Bid Submission Form
Participation in Assignment of Infectious Titer
RFP 9.0

Please complete the following fields:

Contact Information – RFP 9.0

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***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
- ☒ Short-term/Field Stability Studies
- ☐ Long-term Stability Study
- ☐ Other Characterization
- ☐ Donation of Supplies/Other Services for Characterization Phase

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General Capability Statement

Genetic Therapy, Inc. (GTI) proposes to participate in the assignment of infectious titer, using the 96-well plate, CPE-based protocol provided by the ARMWG. GTI has been producing and analyzing adenoviral vectors for over ten years. The ARMWG's Standard Operating Procedure for Determination of Infectious Titer in 293 Cells in a 96-Well Format will be performed by laboratory personnel of GTI's Core Technologies/Cell Biology Core. The Cell Biology Core has been analyzing adenoviral vectors under GLP conditions for three years. Personnel are familiar with a variety of infectious titer assays, including plaque assay and $TCID_{50}$, and have qualified an infectious titer assay that is routinely used. Prior to receiving the samples, personnel will perform at least one assay using the ARMWG's SOP, as training on this procedure. The data from and reports of the analysis of the Adenoviral Reference Material will be reviewed minimally by one Cell Biology Core supervisor who did not participate in the assay, and by GTI Quality Assurance.

Personnel

GTI Cell Biology Core personnel are fully qualified to perform the ARMWG's Standard Operating Procedure. All laboratory personnel have a minimum of a bachelor's degree in Biology (or equivalent field). In addition, all laboratory personnel are trained in GLPs, biosafety, and specific laboratory techniques. A training file is maintained for each GLP employee.

Quality Assurance auditors have a minimum of a bachelor's degree in Biology (or equivalent field), a working knowledge of laboratory procedures, and are trained in auditing GLP and GMP documentation.

Key Personnel:

Cell Biology Core Manager: Mark A. Bowe, Ph.D. in Pharmacology (1992); employed by GTI since 9/1999.

Cell Biology Core/Lab Services Manager: Irina Burimski, M.S. in Cytology and Histology (1980); employed by GTI since 3/1990.

Quality Assurance Technical Specialist: Michael Stefanski, M.S. in Plant Virology (1988), M.S. in Biotechnology (1997); employed by GTI since 8/1997.

Equipment

Cell Biology Core members have been trained on all equipment required by the protocol. Calibration of relevant equipment is as follows:

1. Adjustable microliter pipetttes (Gilson) and multi-channel pipettes (Fisher): calibrated twice a year.
2. Forma CO_2 incubators: calibrated monthly for CO_2 and annually for temperature.

Equipment is maintained and used according to Standard Operating Procedures. Equipment logs and results of assays are reviewed by a Cell Biology Core supervisor.

Timing

GTI is ready to accept Reference Material samples for testing as soon as they are available in mid to late September, 2001. The total time expected to perform the assay (including thawing of the cells) and to review and report the results is 6-7 weeks after receipt of sample.