NCT02133872

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?

Effect of Minocycline Treatment on Drug-Resistant Hypertensive Patients – Study 1

Subtitle: Brain-Gut Microbiome-Immune Axis in Hypertension

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

Principal Investigator: Dr. Carl Pepine (352) 273-9082 (during office hours)

Other research staff:

Dana Leach, DNP, ARNP-BC at (352) 273-8930 during office hours

Evenings, weekends, and holidays: call (352) 265-0111 and ask for the Cardiology Fellow on call.

4. Who is paying for this research study?

The sponsor of this study is 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?

Twenty to thirty percent of patients with high blood pressure (BP) have difficulty keeping it under control with medications. This is because their high BP is controlled by the brain and most known blood pressure medication drugs do not cross the blood-brain barrier to affect the responsible cells in the brain. The purpose of this study is to observe the effects of doses of the drug minocycline on your blood pressure to see if it might be a potential treatment for high blood pressure. This study will also help us to better understand how it works with the chemicals in your brain and if effective in lowering blood pressure, to determine the best dose to use in future studies of patients with high blood pressure. Minocycline is an FDA approved drug used to treat infections.

You are being asked to be in this research study because you have been diagnosed with high blood pressure that has been difficult to control. You will be involved in this study for 180 days.

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

You will have 10 clinic visits and 2 phone follow-up's. Clinic visits will involve various study activities that include but aren't limited to, physical exams, blood pressure measurements, blood draws, dispensing of study medication. All study activities are described in detail throughout this consent form.

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

Minocycline

The study medication is an FDA approved drug and is a well-tolerated antibiotic used every day to treat many different types of infections. Side effects of this drug may include abdominal cramping, diarrhea, nausea, dry mouth, headache or hypersensitivity (skin sensitivity after sun exposure, dizziness or mild skin rashes). Please inform the study doctor if you experience any of these side effects. New signs of infection e.g. fever, chills, persistent sore throat, oral thrush or new yeast infection; ringing in the ears. The drug can cause fetal harm when taken during pregnancy.

Risk of Blood Collection

The risks of drawing blood from vein and/or intravenous catheter (small plastic tubing inserted into your vein to obtain blood samples) include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection and uncommonly faintness from the procedure. Blood drawn for this study will be approximately 6 tablespoons over the 6 month duration of the study.

Risks of twenty-four hour ambulatory blood pressure (ABPM) monitoring

The risks to the ambulatory blood pressure monitoring generally relate to the annoyance of the repeated inflations and may become uncomfortable and/or could irritate the skin or disturb your sleep. Careful monitoring of the arm and removal during non-recording periods can alleviate any irritation.

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

You may or may not benefit from participating in this study. You may potentially benefit from taking minocycline and see improvement in your hypertension. Information generated from this study may help others in the future with hypertension.

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

You are free not to participate in this study. The alternative to being in this study includes standard of care medical treatment for hypertension which includes blood pressure medications and lifestyle changes. If you do not want to take part in this study, tell the Principal investigator and do not sign this Informed Consent Form.

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)?

Your normal clinical care will continue as previously determined by your physician. There will be no changes to that care if you decide to participate in this study.

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

If you agree to participate in this study, you will be asked to review and sign this informed consent. The Principal Investigator and study team will be available to answer any questions you may have as you review this informed consent prior to signing.

After you have signed this informed consent, the following visits and procedures will take place as part of your participation in this study:

Visit 1 Baseline 1 (Screen)

- You will have a medical history taken and will be asked about the medication you are currently taking.
- You will have a physical examination: Your study doctor will listen to your heart and lungs, your vital signs (temperature, blood pressure, heart rate, and breathing rate) will also be measured. Your height and weight will be recorded.
- You will have your office blood pressure measured
  - The "office" blood pressure (BP) measurement (meaning your blood pressure while at the study doctor's office). At each visit, office BP will be recorded as an average of 3 BP readings after you have rested for 30 minutes in a quiet room. In preparation for your office blood pressure measurements you will be asked to try to follow the below guidelines:
    - Take all prescribed medications at your usual times on the day of these office BP measurements. If you have not taken your medications as usual, you will be asked to return for another office BP visit when you have taken your medications.
    - At least thirty minutes before you go in for your study visit, avoid caffeine, smoking and exercising.

