

BISC/ImmPort Data Release 11 studies

August 2014

All publicly available studies have been updated with Planned Visit values.

Study Program: TLRs in Innate Immunity and the Induction of Adaptive Immunity in the Neonate and Infant

Title: Study responses of Adult and neonatal APCs to TLR ligands

Accession: SDY281

Subjects: 80

Study PI, contact: Christopher Wilson, M.D., University of Washington, Seattle, WA

Study Description: The overall goal of the study is to define comprehensively and in molecular and cellular detail, differences in recognition and response to microbes between adults and neonates and how these, in turn, contribute to differences in innate immunity and the induction of antigen-specific (adaptive) immunity.

Publication: none

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Flow Cytometry	3364

Clinical Assessments in ImmPort: none

Notes: New study

Study Program: TLRs in Innate Immunity and the Induction of Adaptive Immunity in the Neonate and Infant

Title: Gene expression changes in neonatal and adult plasmacytoid dendritic cells (pDC) and myeloid dendritic cells (mDC) upon TLR7/8 stimulation

Accession: SDY282

Subjects: 24

Study PI, contact: Christopher Wilson, M.D., University of Washington, Seattle, WA

Study Description: Differences in gene expression changes between neonatal and adult plasmacytoid dendritic cells upon stimulation with TLR7/8 may point to specific signaling pathways which, in turn, may account for the known differential immune response of babies to vaccination or infection when compared to adults.

Publication: none

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Array	72

Clinical Assessments in ImmPort: none

Notes: New study

Study Program: TLRs in Innate Immunity and the Induction of Adaptive Immunity in the Neonate and Infant

Title: Exploration of molecular mechanism(s) for TLR ligand response differences between adults and neonates

Accession: SDY283

Subjects: 89

Study PI, contact: Christopher Wilson, M.D., University of Washington, Seattle, WA

Study Description: The study will perform expression microarrays on RNA from purified subsets of neonatal and adult APCs either stimulated or not stimulated with TLR ligands of interest. Arrays will be performed on cells from neonatal and adult individuals and the arrays for all will be run in parallel on the same day.

Publication: none

Assays in ImmPort:

Assay Type	Number of Exp. Samples
ELISA	948

Clinical Assessments in ImmPort: none

Notes: New study

Study Program: TLRs in Innate Immunity and the Induction of Adaptive Immunity in the Neonate and Infant

Title: Human TLR4/MD-2 knockin (KI) mice and comparison of TLR4 agonists ability to enhance innate immunity and development of adaptive immunity in mice

Accession: SDY284

Subjects: 5

Study PI, contact: Christopher Wilson, M.D., University of Washington, Seattle, WA

Study Description: The study's aim is to generate human TLR and MD-2 knockin (KI) mice to assess host responses to infections with *Y. pestis* and to evaluate the safety and efficacy of purified/synthetic TLR4 ligand immunotherapeutics.

Publication: none

Assays in ImmPort:

Assay Type	Number of Exp. Samples
FCM	83

Clinical Assessments in ImmPort: none

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: Omega-3 Fatty Acids That Affect the Immune System in Kidney Transplant Patients

Accession: SDY352

Subjects: 81

Study PI, contact: J.W. Alexander, M.D., Sc.D., University of Cincinnati, Cincinnati, OH.

Study Description: The purpose of this study is to evaluate the effectiveness of nutritional supplements in increasing the amount of omega-3 fatty acids (and arginine) in the red blood cell membranes and plasma of kidney transplant patients, and, secondarily, to compare patient compliance. The long-term

goal of this study is to develop low risk therapies that will allow improved and lasting survival of donor tissue with minimal suppression of the immune system.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, demographics, hematology, concomitant medications, screening, chemistry, etc...

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: A Study to Test an Anti-Rejection Therapy after Kidney Transplantation

Accession: SDY354

Subjects: 292

Study PI, contact: David Ikle, Ph.D., Rho Federal Systems, Chapel Hill, NC

Study Description: Kidney transplantation is often successful. However, despite aggressive anti-rejection drug therapy, some patients will reject their new kidney. This study is designed to test two anti-rejection approaches. Two medications in this study are currently used in children, but there is no information regarding which drug is safer or more effective. Survival rates in renal transplantation are unacceptably low. Therefore, there is a need for an improved post-transplant treatment, such as the induction therapy used in this study.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, hematology, pathology, chemistry, etc...

