



TEMPLATE INFORMED CONSENT ADDENDUM

PROTOCOL: CTOT-15

Optimization of NULOJIX® (Belatacept) Usage as a Means of Minimizing CNI Exposure in Simultaneous Pancreas and Kidney Transplantation

(All Institutions or organizations who define themselves as “covered entities” should implement HIPAA Privacy Rule regulations, (45 CFR part 160, subparts A&E of part 164.)

PRINCIPAL INVESTIGATOR

(Insert site Principal Investigator as well as other subinvestigator if desired.)

YOUR PARTICIPATION IS VOLUNTARY

The purpose of this consent addendum is to inform you of new findings as well as changes to the research study “Optimization of NULOJIX® (Belatacept) Usage as a Means of Minimizing CNI Exposure in Simultaneous Pancreas and Kidney Transplantation”. It was observed that there were a high number of rejection episodes that occurred at or around the time of low dose Prograf (tacrolimus withdrawal), therefore, the decision has been made to stop any further Prograf (tacrolimus) withdrawal as a part of the study.

In addition, active study participants in the experimental arm currently follow the study therapy regimen outlined in the study protocol. From this point forward, study participants will be transitioned onto a clinical immunosuppressive regimen, based on a discussion between the study participant and his/her study physician. This drug regimen may include belatacept and if so, you will be able to receive the study drug supply of belatacept until the study ends on August 31, 2016.

No changes will be made to subjects in the control arm and/or study participants currently in reduced follow-up.

A total of 43 study participants were randomized, from 5 centers in the United States. Study participants who have not yet reached study completion will be asked to continue following their existing schedule, along with research blood draws, until the study ends.

STUDY FOLLOW UP

Study participants will be asked to continue their existing follow-up schedule until study completion in August 2016. All clinical labs and research blood draws currently on the schedule will still be drawn in order to continue following your transplanted kidney and pancreas.

VOLUNTARY WITHDRAWAL FROM STUDY

You may decide to withdraw from the study at any time. If you decide to withdraw, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive.

CONFIDENTIALITY

INFORMED CONSENT TEMPLATE (RECIPIENT)

VERSION: 7.0 – June 28, 2016




Page 1 of 3

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality. You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication about this study.

Medical and research records may be reviewed by the National Institute of Allergy and Infectious Diseases, including its representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study. In addition, the U.S. Food and Drug Administration, or other health authorities, and the study drug manufacturer may review your medical and research records for regulatory purposes.

A description of this clinical trial is 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.

PROBLEMS OR QUESTIONS

 I can call ... concerns	 At ...	 If I have questions or
<Insert PI Name> Principal Investigator	Phone: <Insert Phone> Pager: <Insert Pager> Beeper #	<ul style="list-style-type: none">▪ General questions about the study▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints
<Insert Research Nurse> Research Nurse	Phone: <Insert Phone> Pager: <Insert Pager> Beeper #	<ul style="list-style-type: none">▪ General questions about the study▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints
<Insert IRB>	Phone: <Insert Phone>	<ul style="list-style-type: none">▪ Rights of a research subject▪ Use of protected health information▪ Compensation in event of research-related injury▪ Any research-related concerns or complaints▪ If investigator/study contact cannot be reached▪ If I want to speak with someone other than the Investigator, Study Contact or research staff

SIGNATURE PAGE

(Site may use the site-specific signature page if required)

Please sign below if you agree to take part in this study.

- **You have read the informed consent and/or had it explained to you**
- **You were given the opportunity to ask questions about the information, and**
- **You voluntarily agree to take part in the study**

Research Subject's Name **Research Subject's Signature** **Date**
(Typed or printed)

OR

Research Subject's Legal Guardian/Representative **Legal Guardian's Signature** **Date**
(Typed or printed)

Witness's Name and title **Witness's Signature** **Date**
(Typed or printed)

(A witness to the research subject's signature is required.)

Signature of person explaining and obtaining the consent:

Name and Title **Signature** **Date**
(Typed or printed)

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research subject. A copy should be placed in the research subject's medical record, if applicable.)