

A study in adults on pre LT dialysis with basiliximab, delayed tacrolimus (TAC), mycophenolate (MMF), steroids (Grp 1) vs. basiliximab, delayed TAC, MMF, steroids, with everolimus 30d post LT(Grp 2), vs. TAC, MMF, steroids (Grp 3).

NCT04104438

2023-05-08

## UNIVERSITY OF CALIFORNIA LOS ANGELES CONSENT TO PARTICIPATE IN RESEARCH

### **Lay Title:**

This is a study to help understand how well new combinations of immunosuppressive medications (medications that weaken your immune system to prevent your body from rejecting the transplanted liver) work compared to standard immunosuppressive medications after your liver transplant. Also the study will assess how safe the new combination of immunosuppressive medicines are and if there are any changes in how your kidneys work after taking these medicines.

### **Study Title:**

A single center, open label, randomized, prospective, pilot study of induction and maintenance immunosuppression in adult subjects >18 years undergoing orthotopic liver transplantation (OLT) with Basiliximab, delayed dose tacrolimus plus mycophenolate mofetil and standard of care (SOC) corticosteroids (Group 1) versus basiliximab, delayed dose tacrolimus plus mycophenolate mofetil, SOC corticosteroids, with addition of delayed maintenance Everolimus at one month post OLT with subsequent mycophenolate mofetil minimization (Group 2) versus standard dose tacrolimus plus mycophenolate mofetil plus SOC corticosteroids (Group 3; control) with concomitant renal dysfunction prior to OLT.

### **INTRODUCTION**

Fady Michael Kaldas, M.D., F.A.C.S. and associates from the Department of Surgery at the University of California, Los Angeles are conducting a research study.

If you are a legally authorized representative signing on behalf of the participant, the word "you" throughout the remainder of the document refers to the participant.

If your representative previously provided consent on your behalf and you have regained the ability to provide consent for yourself, you are now being asked to sign this form for your continued participation in this study. You will be provided with choices at the end of the document to indicate whether you would like to continue to be in the study and if not, what data already collected may be used.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you are on the liver transplant waiting list, with a high risk of developing kidney dysfunction following LT or with some kidney injury prior to LT.

### **WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to evaluate the course of kidney function and need for dialysis after transplant with three different medication regimens to prevent rejection of the transplanted liver. This research study will also assess the efficacy and safety of the drug, basiliximab (which is not FDA approved for liver transplant recipients), in combination with delayed dose tacrolimus plus mycophenolate mofetil, and standard of care corticosteroids versus basiliximab, delayed dose tacrolimus plus mycophenolate mofetil, and standard of care corticosteroids and addition of delayed everolimus/mycophenolate mofetil discontinuation at one month post LT compared to standard triple immunosuppression (tacrolimus, mycophenolate mofetil and corticosteroids) for prevention of acute organ rejection in liver transplant recipients with a high risk of developing kidney dysfunction following LT or with concomitant renal dysfunction prior to LT.

The following definitions may help you understand how this research study is designed:

- Randomized- random in order or arrangement; employ random selection or sampling in (an experiment or procedure)
- Open-label trial or open trial- is a type of clinical trial in which both the researchers and participants know which treatment is being administered
- Standard of Care- the level at which the average, prudent provider in a given community would practice. It is how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances
- Nephrotoxicity- Nephrotoxicity is toxicity in the kidneys. It is a poisonous effect of some substances, both toxic chemicals and medications, on renal function. There are various forms, and some drugs may affect renal function in more than one way. Nephrotoxins are substances displaying nephrotoxicity
- LT- liver transplantation
- Basiliximab- also known as Simulect, it can help prevent organ rejection after a kidney transplant. It is approved by the FDA for kidney transplant patients but has not been approved by the FDA for liver transplant patients.
- Everolimus- also known as Zortress or Afinitor, it can treat cancer of the kidney, pancreas, breast, and brain. It can also be used along with other medications to weaken the immune system and help prevent rejection of a transplanted kidney or liver
- Tacrolimus- also known as Prograf, it can prevent organ rejection after transplant.
- Mycophenolate Mofetil- also known as Cellcept, enteric coated mycophenolate is known as Myfortic
- Corticosteroid- Corticosteroids are a class of steroid medicines commonly used in transplant patients

Rejection- an immune response in which foreign tissue, like a skin graft or transplanted organ, is attacked by the immune system of the transplant recipient

**Novartis Pharmaceuticals Corporation is funding this study**

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Approximately 90 people will take part in this study at UCLA.

**WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

If you join the study, you will be followed at the UCLA Pfleger Liver Institute per the usual standard of care over one year. No additional visits will be required for the study as they will be combined with existing appointments you have. It is important that you come to all visits.

**Before starting the study**, the Study Doctor will ask you about your health and your medical health history. The doctor will examine you and measure your height, weight, blood pressure and heart rate. You will also have a pregnancy test if you are a female and are child-bearing potential. You will need to be eligible for OLT, screened for enrollment qualifications, sign informed consent, have research specific labs drawn.

**Randomization** is a procedure used to assign research participants by chance to a study group in a clinical trial. It is used to make sure study results are not influenced by the selection of participants in one group as compared to another. In this study there are three treatment groups. Groups 1 and 2 will receive the investigational drug Basiliximab and Group 3 will receive standard of care. The chance that you will be assigned to Group 1, Group 2, or Group 3 is 40%, 40%, and 20%, respectively.

**At every visit**, your doctor or study staff will ask about:

- how you are feeling and about any side effects that you have had
- if you have been in the hospital or have been seriously ill
- the medicines that you are taking in addition to your study medicine if you have missed any study medicine.
- You will have routine blood and urine work done. About 3 teaspoons will be taken each time. It is important that this is fasting (that you do not eat or drink anything, except water, for at least 8 hours before the visit).
- Do not take any study medicine the day of your study visit. It is very important that you bring your study medicine with you and keep all empty medicine bottles to return to your study coordinator.

**During the study:**

It is important to come to your visits as scheduled and take your medicines as your doctor has directed. Your participation in the study will last for one year.

The tests that you will have during your time in the hospital that are related to the study are common to usual transplant care.

If you take part in this study, the researcher(s) will assign you to 1 of 3 randomization arms or study groups 1, 2, or 3. A total of 145 subjects will be enrolled in the study: 36 subjects in groups 1 and 2 and 18 subjects in group 3.

**Group 1:**

If you are randomized to group 1, you will be one of 36 subjects randomized to this group. You will receive the study drug basiliximab first dose (20 mg) by an intravenous infusion within two hours of receiving your liver transplant. A second 20 mg dose of basiliximab will be given by intravenous infusion on the fourth day after your liver transplant surgery. Basiliximab is a study medicine that is given to weaken your immune system.

You will also receive the standard of care immune system weakening medication tacrolimus twice a day (8am and 8pm) by mouth beginning on post-operative day 5, or when your kidney starts working as determined by the study doctors. Tacrolimus will be given in regular doses every day for the duration of the study.

You will also receive mycophenolate mofetil by mouth twice a day (8am and 8 pm throughout the study) and steroid immunosuppressive medications by intravenous infusion daily for the first six days post operatively. On post-operative day 7 and throughout the rest of the study, steroids will be given by mouth daily in the morning with tacrolimus as a standard of care. These medicines will both be dosed and closely monitored by your study doctors.

Following completion of the study, you will be switched to a SOC immunosuppressive regimen, also determined by the study doctors.

**Group 2:**

If you are randomized to group 2, you will be one of 36 subjects randomized to this group. You will receive the study drug basiliximab first dose (20 mg) by an intravenous infusion within two hours of receiving your liver transplant. A second 20 mg dose of basiliximab will be given by intravenous infusion on the fourth day after your liver transplant surgery. Basiliximab is a study medicine that is given to weaken your immune system.

You will also receive the standard of care medication tacrolimus by mouth beginning on post-operative day 5, or when your kidney starts working as determined by the study doctors. Tacrolimus will be given in regular doses every day for the first 30 days after your liver transplant. On post-operative day 31 (and for the duration of the study) the study doctors will lower your tacrolimus dose so there is less tacrolimus in your body.

Also, on post-operative day 31, you will be started on another study drug that weakens your immune system, everolimus. Study doctors will dose and monitor the everolimus throughout the study treatment period. Everolimus will also be given throughout the rest of the study twice a day by mouth at 8am and 8pm.

