Official Title: A Prospective, Pilot Trial to Compare the Efficacy of Tacrolimus Extended-Release (Envarsus XR) to Tacrolimus Immediate-Release on Suppression of Donor-Specific Antibodies in HLA Sensitized Kidney Transplant Recipients

NCT #: NCT04225988

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CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

TITLE: A Prospective, Pilot Trial to Compare the Efficacy of Tacrolimus Extended-Release (Envarsus XR) to Tacrolimus Immediate-Release on Suppression of Donor-Specific Antibodies in HLA Sensitized Kidney Transplant Recipients

STUDY SUPPORT PROVIDED BY: VELOXIS PHARMACEUTICALS

PRINCIPAL INVESTIGATOR: EDMUND HUANG MD

STUDY CONTACT PHONE NUMBER AT CSMC: EDMUND HUANG 310-423-2641

AFTER HOURS CONTACT (24 HOURS): EDMUND HUANG 310-423-2641

This research study is supported by Veloxis Pharmaceuticals. Veloxis Pharmaceuticals only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; Veloxis Pharmaceuticals is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine whether the incidence of biopsy-proven acute rejection within the first 12 months of transplant is comparable between highly sensitized patients maintained on Envarsus XR and immediate-release tacrolimus.

You are being asked to take part in this research study because you are a potential recipient of a kidney transplant and are considered highly-sensitized, which means that you are known to have antibodies against human kidney tissue.

The study will enroll up to 20 people in total.

In this study, we want to compare extended release Envarsus XR to the Cedars-Sinai standard treatment of immediate-release tacrolimus to learn which works better for people with your condition. Both drugs are FDA-approved for kidney transplant recipients to prevent organ rejection. They are identical except Envarsus XR is taken once daily and immediate-release tacrolimus is taken twice daily.

Research participants in this study will get either Envarsus XR or immediate-release tacrolimus. You will not get both.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

Overview of study:
This is a randomized research study.

- "**Randomized**" means that you will be assigned to a study group by chance, like flipping a coin. You will be randomized into one of two study groups, and will have an equal chance of being placed in one of the groups described above.

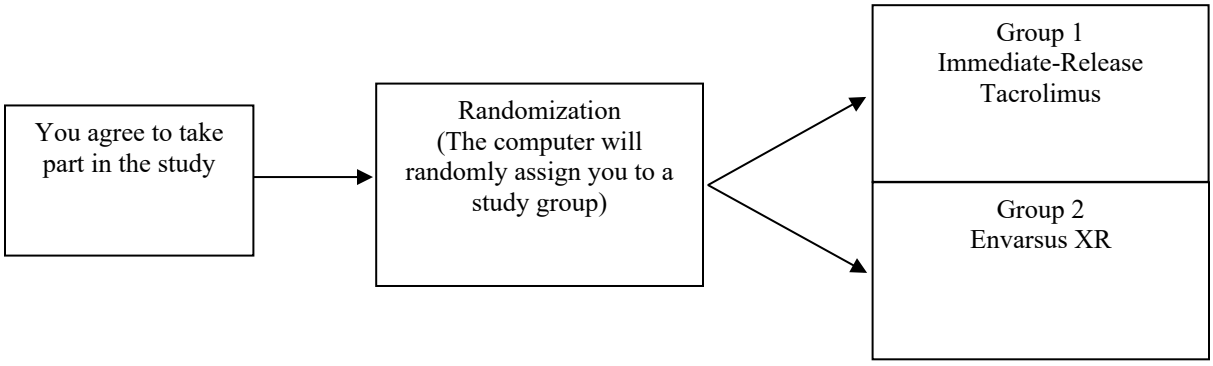
This study has two study groups:

- Group 1 will get the usual immediate-release tacrolimus drug used for the prevention of kidney transplant rejection
- Group 2 will get Envarsus XR drug used for the prevention of kidney transplant rejection

A computer will randomly assign you to a study group. This is done because no one knows if the results experienced by the participants in one study group are better, the same, or worse than the results experienced by participants in the other. Once you are put in one group, you cannot switch to another group. Neither you nor your doctor can choose the group in which you will be placed.

Either of these different approaches could help your condition but could also cause side effects. This study will allow the researchers to learn whether the different approaches are better, the same, or worse than one another. Both drugs have already been tested for safety; however, Envarsus XR is not part of the current Cedars-Sinai standard of care.

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will you be in the study
We think you will be in this study for about one year. The total time includes a screening visit, days 0 (transplant day), 2, 4, 7, 14, 30 and months 2, 3, 6, 9, 12 of treatment.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as Appendix A. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Unknown Risks
There may be other side effects or risks that we cannot predict. Many side effects may go away shortly after the study medication or procedure is stopped. However, in some cases they can be serious, long-lasting, permanent, and/or fatal.

