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March 1, 2019

Invitation to Negotiate No.	19-17-MH
Entitled:	Epigenetics Lab for TEDDY Study
Due Date:	April 04, 2019 at 3:00 p.m.

Addendum No. 1

Review the following changes/additions/clarifications to Invitation to Negotiate (ITN) # 19-17-MH Epigenetics Lab for TEDDY Study to be addressed in submitted proposals: This addendum contains TEDDY Study and USF's responses to vendor questions. Responses are in red.

Questions received from EpigenDx Administration

1. We are trying to fill out the forms for the bid and we have some questions about pages 25 and 26. Could you explain these pages and what we need to fill in?
   The purpose of this form is to provide verification that the proposing entity is valid and to have a person from the organization provide written documentation to that point. The document should be filled out as completely as possible, if the responding entity does not have certain items requested on the form "Not Applicable" is a sufficient response.

Questions received from Barts and The London School of Medicine and Dentistry

2. Are samples available to construct groups?

Total number of Groups as below would be high disease risk (9 groups) and controls (4 groups) at low disease risk (could include those not progressing with single antibodies or those without autoantibodies according to availability). There would be 30 cases in each group. Our understanding is that you have IAA and GADA

seroconverters (n=226 and 212 respectively) and 69 with both. Plus a control cohort. We understand viral infections in stools have been identified pre-T1D in TEDDY (presented at nPOD Fort Lauderdale 2019 by Rick Lloyd).

Pre-IAA (DR4-DQ8) **n=30 each group**

1A. preinfection (earliest)

2A. preinfection (latest)

2B. post infection (respiratory or stool)

3C. post seroconversion

4D. post seroconversion to two or more autoantibodies * (same as 8D)

pre-GADA (DR3-DQ2 and/or DR4-DQ8) **n=30 each group**

5A. preinfection (earliest)

5A. preinfection (latest)

6B. post infection (respiratory or stool)

7C. post seroconversion

8D. post seroconversion to two or more autoantibodies * (same as 4D)

Controls age-gender related n=30 each group

9A. corresponding to preinfection for both IAA and GADA

10B. corresponding to post infection (respiratory or stool)

11C. corresponding to post seroconversion

12D. corresponding to post seroconversion to two or more autoantibodies *(for 4D and 8D)

The primary analysis follows the longitudinal samples from the case-control design, which did not balance on HLA or first appearing autoantibody. After vendor selection, TEDDY will work with the successful applicant to design appropriate analyses given sample availability for important subgroups.

3. Is DNA extracted from samples and 1 ug DNA per sample?:

Our understanding is that whole blood DNA is extracted but PBMCs have not been extracted. Is it possible to extract DNA from PBMCs before transfer to UK? If necessary we can extract DNA.

If DNA is extracted will concentration be normalized across all samples before shipping and to what concentration?

We will need 1 ug DNA per sample, volume is not important (is that realistic)?

It may be that for some very young children PBMCs are not available in which case to what extent can we realize the proposed cohorts with PBMCs and to what extent with whole blood DNA. Whatever we do (PBMCs or whole blood) – the analysis should be consistent across similar sample sets to answer questions posed both cross-sectionally and prospectively.

TEDDY has DNA extracted from supernatants. Most of the aliquots have over 2 ug of DNA. We are not planning to use PBMC samples.

4. What is the ceiling for funds available for analysis?

This will be negotiated with the selected applicant.

Note: **Please note receipt of this addendum by signing and returning with your proposal response**

_____

Authorized Signature & Date

_____

Print Name

_____

Company Name