THE UNIVERSITY OF SOUTH FLORIDA

SPONSORED RESEARCH PURCHASE EXEMPTION FROM GENERAL ACCOUNTING AND PURCHASING PROCEDURES

Under the provision of Section 1004.22, Florida Statutes, the exemption of the following purchase is recommended.

DESCRIPTION: Infinity Bio, Inc.
Subagreement #6163-1103-01-BW

PURPOSE: To perform the services as described in the project funded by the National Institutes of Health (see attached)

JUSTIFICATION: The services to be provided by Infinity Bio, Inc. were approved by the National Institutes of Health. Due to time constraints, because it is more expeditious and efficient to the accomplishment of the project, and because funding to USF was contingent upon all parties participating and the expertise they house, this exception is granted.

DocuSigned by:
Eric M. Kern 10/10/2023 | 14:11 EDT
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Eric Kern, MBA
Director
Sponsored Research

Statement of Work

Project Title:
Primary Site PI: Jeffrey Krischer
Primary Site Institution: USF Health Informatics Institute
Subaward Site PI: H Ben Larman
Subaward Site Institution: Infinity Bio, inc.
Project start/end date: tentatively 11/01/23 – 04/30/24
Project Description:

Objectives:
Samples (plasma and cord blood) collected from T1D children and mother are to be profiled for a global antibody reactivity screen against a library of peptide antigens from all known human viruses (including Enteroviruses) and against a library of peptide antigens from food/environmental origin.

A total of 8000 samples will arrive in multiple batches and will need to be accessioned and aliquoted prior to analysis.

For the viral screen, Infinity Bio will use its VirSIGHT peptide library combined with an IgG capture pull down.
For the Allergy screen, Infinity Bio will use its AllerSIGHT peptide library combined with an IgE capture pull down.

Once processed, these 8000 samples are to be returned to TEDDY repository.

Explanation of work to be performed:

TEDDY will send 8000 samples consisting of a mix of plasma and cord blood samples – Infinity Bio will split them in 3 different aliquots, 2 aliquots will be used to run both VirSIGHT antibody IgG profiling and AllerSIGHT IgE profiling, 1 aliquot for each. The remaining aliquot will be returned to TEDDY.

Tasks:

A dedicated Service Coordination/Project manager will be assigned to the study. Weekly updates will be communicated on the progress of the samples moving through the workflow:

1. Samples accession and intake
2. Sample aliquoting
3. Sample incubation with MIPSA reagents and pull down
4. DNA barcode sequencing and QC

5. Bioinformatics deconvolution and dictionary mapping

Deliverables:

In more details, for a given antibody profiling project, during step 3 above, samples are first submitted to Infinity Bio. Samples are then mixed with the MIPSA reagent containing a library of antigens for peptide sequences of interest, each with a unique DNA barcode. Antibodies in samples bind to antigens in the library, and bound members are captured via magnetic beads. Barcodes on bound antigen-antibody pairs are amplified via PCR, and PCR products are submitted for sequencing.

Once sequencing results are obtained, FASTQ reads for each individual sample are run through the Infinity Bio informatics pipeline to process and compare each sample in the following ways:

Reads for each sample are mapped to a unique dictionary of barcode-peptide pairs specific to the peptide library/libraries of interest for the sequencing project. This is used to align each read and categorize it with a peptide assignment where applicable.

After alignment, the antibody profile of each sample is compared to a set of mock immunoprecipitations (IP) samples on the sample plate as the sample.

A mock IP is a reaction that includes all reagents except input serum/blood and undergoes all steps of the assay process alongside reactions that include the test samples. Then, a determination is made for each sample to determine whether a given peptide is a detected "hit" using three criteria:

- Total sequencing reads (counts) for the antigen must be above 15 in the sample
- Estimate of fold-change versus the mock IPs must be > 5
- p-value to reject the null-hypothesis that the sample read count is drawn from the mock IP background distribution must be < 0.001

For each peptide that passes the above criteria, read counts information in each sample is retained and files detailing the fold-change and enrichment p-values are saved as supplemental outputs.