

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS

In addition to the instructions and format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the solicitation.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information requested here should be used as further guidance for the development of your Business Proposal.

BUSINESS PROPOSAL

SECTION 1 – PROPOSAL COVERSHEET – Form NIH-2403 – PROPOSAL SUMMARY AND DATA RECORD

SECTION 2 – COST OR PRICE SUPPORT

All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

Uniform Cost Assumptions

I. Transition In: assume the Transition In will take approximately 2 weeks. The offeror will be responsible for moving/transferring all of the biological material under appropriate storage temperatures. Assume samples contained in 25 cubic feet of minus 180 degree Celsius storage maintained by liquid nitrogen, 185 cubic feet of minus 80 degrees Celsius storage, and 75 cubic feet of minus 20 degrees Celsius storage will need to be transferred.

II. Core work:

A. Pick-up and delivery of specimens: assume two (2) pick-ups and two (2) deliveries each week. Pick up locations and deliveries will be at NIH Campus (9000 Rockville Pike, Bethesda, MD 20892-1360) or NCI Fort Detrick (810 Schreider Street #1, Frederick, MD 21702).

B. Immunological assays and reagent preparation

1. ELISA technique: assume 3500 ELISAs to detect antibodies or antibody isotypes to either HIV, SIV, or HTLV-1/2 proteins, and pepscan analysis of 100 serum samples with anti-HIV envelope activity shall be performed per year.

2. Purifications of Lymphocytes: assume that 250 such purifications will be performed each year.
3. Purifications – HIV/SIV: assume that 20 mg of both SIV_{mac251} and HIV native gp120, 5 mg of SIV_{E660} native gp120, and 2 mg of SIV p27 will be purified and supplied in the first contract year. Assume 7 mg of His-tagged HIV gp120 will be supplied in the first year. In addition, IgG containing low endotoxin levels will be purified from 1800 ml of rhesus macaque plasma and supplied in the first contract year then similar quantities of similar proteins will be supplied in year two and three.
4. Synthesize peptides: assume that 3 sets of overlapping peptides, 5 mg each peptide, representing 2 HIV or SIV gp160s, 2 HIV or SIV pol, one SIV gag, and one Ad5 fiber protein will be provided in the first year then similar quantities of similar proteins will be supplied in year two and three.
5. Sort antigen specific B-cells and assume that 2 monoclonal antibodies will be scaled up, characterized and supplied per year.

C. Viral Stock preparation and Virological Assays

1. Purified and Titered Stocks of attenuated recombinant poxviruses : assume that one (1) such purified stock, approximately 10 ml with a titer of 10^9 TCID₅₀/ml, will be produced each year
2. Titered field isolate stocks: assume that three (3) titered field isolate stocks consisting of 100 one (1) ml aliquots each, 1 TCLA HIV and 1 TCLA SIV stock of 100 aliquots each, and 1 challenge stock with a titer appropriate for intravenous or mucosal challenge and in quantities sufficient for challenging 100 macaques, will be provided each year.
3. In vitro cultures: assume that culture of HIV, SIV, or SHIV will be requested from 25 samples each year for end point dilution analysis.
4. Real time PCR assays: assume that 2500 real time PCR assays for SIV gag in plasma and 200 for SIV gag in tissues shall be performed per year.
5. Assays to quantitate viral DNA levels: assume that 100 - 200 such assays will be conducted each year.

C. General molecular assays and reagent preparation

1. MHC class I haplotypes: assume that MHC haplotype determinations on 200 macaques samples and TRIM5 α allele determinations on 100 macaques will be performed each year.

2. Design, synthesize and purify: assume that 5 mg of a codon-optimized HIV primary isolate gp160 will be designed, synthesized and purified each year.
3. Pre-clinical grade plasmid DNA: assume that DNAs encoding 1 SIV and 1 HIV envelope and 1 SIV gag-pro, 50 mg each, will be provided each year.

D. Storage of Biological materials - storage capacity and temperature requirements:

50 cubic feet of minus 180 degree Celsius storage maintained by liquid nitrogen, 375 cubic feet of minus 80 degrees Celsius storage, and 150 cubic feet of minus 20 degrees Celsius storage.

E. Transition out: Assume the new contractor will be responsible for moving/transferring all the biological materials.

III. Optional work: Determination of CD4, CD, and B cell counts

CD4/CD8 and B Cells: assume that 1000 CD4/CD8 and 800 B cell counts will be performed each year.

Cost and Price information:

Please separate each task out separately. Task I (Transition in), Task II (Core Work) and Task III (Optional Work). In addition, please price out each task separately for the base and options below as follows:

- Base : October 15, 2014 – April 14, 2015
- Option 1: April 15, 2015 – October 14, 2015
- Option 2: October 15, 2015 – April 14, 2016
- Option3: April 15, 2016 – October 14, 2016
- Option 4: October 15, 2016 – April 14, 2017
- Option 5: April 15, 2017 – October 14, 2017

	Base	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Total
Task I (Transition In)								
Task II (Core Work)								
Task III (Optional Work)								