this "Research Study")?**

   A phased clinical trial of dietary supplemental kava: kava pharmacokinetics

3. **Whom do you call if you have questions about this Research Study (the "Study Team")?**

   Principal Investigator: Carol A Mathews MD (352) 294-4900

   Other research staff: Robyn Nelson (352) 294-5563

4. **Who is paying for this Research Study?**

   The sponsor of this study is the National Institutes of Health

5. **In general, what do you need to know about this Research Study?**

   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 main purpose of this research is to better understand how your body processes the dietary supplement kava. You will be in this study for 12 weeks.

**b) What is involved with your participation, and what are the procedures to be followed in the research?**

You will complete an initial screening visit which will include a blood draw, collection of vital signs, questionnaires to assess mental health and medical history, urine drug screen and urine pregnancy screen (for women of child bearing potential) to determine your eligibility. This visit should take approximately 2 hrs. Once you have completed the screening visit and have met criteria for the study, you will return to the CRC for a12 hour visit where you will take kava capsules and complete 10 blood draws. After this visit, you will return for 4 follow up visits (1, 4, 8, 12 weeks) for a single blood draw.

**c) What are the likely risks or discomforts to you?**

You may experience nausea and fatigue after taking kava. Some individuals may experience soreness and possibly dizziness during blood draws. Although in very rare cases, use of kava has been shown to cause liver problems, this study uses a form of kava that does not contain the compounds that are thought to cause liver damage.

**d) What are the likely benefits to you or to others from the research?**

There are no direct benefits to you for participating in the research.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**

Only healthy volunteers that do not require clinical care or treatment will participate in this study. An alternative option would be to not 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.

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.

## 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)?**

There will be no change to your clinical care as part of this study. Only healthy volunteers will participate in the study.

**7. What will be done only because you are in this Research Study?**

The screening visit will include the review and signing of this informed consent document, physical exam, a blood collection to test if your genetics effect the way your body uses the study drug and your basic metabolic and liver function, a urine drug screen, a urine pregnancy screen for women of child bearing potential and screening questionnaires to assess for psychiatric disorders, your medical history, and demographic information.

You must meet the following criteria to be eligible for participation in the study (a) be between the ages of 18 and 50 years (b) Females of potential childbearing status must complete a pregnancy test to confirm you are not pregnant. You will be excluded if any of the following are true at the time of screening or the 12-hour visit: (a) You are currently taking any medication other than contraception or supplement other than vitamins. (b) Have a history of liver disease or currently have liver disease. (c) Your blood tests reveal an issue with your liver function. d) You have a current active medical, psychiatric, or neurological condition (f) Have a positive urine drug test (g) are a current smoker, (h) are unable to abstain from alcoholic beverages for the duration of the study visit and 72 hours prior to your baseline visit date. Individuals who have an abnormal or elevated liver function test will be excluded from the study. All abnormal test results will be reviewed by the study's medical monitor. Individuals will be referred to their primary care provider for follow up examination and care advice if appropriate. No treatment will be offered by the study team as a result of the testing performed as part of the screening procedures.

For the baseline visit, you must abstain from food and liquid other than water for 12 hours prior to the 12 hour CRC visit.

You will stay in the out-patient Clinical Research Center (CRC) at the CTSI during the 12-hour study period. You will have a catheter placed in your lower arm to allow for multiple blood sample collections during the study. You will take three 75 mg kava capsules and have your blood drawn nine times during your 12-hour visit. Specifically, 2 milliliters, which is less than 1/2 teaspoonful of blood, will be withdrawn at the beginning and again 0.5, 1, 2, 3, 4, 5, 6, 8 and 12 hours for a total of about 2 tablespoonfuls of blood, after you take the kava. You will be followed for a full 12 weeks after your last kava ingestion. You will return to the CRC to provide a single blood sample to test your liver 1, 4, 8, and 12 weeks after your 9 hour visit.

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 this Research Study, please contact one of the Research Team members listed in question 3 of this form.

**8. What identifiable health information will be collected about you and how will it be used?**

The Research Team will collect your name, address, date of birth, phone number, complete medical history, social security numbers, and medication use.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

**9. With whom will this health information be shared?**

This health information may be shared with:

- the study sponsor (National Institutes of Health);
- United States governmental agencies which 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 which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

**10. How long will you be in this Research Study?**

Your participation in this research study will last 12 weeks.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

**11. How many people are expected to take part in this Research Study?**

In total, 10 people will complete this research study.