You will also receive mycophenolate mofetil (which weakens your immune system) by mouth twice a day (8am and 8 pm) for the first 30 days after liver transplant. Beginning on day 30, the study doctors will lower dose of mycophenolate. Lower doses of mycophenolate mofetil will be given for the remainder of the study period.

Steroid immunosuppressive medications will be given as a standard of care by intravenous infusion daily for the first six days post operatively. On post-operative day 7 and throughout the rest of the study, steroids will be given by mouth daily in the morning with tacrolimus and everolimus. This medicine will be dosed and closely monitored by your study doctors.

Following completion of the study, you will be switched to a SOC immunosuppressive regimen, also determined by the study doctors

**Group 3:**

If you are randomized to group 3, you will be one of 18 subjects randomized to this group. You will receive the immune weakening medicines (tacrolimus) by mouth twice a day at 8am and 8pm, mycophenolate mofetil by mouth twice a day at 8am and 8pm, and steroid immunosuppressive medications. Steroid immunosuppressive medications will be given as a standard of care by intravenous infusion daily for the first six days post operatively. On post-operative day 7 and throughout the rest of the study, steroids will be given by mouth daily in the morning. These medicines will all be dosed and closely monitored by your study doctors. You will not receive basiliximab or everolimus if you are in group 3.

Study visits and tests following transplant will be done as follows:

Testing the effects of everolimus and basiliximab, or basiliximab alone will be done at 2, 3, 4, 5, 6, 9, and 12 weeks after transplant

- Blood draws will be done at weeks 1, 2, 4, 8, 12, 16, 20 and 24. We will take a maximum of 40 cc of blood over the whole study and will be done at the same time as your standard of care lab draws.
- All visits will be at your standard transplant follow up times.

**HOW LONG WILL I BE IN THIS STUDY?**

This study will last one year and each subject will have approximately 14 visits

**WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?**

**Potential risks and discomforts:**

The possible risks and/or discomforts associated with the procedures described in this consent form include known adverse reactions to the study drugs Basiliximab and Everolimus." (While these drugs are FDA approved, Basiliximab is being used for an indication that is not approved by the FDA).

**Basiliximab**

The following adverse events occurred in >10% of basiliximab treated patients:

- Gastrointestinal System: constipation, nausea, abdominal pain, vomiting, diarrhea, dyspepsia
- Body as a Whole-General: pain, swelling (edema), fever, viral infection

- Metabolic and Nutritional: high potassium,, low potassium, , high blood sugar, high cholesterol, low phosphate, high uric acid
- Urinary System: urinary tract infection
- Respiratory System: difficult or labored breathing, upper respiratory tract infection
- Skin and Appendages: surgical wound complications, acne
- Cardiovascular Disorders-General: high blood pressure
- Nervous System: headache, tremor; Psychiatric: insomnia
- Blood Cells: anemia.

The following side effects, not mentioned above, were reported with an incidence of ≥3% and <10% in patients treated with basiliximab:

- Body as a Whole-General: accidental trauma, weakness, chest pain, increased drug level, infection, swelling of the face and legs, fatigue, malaise, sudden feeling of coldness with shivering, infection
- Cardiovascular: abnormal heart sounds, sudden high blood pressure, heart failure, chest pain, low blood pressure
- Endocrine: increase in your body's natural production of steroids
- Gastrointestinal: enlarged abdomen, inflammation of the esophagus, gas, stomach inflammation, stomach bleeding, overgrowth of the gums , dark feces, yeast infection in the mouth, painful ulcers in the mouth
- Heart Rate and Rhythm: irregular heartbeat, fast heart beat
- Metabolic and Nutritional: acidosis, dehydration, diabetes, fluid overload, high or low calcium, high lipids, high triglycerides, low blood sugar, low magnesium, low proteins in the blood, weight increase
- Musculo-Skeletal: joint pain, joint disease, back pain, bone fracture, cramps, hernia, muscle pain, leg pain
- Nervous System: dizziness, nerve damage, tingling feelings in the skin, numbness
- Platelet and Bleeding: bruising, bleeding, spots on the skin, low platelets, blood clots
- Psychiatric: agitation, anxiety, depression
- Red Blood Cell: too many red blood cells
- Reproductive Disorders, Male: genital swelling, impotence
- Respiratory: inflammation or tightening in the airways leading to the lungs, abnormal chest sounds, coughing, swelling in the throat, infection in the lungs, fluid in the lungs, swelling inside the nose, swelling in the sinuses
- Skin and Appendages: cyst, herpes, chicken pox, extra hair growth, itching, rash, skin disorder, skin ulcers
- Urinary: bladder problems, painful or difficult urination, need to urinate more often, urine retention, blood in the urine, low amounts of urine, abnormal kidney function
- Vascular Disorders: blood vessel problems
- Vision Disorders: cataract, conjunctivitis, abnormal vision
- White Blood Cell: low white blood cells.