  - During the measurements you will be asked to sit quietly in a chair with both of your feet flat on the ground for at least 5 minutes before multiple BP readings are taken.

- You will have blood drawn (4 tablespoons approximately). Three tablespoons of blood will be collected and analyzed for the following: lipid panel, high sensitivity-C reactive protein, high sensitivity troponin, a complete metabolic profile, cystatin C and albumin. An additional tablespoon of blood will be drawn for additional biomedical tests.
- If you are a woman able to become pregnant, you will be asked to take a pregnancy test that must have a negative result before you can continue in this study. If sexually active, you must agree to use two appropriate contraceptive measures while taking part in this study. Medically acceptable contraceptives include: (1) surgical sterilization (such as tubal ligation or hysterectomy), 2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) intrauterine device (IUD). If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor and discontinue the use of Minocycline immediately.
- You will be fitted with an ambulatory blood pressure monitor or ABPM (blood pressure machine to take home) and will receive training and instruction on how to obtain your blood pressure at home.
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.

Visit 2 Baseline 2 (Day 0 ± 3 days)

- Your medications will be reviewed and we will ask you about any hospitalizations you may have had.
- You will have a brief medical exam performed.
- Your home blood pressure monitor log with readings that you recorded will be reviewed
- You will be dispensed study medication (minocycline 50mg).
- You will have your office blood pressure measured. This is described under “Visit 1”.
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.

- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 3 (2 week ± 7 days)

- You will bring any unused study medication and bottles including empty bottles to this visit.
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will be re-dispensed study medication (minocycline 50mg). You will be instructed to continue to take study medication (minocycline 50mg by mouth once a day).
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 4 (Day 60 ± 14 days)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will have blood drawn (1 tablespoon approximately) for additional biomedical tests.
- You will be re-dispensed study medication (minocycline 50mg). You will be instructed to continue to take study medication (minocycline 50mg by mouth once a day).
- You will be fitted with a 24 hour ambulatory blood pressure monitor (ABPM). This is described under “Visit 1”.

- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 5 Phone Call (within 10 days of Visit 4)

- You will be given results of your ABPM blood pressures by the study team and told if your participation in this study will end or continue on to the next visit.

If you are told by the study staff that your participation is continuing, you will be asked to return to clinic within approximately 1 week to increase your study medication dose to 100mg by mouth once a day.

If you are told by the study staff that your participation has ended, you will be asked to return to clinic within approximately 1 week for a final visit (see Visit 12 Final Visit for description).

Visit 6 Dose Titration (within 7 days of Visit 5)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will have a brief physical examination. This is described under “Visit 1”.
- You will be dispensed study medication (minocycline 100mg). You will be instructed to continue to take study medication (minocycline 100mg by mouth once a day).
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 7 (Day 90 ± 14 days)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will be re-dispensed study medication (minocycline 100mg). You will be instructed to continue to take study medication (minocycline 100mg by mouth once a day).
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 8 (Day 120 ± 14 days)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination and vital signs. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will have blood drawn (1 tablespoon approximately). This is described under “Visit 4”.
- You will be re-dispensed study medication (minocycline 100mg). You will be instructed to continue to take study medication (minocycline 100mg by mouth once a day).
- You will be fitted with a 24 hour ambulatory blood pressure monitor (ABPM). This is described under “Visit 1”.

- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 9 Phone Call (within 10 days of Visit 8)

- You will be given results of your ABPM blood pressures by the study team and told if your participation in this study will end or continue on to the next visit.

If you are told by the study staff that your participation is continuing, you will be asked to return to clinic within approximately 1 week to increase your study medication dose to 200mg (100mg by mouth **twice a day**).

If you are told by the study staff that your participation has ended, you will be asked to return to clinic within approximately 1 week for a final visit (see Visit 12 Final Visit for description).

