Trial of Preemptive Pharmacogenetics in Underserved Patients

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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?

Trial of Preemptive Pharmacogenetics in Underserved Patients (TOPP UP)

3. Whom do you call if you have questions about this study (the "study team")?

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

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

4. Who is paying for this study?

The sponsor of this study is the U.S. National Institutes of Health (NIH).

5. In general, what do you need to know about this study?

Research studies like this only include people who choose to take part. By signing this form, you are not waiving any of your legal rights. If you decide not to take part in this study, you will still get your regular medical care. 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 study? How long will you be involved?

The purpose of this study is to see if having information about a person's genes changes the medicine a doctor will prescribe them. We also want to see if having this information improves a patient's satisfaction with their medicines. Your taking part in the study will last about 12 months.

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

If you choose to be part of this study, we will take a sample of your blood or a cheek swab sample. The sample will provide information about your genes and how you process certain medicines. The results will be stored in your medical record for your doctor to review. We will also collect some information about you. For example, your medical history and what medicines you are taking. You will also be asked to complete 3 surveys over 12 months.

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

- Loss of private information
  To reduce this risk, electronic data will be stored in a local database. This database is password-protected and secured by the University of Florida. Any paper documents will be stored in a locked cabinet in a secure and private office.

- Blood Draw
  The risks of a blood draw include pain, bruising, and the slight possibility of infection at the location of needle insertion. Some participants may feel dizzy or may faint during or after a blood draw.

- Genetic Information
  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. 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. Additional information can be obtained at http://irb.ufl.edu/gina.html or by calling 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.

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

You may not benefit directly from this study. However, you and your provider may be able to make more informed decisions about your healthcare. We hope the information learned from this study will help other people in the future.

e) What are my other choices than taking part in this study?

Your provider can order the genetic test as part of your regular care without you being in the study. You are responsible for the test cost if it is ordered outside of this study.

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 take part in this study)?

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

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

If you choose to join this study, you will be asked to provide either a cheek cell sample by rubbing a soft brush on the inside of your cheek or a blood sample. The sample will be used to collect information about your genes and how you process certain medicines. If you decide to take part in this study, you will be randomly assigned (like flipping a coin) into one of two groups. If you are in Group 1, your sample will be tested right away and the results will go into your medical record. If you are in Group 2, your sample will be stored at the lab and no testing will be done until you finish the study (about 12 months after you start the study). In the rest of this form, the Group 1 will be called the immediate group and Group 2 will be called the delayed group.

Genetic Test results:

- Your test results will be shared with your doctor and placed in your medical record. If you are in the immediate group, your results will be stored in your medical record as soon as they are available. If you are in the delayed group, your sample will be stored at the lab and not tested until after you finish the 12-month study visit. Your results may help guide your physician on what medicines you take in the future. If your first sample does not provide a result, we will mail you a sample collection kit to collect a new sample for us to test again. We also may ask that you come to the clinic for a blood draw. This is so your test results can be available to your doctor before your next clinic visit.

- Study Surveys:

  You will be asked to complete 3 short surveys as part of the study. One survey when you start the study, one about 6-months later, and the last one at about 12-months after you start the study. These surveys can be completed in the clinic, by telephone, or through a link sent to you by email. The survey will ask about your medicines and how happy you are with how they are working.

- Interview (optional)

  You may also be asked to complete a short (about 20-30 minutes) interview over the phone or via zoom 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. Please note that this interview will be recorded and the recording will be destroyed once the study is closed. 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.

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

The study team will collect:

- Demographic data
- Medication records
- Laboratory results
- Medical history

The study team may collect this information from other healthcare providers, laboratories that are part of this study, as well as healthcare providers that are not part of this study (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 study 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 that 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 that 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 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 study?

Taking part in the study will last about 12 months. The study team may still collect medication information from your medical records after this period. Permission to use and share your health information expires at the end of the study unless you take it back sooner.

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

542 people are expected to take part 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 a few risks to participating in this study. The biggest risk is that your health or genetic information could be released by accident. However, safety measures are in place to minimize the risk of this happening. These safety measures are explained below.

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.

Other possible risks to you may include:
If you provide a blood sample for this study, the risks of a blood draw include pain, bruising, and the slight possibility of infection at the location of needle insertion. Some participants may feel dizzy or may faint during or after a blood draw.

Please note, that 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 study 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 study 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 study team members listed in question 3 in this form.

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

You may not benefit directly from taking part in this study. However, what is learned from your participation in the study may be used to help future patients.

13b. How could others possibly benefit from this 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 study team members benefit from this study?

In general, sharing 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 shared 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 same test completed as part of your regular 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 be in this study, your doctor will continue to give you the best possible care without the use of these test results.

In the future, if you change your mind and want your doctor to use a test like this to help manage your medications, please speak with your doctor.

You may also refuse to allow the use of your health information, but if you refuse, you may not be allowed to be in this study. Your decision not to sign this form 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 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 take part in this study for any reason, please contact the study 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 refuse permission by sending a written notice to the study team listed in question 3 of this form to let them know your decision. If you refuse permission, the study 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. However, if you refuse permission, you may not be able to continue in this study. Please discuss this with a member of the study team listed in question #3.

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

You may be withdrawn from this study without your consent for the following reasons:
At the decision of the Principal Investigator or study physician based on what is best for your health and safety. You could also be withdrawn if you no longer qualify for the study or if you do not complete the required study surveys.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

No, there will be no added costs to you or your health plan as a result of you taking part in this study. The study will pay for all health care costs related to your participation. This includes 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 study team. 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 study?

If you agree to take part in this study, you may receive up to a total of $75. You will receive a pre-loaded gift card and/or can receive a digital payment through Zelle in the amount of $25 after you complete each of the three study visits which occur when you start the study, at 6, and at 12 months after starting the study.

Participants who complete an optional semi-structured interview portion of the study will receive an additional $40 after completion, for a total of $115, based on how many surveys are completed.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on the amount of money you are paid) is protected. Access to the (RPP) 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 study?

If you are injured as a direct result of taking part 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 may 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 direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions the study team 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