## **Everolimus**

Most common adverse reactions (incidence  $\geq 30\%$ ) include:

Mouth ulcers

Respiratory tract infections

Skin problems: rash, dry skin

Gastrointestinal problems: diarrhea, abdominal pain, nausea

Other possible side effects: fever, swelling, weakness, cough, headache benign kidney tumors and decreased appetite.

If you are receiving everolimus, an increased risk of hepatic artery thrombosis (a blood clot in the main artery that gives the liver oxygen rich blood) may occur if everolimus used within 30 days of your liver transplant. This could lead to graft loss and death. However, this increased risk of hepatic artery thrombosis has not been seen when everolimus is used after 30 days, as will be done in this study.

### **Potential risks and discomforts:**

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

### **Mycophenolate (Cellcept and Myfortic)**

Gastrointestinal: diarrhea or constipation, nausea or vomiting. The gastrointestinal side effects may be reduced by the use of the enteric coated form of mycophenolic acid (myfortic).

Abnormal blood cell counts: low white cells, low red cells (anemia) or low platelets.

Other possible side effects: pains in the abdomen, chest or back, headache, high blood pressure (hypertension), or swelling (edema).

If you are pregnant, mycophenolate can cause harm to your unborn baby. You could lose the pregnancy (miscarry) during the first three months or your baby could have birth defects. For this reason, you will not be able to enroll in this study if you are pregnant or plan to become pregnant. Before you start if you are a female of child bearing potential, you will have a pregnancy test. You also cannot participate if you are nursing.

### **Tacrolimus (Prograf)**

The most common side effects of tacrolimus include:

Kidney damage

Nervous system problems: shaking of the hands, headache, tingling in the fingers and toes, drowsiness, hallucinations

High blood pressure (hypertension)

High blood sugar (hyperglycemia)

### **Steroids (prednisone)**

All patients in this study will receive corticosteroids (prednisone). The most common side effects of steroids include:

High blood sugar (hyperglycemia) High blood pressure (hypertension)

High cholesterol (hypercholesterolemia)

Mood changes (feeling very happy then suddenly feeling very sad)

Other possible side effects: weight gain, increased risk of infections, poor wound healing, thinning of skin, easy bruising, weak bones.

Water retention or swelling

Problems or side effects that are not yet known could also occur. You will be given any new information that may affect your willingness to start or continue in the study.

### **Drawing Blood**

The risk of drawing blood may include pain, bruising, small blood clot formation and/or bleeding at the site of needle insertion for blood drawing. Very rarely an infection may occur at the site. You may also experience dizziness and/or fainting.

### **Biopsies**

There is some discomfort associated with the procedure. The discomfort should not last more than several hours. The risks include bleeding from the biopsy site, significant bleeding requiring a blood transfusion or surgery to control the bleeding (less than 1 of 1,000 patients), perforation of internal organs (less than 1 of 1,000 patients) and death (less than 1 of 10,000 patients).

### **Pregnancy**

Myfortic has been associated with increased risk of pregnancy loss (miscarriage) during the first three months, as well as an increased risk of birth defects.

Therefore, if you are a woman, capable of becoming pregnant, you will not be enrolled in this clinical study until a negative pregnancy test result is obtained.

You must agree to receive birth control counseling, and you must use effective birth control. You and your study doctor must discuss exactly what types of birth control are acceptable. It is important for you and your doctor to agree upon two methods, and you must use the methods chosen. Unless you decide to avoid sexual intercourse completely, you must continue birth control, during the one-year study, and for eight weeks after stopping your participation in the study. If you do become pregnant, you must notify your study doctor immediately. You will be removed from the study and they will change your treatment to a different combination of standard of care immunosuppressive drugs.

### **Randomization**

This is a randomized study. This means that you will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups, or standard treatments available for your condition.