Risks of Envarsus XR

> In the list below, "**Serious**," refers to those side effects that may require hospitalization, may be irreversible, long-term, life-threatening or fatal.

Likely, Some May Be Serious (*Occurs in greater than 20% and up to 100 % of people***)**
- Diarrhea
- Constipation
- Nausea
- Abdominal pain
- Hair loss
- Headache
- Difficulty sleeping
- Tremor
- Fever
- Increased blood pressure
- Edema (swelling)
- Electrolyte abnormalities (may require electrolyte supplements) such as nausea, vomiting, mood changes, excessive thirst
- Elevated cholesterol
- Elevated blood sugar

Less Likely, Some May Be Serious (*Occurs in >3% - 20 % of people)*
- Vomiting
- Reduced red blood cells (lead to fatigue)
- Reduced platelets (increased risk of bleeding)
- Reduced white blood cells (increased susceptibility to infections)

- Rash
- Itching

Rare AND Serious (*Occurs in 3% or less of people* ***and*** *may require hospitalization or may be irreversible, long-term, life-threatening or fatal***)**

- Viral, bacterial and fungal infections
- Sun sensitivity
- Viral kidney infection
- Injury to kidneys
- All immunosuppression treatments increase risk of developing lymphomas and other malignancies particularly skin cancer
- Changes in the electrical activity of your heart (QT prolongation)
- PRES (posterior reversible encephalopathy syndrome; a serious condition of the brain of which symptoms include altered mental status, headache, high blood pressure, seizures, and visual disturbances; symptoms are generally reversible with dose reduction or discontinuation of therapy

In addition to the risks summarized above, the FDA has issued the following warning for Envarsus XR:

FDA Blackbox warning:

Malignancies and serious infection:

Increased likelihood of bacterial, viral, fungal, and protozoal infections, including opportunistic infections and the possible development of malignancies such as lymphoma and skin cancer may result from immunosuppression and may lead to hospitalization or death.

Experienced physician:

Only health care providers experienced in immunosuppressive therapy and management of organ transplant patients should prescribe tacrolimus. Manage patients receiving the drug in facilities equipped and staffed with adequate laboratory and supportive medical resources. The health care provider responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Reproductive and Lactation Risks
Taking part in this research study can affect an unborn baby. Therefore, you should not become pregnant or father a baby while on this study. If you or your partner are capable of becoming pregnant you will need to use birth control. Check with the researcher about approved birth control methods to use while participating in this study.

Women should not breastfeed a baby while on this study.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the study drug might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

Incidental Findings
It is possible that the research procedures could uncover information related to your health that you did not know about before and that is unrelated to the Study. Some of these findings may be too preliminary to share. Cedars-Sinai will carefully consider the research findings and determine if they should be shared with you. Research findings would only be shared with you if such sharing is approved by the Cedars-Sinai IRB and is permitted by applicable law. In some cases, additional clinical testing may be required. The cost of any additional testing and any related treatment will be your responsibility.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct medical benefit to you. The possible benefit of taking part in the research study is that, if you end up taking Envarsus XR, you will only have to take a pill once daily and this decreases pill burden. It is also possible that having to take the medication only once a day will help you to avoid missing doses by accident, which may decrease the chances of rejecting your kidney. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

We hope the information learned from this research study will benefit other highly sensitized individuals with end-stage renal disease in the future by helping us to learn whether the incidence of biopsy-proven acute rejection within the first 12 months of transplant is comparable between highly sensitized patients maintained on Envarsus XR and immediate-release tacrolimus.

5. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

6. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach (immediate-release tacrolimus)
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.

The researcher will discuss these options and their risks and benefits with you.

7. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not

be used. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

The study team will facilitate any required access to your records by authorized representatives of the Sponsor to verify the information collected for the study.

You will be asked to sign a separate "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

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.

8. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your researcher at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your researcher of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Charity Care Policy and Procedure. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783.

9. FINANCIAL CONSIDERATIONS

Costs of Participation

Please review the attached flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

Only items, drugs and services that are reasonable and necessary for your medical care throughout the study will be billed to your insurance. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

You can elect to remain on Envarsus XR or be switched to immediate release tacrolimus after the completion of the study. Remaining on Envarsus XR after the study is completed may result in

higher out of pocket costs to you. Please discuss with your study doctor if you have more questions about medication therapy after the 12 month treatment period.

Compensation for Participating
You will not be paid for taking part in this research study.

Financial Interest in the Research
The PI and institution have no potential financial conflict of interest with respect to this study.

10. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact one of the investigators listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP) Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

11. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights (other than the postponement of your access to certain health information as described in this informed consent form);
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and a copy of the Experimental Subject's Bill of Rights.

SIGNATURE BY THE PARTICIPANT:

_____	_____	_____
Name of Participant (Print)	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR:

I have personally explained the research to the participant in non-technical terms, answered all questions, and attest that he/she freely consents to participate. The participant has been provided with the Experimental Subject's Bill of Rights.

_____
Name of Investigator (Print)

_____	_____
Signature of the Investigator Who Obtained Consent	Date of Signature

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English-speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

_____

Name of Interpreter/Witness (Print)

_____ _____

Signature of Interpreter/Witness Date of Signature

CEDARS-SINAI MEDICAL CENTER

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Distribution instruction for researchers:

The signed (i) Consent form, (ii) Authorization for Use and Disclosure of Identifiable Health Information and (iii) "Experimental Subject's Bill of Rights" (the latter required if the research study involves medical interventions)* should be distributed to:

1) Medical Chart
2) Research Participant
3) Pharmacy (if a drug study)
4) Principal Investigator's research records (original)

APPENDIX A: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated, or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Blood draw: A needle is placed in the vein in your arm to draw blood	Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
Medical History Review: You will be asked about your medical and surgical history with attention to information about your kidney disease.	There are no physical risks associated with this procedure.
Demographic Information: You will be asked about your age, gender, race, ethnicity	There are no physical risks associated with these procedures.

CEDARS-SINAI MEDICAL CENTER

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION (RESEARCH)

Use and Disclosure of Health Information

This Authorization is being completed in connection with the Consent Form for Research relating to the **"A Prospective, Pilot Trial to Compare the Efficacy of Tacrolimus Extended-Release (Envarsus XR) to Tacrolimus Immediate-Release on Suppression of Donor-Specific Antibodies in HLA Sensitized Kidney Transplant Recipients"** research study described in the Consent Form. The principal investigator for the research study is Edmund Huang, MD ("Principal Investigator"). The sponsor of the research study is Veloxis Pharmaceuticals (the "Study Sponsor"). You are being asked for your authorization to allow the research team acting under the direction of the Principal Investigator as described in the Consent Form to review your medical records and collect health information about you ("private information") from the following sources:

- laboratory tests [CBC with diff, metabolic panel, urinalysis, BKV, CMV]
- other tests [CYP3A5 genotyping, DSA, Donor-derived cell-free DNA]
- x-rays [chest x-ray]
- doctor/clinic records
- hospital/medical records
- pathology reports

The following private information about you will be placed in the research study records:

- Name;
- Street address [city, county, precinct, zip code, and their equivalent geocodes];
- Birth date and other indicators of your age;
- Admission date/ discharge date;

- Date of death;
- Telephone numbers;
- Fax numbers;
- Electronic mail address;
- Medical record numbers;
- Codes assigned in connection with the study to only your information that could be used to identify you.

Who will have access to your private information?

Your private information will be used by and/or shared with the following specific **investigators Stanley Jordan, MD; Alice Peng, MD; Edmund Huang, MD; Reiad Najjar, MD; Supreet Sethi, MD; Ashley Vo, PharmD; Noriko Ammerman, PharmD and their research team** as part of the research study. Reasonable efforts will be made to assure that the research team will have access only to the private information about you that is minimally necessary to conduct the research study. In addition to the research team, various committees of Cedars-Sinai Medical Center, the Sponsor and governmental agencies that oversee research may ask for access to your private information from the research team. These include one or more of the Institutional Review Boards (IRB's) of Cedars-Sinai Medical Center, the Cedars-Sinai Office for Research Compliance, the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and other agencies that must receive reports about certain diseases. Additionally, the following parties may receive information about you:

- Medical and other health care professional students who are assisting with tasks for the research study
- The Study Sponsor (in other words the organization that is paying for the costs of the research study) for matters related to research study oversight, data analysis and use of research results in product development
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

How long will my authorization for use of private information be in effect?

By signing this document, you authorize the use and sharing of your private information until January 31, 2035.

Withdrawal of Authorization

You have the right to withdraw your authorization for us to use your health information at any time. You must write to the principal investigator to withdraw your authorization. The mailing address is: **8900 Beverly Blvd, Los Angeles, CA 90048.** However, if we have provided your information to the sponsor of this research, the study's data coordinating center, or other outside entities, that information cannot be withdrawn. Any information already obtained at the time you withdraw your authorization may continue to be used as necessary to ensure study integrity. For example, it may be necessary to continue to use your information to conduct investigations or to report adverse events.

