Addendum No. 1

Review the following changes/additions/clarifications to Invitation to Negotiate (ITN) No. 16-02-MH TEDDY RNA Laboratory to be addressed in submitted proposals:

Below are questions we received from potential vendors related to ITN 16-02-MH, the TEDDY responses are in red.

1. Do you offer Vendors the possibility to submit their response electronically via email? No, all proposals must be submitted in hard copy as per the instructions in the ITN re. section II, item 1, page 5.

2. Vendors are required to submit one electronic copy on a flash drive. Are we allowed to submit it on a CD instead? Yes, a CD is acceptable.

3. Are Vendors allowed to propose their standard terms and conditions along with their response? Yes.

4. Does the Letter of Intent need to be mailed or emailed? We will accept an emailed Letter of Intent.

5. Should the Letter of Intent be submitted in a particular format? No, any format is acceptable.
6. I went on your website and it explains the study clinically but I was more interested on knowing about it from the lab perspective, mainly on how the samples need to be processed and what the downstream applications will be for the RNA after it is extracted from blood?

The selected laboratory will perform RNA extractions, from whole blood samples, for the TEDDY Study. After extraction the RNA samples will be sent to the NIDDK Repository for long-term storage. Specific analyses that will be run on the extracted RNA are to be determined at a later point in time by the TEDDY Steering Committee. The RNA samples will be used to identify novel disease markers and environmental triggers (RNA Seq). RNA can also be used to study gene expression of inflammation, infection, immunity, and molecular mechanism arising from TEDDY findings (epigenetics). These studies will be performed using a nested case-control study design, as well as longitudinal studies, with subjects who have progressed to autoantibody-positive and/or diabetes. The genes to be analyzed will be determined by the steering and appropriate advisory committees. The specific RNA studies to be done are not yet decided.

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

__________________________________________  
Authorized Signature & Date

__________________________________________  
Print Name

__________________________________________  
Company Name