APPLICATION FORM: CELLULAR THERAPY PRODUCT 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**

Cellular Product requested (e.g. transduced T cells): Click here to enter text.

Cell number required: Click here to enter text.

Approximate date required: Click here to enter a date.

Have you prepared these cells previously?: Yes No

If Yes, under GMP conditions?: Yes No

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

If yes, have you used, or sourced clinical grade reagents and supplies?: Yes No

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

If Yes, indicated the type of contact and/or project status:

Pre-pre IND meeting

Pre-IND meeting

IND in preparation

IND submitted

IND approved

No FDA contact

Will the cells be gene-modified?: Yes No

If Yes, please indicate the vector type and whether the GMP grade product is currently available

Lentiviral vector

Retroviral vector

Transposon/

Transposase

Provide brief description of vector:

Can the cells be cryopreserved?: Unknown  Yes No

Provide a brief (250-500 words) description of the proposed indication and clinical trial:

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!