CARMIT APPLICATION FORM: VECTOR MANUFACTURING

Please complete all information in one session as **this form cannot be saved before submission**

Applicant name: Click here to enter text.

Texas Academic Institution: Click here to enter text.

Staff Position: Click here to enter text.

Is this product intended for a trial to treat pediatric cancer?: Yes No

**If No, you are not eligible for this program**

Vector Product requested: Click here to enter text.

Approximate number of cells to be transduced for the entire study: Click here to enter text.

Will you be collecting/providing the cells for manufacturing? Yes No

Approximate date product required: Click here to enter a date.

Have you prepared this vector previously?: Yes No

If Yes, under GMP conditions?: Yes No

Has the vector been tested for replication competence?: Yes No

Results: Negative Positive

Do you have a written procedure for preparing the vector?: Yes No

Have you used, or sourced clinical grade reagents and supplies?: Yes No

By which method would you like the vector to be prepared

Using a Producer Cell Line

Is this cell line available?: Yes No

By Transient Transfection

Do you have the GLP/GMP plasmid DNA available? Yes No

Provide a brief (250-500 words) description of the proposed indication and clinical trial: Click here to enter text.

Have you had contact with the FDA about the proposed study:? Yes No

If Yes indicate the type of contact and or proposal status:

Pre pre-IND Meeting

Pre\_IND Meeting

IND in preparation

IND Submitted

IND Approved

No FDA Contact

Do you have any existing funding for product manufacture and or the clinical trial? Yes No

If Yes, is it for:

Product manufacturing and testing?

Clinical trial?

Both?

Indicate source of funding: International

Federal

State

Institutional

Foundation

Once submitted, this application will be evaluated by a Review Panel. If acceptable you will be asked to complete a more detailed application that will undergo external review.

Thank you for your interest!