## **ARE THERE ANY BENEFITS IF I PARTICIPATE?**

### **Possible benefits to me:**

The possible benefits you may experience from being in this study include nephroprotective effects of study drugs everolimus and/or simulect

Potential benefits of participants in Groups 1 and 2 may include improved renal function and reduced chance of continued renal dysfunction from the delay and reduced dose of Prograf therapy. Participants will possibly maintain adequate immunosuppression to reduce acute rejection episodes.

Group 3 will receive standard of care and may receive no direct benefit from being in this study other than increased monitoring of your health by study center personnel.

**Possible benefits to others or society:**

Society may benefit from any experimental research. Such benefits include the possibility that this study may help develop a new therapy for others with similar conditions. This study could be useful in determining the future for patients who require an organ transplant and have kidney problems. Your participation in this study will help researchers learn more about basiliximab and everolimus related to nephrotoxicity. Hopefully, this information will help in the treatment of future patients with OLT and kidney issues.

**WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?**

If you decide not to take part in this study, or if you withdraw from this study before it is completed, you will still receive standard of care for your diagnosis and condition. You do not have to participate in this research to receive care for your medical problem. Please ask your Study doctor as many questions as you wish. The doctor's answers to your questions could help you decide whether to participate in this research or receive the standard care that is currently available for you. If you decide to participate in research now, and later change your mind, you may stop your participation in the research then and receive the alternative care.

**CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?**

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study supporter might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to return for a final close-out visit or evaluation and return unused study medication. The data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?**

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in

confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

**Use of personal information that can identify you:**

UCLA values and respects your private information. Federal and state laws protect your privacy. Every reasonable effort will be made to keep your records confidential, such as storing your private information in a secure location where only authorized individuals will have access to it. Identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be maintained in a secure location at UCLA, only authorized individuals will have access to it. Some research data and records will be stored electronically on a secure computer or with password protection. The researchers intend to keep the research data and records for a period of at least three years after completion of the trial and make them available upon request from the regulatory authority(ies) according good clinical practice.

The research team, authorized UCLA personnel, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

**ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?**

You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in the study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items and/or services

The study supporter will supply and pay for the cost of supplying and administering the study drug (basiliximab and everolimus), extra related laboratory tests (including pregnancy test, if needed), a liver biopsy if your physician thinks it might be necessary and physical exams. However, you and your insurer will be billed for the costs of all other study procedures as these are considered standard of care.

**WILL I BE PAID FOR MY PARTICIPATION?**

You will not be paid for your participation in this research study.

**WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

**The Research Team:**

You may contact Fady Kaldas, M.D. at 310-825-1037 [er.Curtis Holt, Pharm. D 310-206-4952](#) with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Fady Kaldas, M.D. 24 hours a day, 7 days week.

**UCLA Office of the Human Research Protection Program (OHRPP):**

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: [mirb@research.ucla.edu](mailto:mirb@research.ucla.edu) or U.S. mail: UCLA OHRPP, 10889 Wilshire Blvd, Suite 830, Los Angeles, CA 90095-1460.

**Public Information about this Study:**

*ClinicalTrials.gov* is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?**

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study supporter do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to [mirb@research.ucla.edu](mailto:mirb@research.ucla.edu).

**WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?**

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

**HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?**

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. Your Protected Health Information as defined by HIPAA will be accessed therefore, you

will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

### **IF YOU WERE ENROLLED USING A LEGALLY AUTHORIZED REPRESENTATIVE**

If you were initially consented via your legally authorized representative and have now regained capacity to consent, you are being asked whether you want to continue in the research study and have the following three options:

- (1) Wish to continue in the study
- (2) Do not wish to continue in the study, but allow data collected so far to be used for research purposes
- (3) Do not wish to continue in the study and do not allow data already collected to be used. Since this study is of an FDA-regulated drug, some data may be kept due to FDA reporting requirements for studies involving FDA-regulated drugs.

### **SIGNATURE OF THE PARTICIPANT**

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Name of Participant

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Signature of Participant

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Date

### **SIGNATURE OF LEGAL REPRESENTATIVE**

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Name of Legal Representative

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Date

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Signature of Legal Representative

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Relationship to patient

### **SIGNATURE OF PERSON OBTAINING CONSENT**

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Name of Person Obtaining Consent

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Contact Number

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Signature of Person Obtaining Consent

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Date