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

**12. What are the possible discomforts and risks from taking part in this Research Study?**

In the past, kava use has very rarely been associated with liver toxicity, including liver failure. The reported risk of liver toxicity occurring with a single dose is less than 1 per million. This study has minimized this already very low risk by using a form of kava that does not include the chemicals that are thought to have caused the liver problems in the past. Nevertheless, we will carefully monitor you for any signs or symptoms of liver problems. We will closely monitor your liver after you take kava. We will test your liver at weeks 1, 4, 8 and 12. Although the timing of any potential liver toxicity with kava is not known, symptoms related to liver toxicity include nausea and fatigue. It is likely that if you experience these symptoms, it will be between 2 weeks and 12 weeks after your 12 hour visit. You are encouraged to contact the study team for any concerning symptoms that you may have for up to 6 months after taking kava to ensure that no delayed reactions, no matter how unlikely, are missed. We will carefully educate you about symptoms to watch for throughout the study and following treatment. You will be free to discontinue your participation at any time if you feel that it is causing unacceptable distress or discomfort.

A venous indwelling catheter (often called an IV) will be used to perform blood collection at baseline and 0.5, 1, 2, 3, 4, 5, 6, 8 and 12 hours after taking the dose of kava. The risks associated with an IV include pain at the puncture site, swelling, clotting, bruising, and rarely infection. An aseptic technique will be used to place the catheter and all precautions will be taken to prevent clotting, infection, and discomfort.

It is possible that answering questions about your state of mind may increase feelings of sadness you might already have. If this should occur, you may stop the testing at any time. You may also refuse to answer questions or to complete a questionnaire if you find them too upsetting. Should you confirm questions about depression or suicidality in any of the questionnaires you may be asked follow up questions to assess your risk of self-harm. If you show significant risk of harming yourself research staff will escort you to emergency services to receive care.

All research material will be treated in a confidential manner and only research staff will have access to the data. Confidentiality will be maintained by assigning a unique ID number to your sample and data; all data entered into computer databases will use only this identifier. This consent form and the key for identification of your name

corresponding to your ID number will be stored in a separate file cabinet. Your name and files are kept confidential and your name will not be used in the data files, only identifying codes. Once the study is complete, the code will be destroyed and all of your data will be de-identified.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer. In some states, such as Florida, upon your request, your DNA information will be made available to your physician.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a 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.

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

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot

withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

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.

**13a. What are the potential benefits to you for taking part in this Research Study?**

There are no direct benefits to you for participating in this research.

**13b. How could others possibly benefit from this Research Study?**

Participation in this study could advance our understanding of how the body processes kava and eventual lead to new insights into more innovative approaches to the treatment of pathologic anxiety.

**13c. How could the Research Team members benefit from this Research Study?**

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

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

This is not a treatment study. Taking part in this research study is voluntary. Your alternative is to not take part in the study. If you choose to not take part, your Healthcare at the University of Florida will not be affected.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

**15a. Can you withdraw from this study?**

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

**15b. Can the Principal Investigator withdraw you from this Research Study?**

You may be withdrawn from this Research Study without your consent for the following reasons:

1. You have a serious or unexpected adverse event.
2. You become pregnant.
3. Study doctors decide it is not in your best interest to continue the study.
4. You do not or cannot adhere to the instructions provided to you.
5. The IRB decides to stop the study early.

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**16. If you choose to take part in this Research Study, will it cost you anything?**

**Study Drug**

Dietary supplement Kava and its administration 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 Carol A. Mathews MD (352) 294-4900 or Robyn Nelson (352) 294-5563.

**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.

**17. Will you be paid for taking part in this Research Study?**

At the completion of all study visits you will be given a $150 gift card.

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, 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 and your information will be coded with that number to protect your identity.

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

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.

**18. What if you are injured while in this Research 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 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 and study physician will review your situation together and consult the IRB to determine whether your injury is related to your participation in this study.

No additional compensation is 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 one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.*

## 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 above. By signing this form, you are not waiving any of your legal rights.

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