



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")?

Clinical implementation pilot of preemptive pharmacogenetic testing in medically underserved patient populations

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

Principal Investigator: Julio Duarte, PharmD, PhD; Phone: 352-273-8132

Study Coordinator: Joshua Terrell; Phone: 352-294-5644

Asia Cobb; Phone: 352-273-6314

4. Who is paying for this Research Study?

The sponsor of this study is University of Florida Clinical and Translational Science Institute's Learning Health System Initiative.

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 purpose of this research is to find out if information about a patient's genetic make-up that is available before drugs are prescribed affects how doctors manage medication prescribing and improve patients' satisfaction with their prescriptions. Your participation in the study will last about 6 months.
- b) What is involved with your participation, and what are the procedures to be followed in the research?** You will be asked to provide a DNA sample (from your mouth) and genotype data will be reported in your medical record for your doctor to review. We will also collect some information about your demographics, medical history and your medications. Lastly, you will be asked to complete a survey 3 times within 6 months.
- c) What are the likely risks or discomforts to you?** There are few risks to you. The most likely risk is that some of your health information is accidentally released, but we have safeguards in place to guard against this risk.
- d) What are the likely benefits to you or to others from the research?** You may not benefit directly. However, the information learned from your participation in the study may be applied to future patients
- e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?** The alternative to genetic testing is not doing genetic testing, which is what is usually done today.

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)?

You will receive the same clinical care to manage your medications that your doctor would normally provide.

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

If you choose to participate in this study you will be asked to provide a 2 ml (one-half teaspoon) saliva sample by spitting into a special tube or cheek tissue by using a soft brush or swab. This saliva or cheek sample will be used to collect your DNA. Your genetic make-up will be determined from the DNA in your saliva or cheek cells. Your genetic test results will be shared with your doctor and placed in your medical record. Your results may influence what medications your doctor prescribes for you in the future. If your first DNA sample does not produce results, we will mail you



a DNA collection kit for re-collection of your DNA to test again. This is so that your genetic results can be available to your doctor before your next clinic visit.

You will be asked to complete a short survey about 3 months after you give your DNA sample, and again in another 3 months. The questionnaires can be completed with the study coordinator in the clinic, by telephone, or electronically through a link sent to you by text message to your cell phone or by email. The questionnaire will ask about how you take your medications, how satisfied you are with how they are working, and some additional demographic questions.

You may also be asked to complete a short (about 20-30 minutes) interview over the phone that asks questions about your thoughts about providing your doctor genetic test results to help him/her make decisions on what medications to prescribe you. Not everyone in this study will be asked to be interviewed and it is optional. If you do not complete an interview, you can still stay in this study.

We will also collect health and demographic information about from your electronic health records. This will include demographic data, your prescription records, laboratory data, and your medical history as it relates to your medication usage.

Once this research study is completed, any information that could identify you will 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 demographic information, medical history, laboratory test results and medication history.

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 (listed in Question 4 of this form);
- 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.

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.

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

Your participation in the study should last about 6 months. The Research Team may collect medication information from your medical records after this period.

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?

Up to 120 people are expected to participate in this 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?

There are few risks to participating in this study. The biggest risk is that your health or genetic information could be accidentally released. However, safeguards are in place to minimize the risk of this happening (discussed below).



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.

To help us protect your privacy, we have requested 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.

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.

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?

You may not benefit directly from taking part in this study. However, the information learned from your participation in the study may be applied to future patients.

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

Others might one day benefit by a decreased risk of side effects and/or improved effectiveness of certain medications, if they need to be prescribed.

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?

You can have the genetic test determined as part of your clinical care without participating in this study. This should be discussed with your doctor. You would be responsible for the cost of the test.

If you choose not to participate in this study, your doctor will continue to provide you with the best possible care without the use of your genetic information.

In the future, if you decide you do want your doctor to use your genetic information for medication management, please discuss this with your doctor.

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. 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:

- At the discretion of the Principal Investigator or study physician based on what is best for your health and safety
- If you do not complete required study surveys.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

No, there will be no additional costs to you or your health plan as a result of your participation in this study. The sponsor will pay for all health care costs related to your participation, including all required study items, services and procedures described in this consent form. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.

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

You will receive up to \$60 for your participation in this study: \$20 for completing the baseline survey, \$20 for completing the 6-month survey, and \$20 if you complete an optional interview.

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, and date of birth, 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.



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 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 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 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



Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

photographed video recorded audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Duarte, or his successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

The following will be **destroyed once the study is closed** (initial next to all that apply):

_____ photograph(s) _____ video recording(s) _____ audio recording(s)

As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

_____ photograph(s) _____ video recording(s) _____ audio recording(s)

As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

_____ photograph(s) _____ video recording(s) _____ audio recording(s)

Signature

Date