

**Bid Submission Form
Short-term and Field Stability Studies
RFP 10.0**

Please complete the following fields:

Contact Information – RFP 10.0

*Contact Individual:	Maria A. Croyle Ph.D.
Institution:	The University of Texas at Austin
Address:	College of Pharmacy PHR 4.214D Austin, TX 78759
Phone Number:	512-471-7474
Fax Number:	512-471-7474
Email Address:	macroyle@mail.utexas.edu

***If laboratories are submitting a proposal as a group, a main contact should be provided along with contact information for each participating laboratory (attach additional copies of this form).**

Please indicate if your institution is also submitting proposals for the other activities:

- Determination of Particle Concentration
- Determination of Infectious Titer
- Long-term Stability Study
- Other Characterization
- Donation of Supplies/Other Services for Characterization Phase

We propose to perform particle size analysis of the reference material by dynamic light scattering. This assay is routinely performed in the lab to characterize recombinant viral preparations for gene therapy. The SOP for this test is included with this statement. Amount of material needed is 2×10^{11} particles (44 ml) of the preparation.

Capability Statement UT College of Pharmacy

Part of Dr. Croyle's research program at The University of Texas at Austin focuses on issues associated with large-scale production, characterization, formulation, delivery and long-term stability of adenoviral vectors for gene therapy under GLP conditions. Laboratory staff routinely performs the procedures outlined below on most viral preparations generated in the lab.

Personnel Qualifications, Experience and Training

A) Personnel Involved in Performing the Procedure

Xuan Cheng M.D. Shuzou Medical College, People's Republic of China
M.S. Molecular Pharmacology, University of Maryland, Baltimore, MD USA

Xuan has 2 years experience in formal stability testing of adenoviral vectors.

B) Personnel Involved in Reviewing the Data

Maria Croyle, R.Ph., Ph.D. **Ph.D. Pharmaceutics, University of Michigan**

Maria has over 10 years experience working with adenoviral vectors for gene therapy. Her graduate work involved the development of adenoviral vectors for oral gene delivery. As a post-doctoral fellow at the University of Pennsylvania's Institute for Human Gene Therapy, she was responsible for initiation and design of stability studies for viral vectors used in clinical trials at the Institute and developed and produced lyophilized clinical grade viral vectors for shipment to external clinical sites.

Equipment

Light Scattering Detector/Device

DynaPro LSR (Protein Solutions)

Device is connected to a Hewlett-Packard computer equipped with Dynamics (version 5.25.44) and DynaLS software.

Equipment is less than 6 months old and in excellent working condition.

Biological Safety Cabinets

Laboratory is equipped with 2 NuAire Class II Type A/B3 cabinets

Cabinets are inspected yearly by a contract company through UT.

Pipettes Adjustable microliter pipettes (Ranin, Eppendorf) 1-20, 20-200 and 200-1000 μ l
Calibrated annually by a contract company through UT.

Timeline Performance of the procedure, data analysis, review and reporting will take place
2 weeks after receipt of material.