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: An Evaluation of IV Gamma Globulin as a Method to Improve Kidney Transplant Survival in Patients with End-Stage Renal Disease Who Are Highly Sensitized to Transplant Antigens

Accession: SDY355

Subjects: 26

Study PI, contact: David Ikle, Ph.D., Rho Federal Systems, Chapel Hill, NC

Study Description: This study is designed to test the clinical and laboratory observations that suggest IVIG given before and after kidney transplant to patients who are sensitized (highly sensitive) to certain transplant antigens could result in reduced sensitization and reduced rates of kidney rejection. Some ESRD patients are highly sensitive to certain transplant antigens (foreign substances that activate the immune system) and must wait for a long time before a well-matched kidney becomes available. Transplant rejection is more likely among highly sensitized patients than in patients who are not highly sensitized. There is no proven method to improve a highly-sensitized patient's chances of receiving and keeping a transplanted kidney.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, hematology, chemistry, acute symptoms, etc...

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: IG03 Improving Transplant Options of Highly Sensitized Recipients Using IGIV-C 10%

Accession: SDY356

Subjects: 74

Study PI, contact: David Ikle, Ph.D., Rho Federal Systems, Chapel Hill, NC

Study Description: The purpose of this study is to determine if IGIV-C, 10% will be effective in converting a donor-recipient crossmatch status from positive to negative. The crossmatch test is used to determine if the donor tissue and recipient tissue are compatible. The study will also evaluate if IGIV-C, 10% will allow successful kidney transplantation in a patient who otherwise would not be able to receive a transplant. Three dose levels of IGIV-C, 10% will be evaluated to determine what dose level is most effective.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, acute symptoms, concomitant medications, etc...

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: VZV A Study of the Safety and Effectiveness of Varivax (the Chicken Pox Vaccine) in Children Who Have Received Kidney Transplants

Accession: SDY357

Subjects: 7

Study PI, contact: David Ikle, Ph.D., Rho Federal Systems, Chapel Hill, NC

Study Description: The purpose of this study is to find out whether Varivax is safe for use in children with kidney transplants and whether it protects children from serious infection. Varivax is a vaccine against varicella zoster virus (VZV), the virus that causes chicken pox (varicella) and shingles (zoster). Healthy children are already receiving Varivax shots to protect them from chicken pox. Few children with kidney transplants have received Varivax because doctors have been concerned that Varivax might cause serious reactions in them. On the other hand, VZV infection can be a life-threatening disease in these children. For this reason, doctors want to learn whether Varivax might safely prevent VZV infections in children who have had kidney transplants.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, vaccination and follow-up

Notes: New study

Study Program: Data Coordinating Center for Cooperative Clinical Trials in Pediatric Transplantation

Title: SRL1 A Study to Compare Treatment with Sirolimus versus Standard Treatment in Patients Who Have Received a Kidney Transplant

Accession: SDY358

Subjects: 102

Study PI, contact: William Harmon, M.D., Boston Children's Hospital, Boston, MA

Study Description: The purpose of this study is to compare treatment with the new drug sirolimus (SRL) versus the standard treatment with cyclosporine (CsA) or tacrolimus in children who have received kidney transplants. SRL is a new medication that may prevent the body's immune system from rejecting organ transplants. After receiving a kidney transplant, the body recognizes the donated kidney as a foreign invader and triggers the immune system to attack the kidney. This can lead to rejection of the new kidney and a failed transplant. To help reduce the risk of kidney rejection, transplant patients are given immunosuppressant drugs, which reduce the body's normal immune response and allow the transplanted organ to function. CsA or tacrolimus are two drugs that are often given to transplant patients. However, these are powerful drugs, and it can cause serious side effects and put a patient at increased risk for infections. SRL is a new drug that has been shown to reduce a transplant patient's

chance of rejecting a new kidney, without serious side effects. This study is necessary to test the safety and effectiveness of SRL in children.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, therapy change, lab tests, hematology, etc...