Further disclosure (sharing) of your private information

Your private information will be shared by the Principal Investigator and Cedars-Sinai Medical Center only as needed for the research study. Cedars-Sinai Medical Center makes an effort to ensure that recipients of your information take steps to maintain the confidentiality of your private information and only receive the information that they need, and not more. Certain individuals or organizations that may receive your private information could though, in very limited circumstances, reveal it for purposes not related to the research study. This would be an unauthorized and illegal disclosure (sharing) of your information. In this study, the Principal Investigator does not anticipate that this will happen. Moreover, in California, the law prohibits such further disclosure of private information without another signed authorization from you (unless the law requires the particular disclosure, such as to report suspected child abuse).

Notice of Rights and Other Information

You may refuse to sign this Authorization. If you refuse to sign this Authorization, you will not be able to participate in the research study. However, standard of care treatment by Cedars-Sinai Medical Center will still be made available to you regardless of whether you provide or refuse to sign this Authorization.

You have a right to receive a copy of this Authorization.

The Principal Investigator and Cedars-Sinai Medical Center are required by law to protect your private information. By signing below, you authorize the use or disclosure of your private information in connection with the research study as described above.

SIGNATURE BY THE SUBJECT:

Name of Subject (Print)	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR:

I attest that all the elements of this have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Name of Investigator (Print)

Signature of the Investigator	**Date of Signature**

SIGNATURE BY THE INTERPRETER/WITNESS
(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Name of Interpreter/Witness (Print)

Signature of Interpreter/Witness	Date of Signature

FLOWCHART OF PROCEDURES												
Procedures	**Screening Visit**	**Tx Day 0**	**Day 2 ± 1 day**	**Day 4 ± 2 day**	**Day 7± 3 day**	**Day 14- 3 day/+5 days**	**Day 30± 7 day**	**Month 2± 14 day**	**Month 3± 14 day**	**Month 6 ± 14 day**	**Month 9 ± 14 day**	**Month 12 ± 14 day**
Informed Consent[6]	R											
Inclusion/Exclusion[6]	R											
Randomization	R											
Physical Exam	S	S	S	S	S	S	S	S	S	S	S	S
Chest X-ray[1]	S											
EKG[1]	S											
Alemtuzumab Administration		S										
CBC with diff	S	S	S	S	S	S	S	S	S	S	S	S
Complete Metabolic Panel	S	S	S	S	S	S	S	S	S	S	S	S
Urinalysis				S	S	S	S	S	S	S	S	S
Tacrolimus trough level[2]			S	S	S	S	S	S	S	S	S	S
Viral testing: Polyomavirus BK							S		S	S	S	S
Viral testing: Cytomegalovirus							S		S	S	S	S
Serum Pregnancy Test[3]	S											
Donor Specific Antibody[4]	S						S		S	S	S	S
Donor -derived cell-free DNA (Allosure)							S		S	S	S	S
Adverse event monitoring	R	R	R	R	R	R	R	R	R	R	R	R
Valganciclovir	S	S	S	S	S	S	S	S	S	S		
TMP/SMX (Bactrim)	S	S	S	S	S	S	S	S	S	S	S*	S*
Fluconazole	S	S	S	S	S	S	S					
Envarsus XR[5]		R[2]	R	R	R	R	R	R	R	R	R	R
Immediate-Release Tacrolimus[5]		S[2]	S	S	S	S	S	S	S	S	S	S
Mycophenolate mofetil (cellcept) or mycophenolate acid (myfortic)		S	S	S	S	S	S	S	S	S	S	S
Prednisone		S	S	S	S	S	S	S	S	S	S	S

LEGEND
R = Research item/procedure done only for research purposes and covered by the study
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance

Footnotes:
*TMP/SMX (Bactrim) may be discontinued as per standard of care at months 9, 10, 11 or 12

1: Can be done within 6 months of screening date

2: Depending on the time of the kidney transplant, Envarsus XR and Immediate-Release Tacrolimus will be given either same day as transplant or the next day or delayed to post-operative day #2 per PI discretion
3: If subject is of childbearing age. (Not required if subject has a histroy of hysterectomy).

4: DSA will be doneat time of transplant and quarterly for the first year. For deceased donor, sample will be drawn pre-op, prior to IVIG. Majority of pts would have received desensitization within the past 6-9 months prior to transplant. For living donors, sample will be drawn prior to IVIG2 but pt would already have received IVIG1 and ritux 5 weeks prior to sample drawn
5: Subject will be taking either Envarsus XR or Immediate-Release Tacrolimus; not both. Envarsus XR will be provided by study staff.
6: Consent & Inclusion/Exclusion can be obtained prior to screening visit. Inclusion/Exclusion will be reviewed at time of screening to confirm the patient remains a study candidate.