Visit 10 Dose Titration (within 7 days of Visit 9)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination and vital signs. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will be dispensed study medication (minocycline 100mg). You will be instructed to continue to take study medication (minocycline 100mg by mouth twice a day).
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 11 (Day 150 ±14 days)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination and vital signs. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will be re-dispensed study medication (minocycline 100mg). You will be instructed to continue to take study medication (minocycline 100mg by mouth **twice a day**).
- You will be given a home blood pressure log and you will be instructed to begin recording your home blood pressure monitor readings if you are not currently doing so. You will need to record your blood pressure readings at least 3 times a week. This log with your recordings will need to be brought with you to your clinic visits.
- You will be asked to bring asked to bring any unused study medication and bottles including empty bottles to this visit.

Visit 12 Final Visit
(Day 180 ±14 days or at any time your participation ends)

- You will bring any unused study medication and bottles including empty bottles to this visit
- You will have an updated medical history taken and will be asked about the medication you are currently taking.
- You will have a brief physical examination and vital signs. This is described under “Visit 1”.
- You will have your office blood pressure measured. This is described under “Visit 1”.
- Your home blood pressure monitor readings that you recorded will be reviewed
- You will have blood drawn (4 tablespoons approximately). This is described under “Visit 1”.
- You will be fitted with a 24 hour ambulatory blood pressure monitor (ABPM). This is described under “Visit 1”.

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?

Your participation will last up to 180 days.

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

Thirty-five (35) subjects will need to complete this protocol.

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?

Minocycline

The study medication is an FDA approved drug and is a well-tolerated antibiotic used every day to treat many different types of infections. Side effects of this drug may include abdominal cramping, diarrhea, nausea, dry mouth, headache or hypersensitivity (skin sensitivity after sun exposure, dizziness or mild skin rashes). Please inform the study doctor if you experience any of these side effects. New signs of infection e.g. fever, chills, persistent sore throat, oral thrush or new yeast infection; ringing in the ears. The drug can cause fetal harm when taken during pregnancy.

Risk of Blood Collection

The risks of drawing blood from vein and/or intravenous catheter (small plastic tubing inserted into your vein to obtain blood samples) include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection and uncommonly faintness from the procedure. Blood drawn for this study will be approximately 6 tablespoons over the 6 month duration of the study.

Risks of twenty-four hour ambulatory blood pressure (ABPM) monitoring

The risks to the ambulatory blood pressure monitoring generally relate to the annoyance of the repeated inflations and may become uncomfortable and/or could irritate the skin or disturb your sleep. Careful monitoring of the arm and removal during non-recording periods can alleviate any irritation.

Confidentiality:

There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information but this cannot be guaranteed. Study records that identify you will be kept confidential, as required by law.

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.

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. The NCT number for this study is NCT02133872.

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

You may or may not benefit from participating in this study. You may potentially benefit from taking minocycline and see improvement in your hypertension.

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

Information generated from this study may help others in the future with hypertension.

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?

You are free not to participate in this study. The alternative to being in this study includes standard of care medical treatment for hypertension which includes blood pressure medications and lifestyle changes. If you do not want to take part in this study, tell the Principal investigator 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, the investigators will report the results of the testing that you have completed, but only as part of the overall study results. Your individual results will not be reported.

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 it is medically necessary;
- the sponsor stops the study;
- you become pregnant;
- if you do not follow the instructions given to you by the investigator;

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, Devices

The study drug Minocycline and an ambulatory blood pressure monitoring device 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. Carl Pepine (352) 273-9082 or Dana Leach, DNP, ARNP-BC (352) 273-8930 during office hours.

Items/Services Not Paid for by the Sponsor

All 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 be paid $25.00 for the cost of mileage and parking expenses for all study related visits that require you to come to clinic to complete the visit. You will be paid with a pre-paid debit card at the conclusion of the visit. The total amount of money you could be paid for your participation in this study will not exceed $250.00. You will not be paid for phone call visits (Visit 5 and Visit 9).

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. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts payable department and the University must report the amount you received to the Internal Revenue Service (IRS). 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.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

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 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.

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:

- Complete past medical history
- Laboratory, x-ray imaging reports and other test results
- Records about medications
- Ability or potential to conceive a child, or document pregnancy

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 purpose(s):

- To observe the effects of low and high doses of the drug minocycline and its interaction with the chemicals in your brain, its ability to inhibit the activation of these brain cells and to determine the best dose to use in future studies

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 who 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.

- Your insurance company for purposes of obtaining payment

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 study is completed.

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