Notes: New study

Study Program: Virginia Bioinformatics Institute Modeling Immunity

Title: IL-21 expression during H. pylori infection

Accession: SDY302

Subjects: 36

Study PI, contact: Raquel Hontecillas, Josep Bassaganya-Riera, Virginia Bioinformatics Institute, Blacksburg, VA

Study Description: To elucidate the role IL-21 in vivo, IL-21 deficient mice and wild-type littermates were infected with H. pylori strain SS1 and colonization, gastric inflammation, cellular infiltration, and cytokine profiles were assessed in the gastric tissue.

Publication: none

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Flow Cytometry	24
Luminex_xMap	36
Microscopy	36
Q-PCR	36
CFU count	36

Clinical Assessments in ImmPort: none

Notes: New Study

Study Program: Defining signatures for immune responsiveness by functional systems immunology

Title: Immunologic and genomic signatures of response to Hepatitis C Virus infection

Accession: SDY162

Subjects: 20

Study PI, contact: David Hafler, M.D., MSc, Yale University, New Haven, CT

Study Description: Examine the immune response in primary immune cells from subjects who have spontaneously cleared HCV compared to HCV chronically infected subjects

Publication:

- Impaired toll-like receptor 3-mediated immune response from macrophages of patients chronically infected with Hepatitis C virus. *Clinical and Vaccine Immunology* 2013 Feb;20(2):146-55 doi: 10.1128/CVI.00530-12 [[PubMed](#)]

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Array	80

Clinical Assessments in ImmPort: none

Notes: updated microarray data

Study Program: NIAID Vaccine Research Center (VRC)

Title: VRC304 - A Phase I Study of the Safety and Immunogenicity of a Recombinant DNA Plasmid Vaccine (VRC-AVIDNA036-00-VP) Encoding for the Influenza Virus H5 Hemagglutinin Protein in Healthy Adults

Accession: SDY167

Subjects: 45

Study PI, contact: Julie Ledgerwood, D.O., Vaccine Research Center, NIAID, Bethesda, MD

Study Description: VRC304 - A Phase I, double-blind, placebo-controlled, randomized, dose escalation study to evaluate safety, tolerability, and immunogenicity of a recombinant DNA vaccine against the influenza virus hemagglutinin H5

Publication:

- Influenza virus h5 DNA vaccination is immunogenic by intramuscular and intradermal routes in humans. *Clinical and Vaccine Immunology* 2012 Nov;19(11):1792-7. doi: 10.1128/CVI.05663-11. [\[PubMed\]](#)

Assays in ImmPort:

Assay Type	Number of Exp. Samples
ELISA	430
ELISPOT	300
FCM	874
Hemagglutination Inhibition	44
Virus Neutralization	88

Clinical Assessments in ImmPort: adverse event, chemistry, hematology, etc...

Notes: updated biological samples and study files VRC304_Detailed_Derived_ICs_Data, Protocol_Deviation, Actual_Visit, Chemistry_Results

Study Program: Vaccination and Infection: Indicators of Immunologic Health and Responsiveness

Title: Apoptosis and other immune biomarkers predict influenza vaccine responsiveness

Accession: SDY212

Subjects: 91

Study PI, contact: Mark M. Davis, Stanford University School of Medicine, Stanford, CA

Study Description: In an effort to identify benchmarks of immunological health, influenza vaccination was used in 30 young (20 to 30 years) and 59 older subjects (60 to 89 years) as models for strong and weak immune responses, respectively.

Publication:

- Apoptosis and other immune biomarkers predict influenza vaccine responsiveness. *Molecular Systems Biology* 2013 Apr 16;9:659. doi: 10.1038/msb.2013.15. [\[PubMed\]](#)
- Effects of aging, cytomegalovirus infection, and EBV infection on human B cell repertoires. *Journal of Immunology* 2014 Jan 15;192(2):603-11. doi: 10.4049/jimmunol.1301384. [\[PubMed\]](#)

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Hemagglutination Inhibition	534
DNA Microarray	91
Peptide Microarray	91

PhosphoFlow	63
Flow Cytometry	1023
MBAA, Luminex	91

Clinical Assessments in ImmPort: none

Notes: Updated whole blood microarray data
