UC San Diego
SCHOOL OF MEDICINE

Advanced Cell Therapy Laboratory

Cell Therapy Product Proposal

Instructions

Please complete the sections below to request access to ACTL cGMP systems and facilities. Submit completed form and attachments to actl@ucsd.edu.

Date Prepared

1. Client Information

Organization Name			
Organization Address			
Client Name			
Client Phone			
Client Email			
Additional project-related contacts			
Name	**Title**	**Phone**	**Email**

2. Service Requested

Choose the services requested for this project (check all that apply):

Service 1: Consultation ☐ Service 2: Process Development ☐

Service 3: Manufacturing ☐ Service 4: Storage ☐

3. Project/Clinical Protocol Information

Briefly describe the rationale for use, the therapeutic goal and clinical impact of your cell therapy product.

4. Regulatory Status

Provide the regulatory status of the project (check all that apply):

IND/Health Authority (HA) submission filed	☐	Pre-IND Meeting completed	☐
IRB Review completed	☐	Other (please describe below)	☐

Provide description of communication with FDA/HA or other regulatory approval status if applicable.

5. Cell Therapy Product Information

A. Cell Therapy Name and Description

Briefly describe the cell therapy product, the cell source/starting material and culture methods to be used for production.

B. Raw Materials

Provide a list of critical components including their source and qualification status, if known.

C. Cell Therapy Manufacturing Process

Briefly describe proposed plan of GMP manufacturing and characterization for the cell therapy product, including scale/format of the process and duration of production campaign. Please also provide a list of anticipated in-process/intermediate analytical tests to be performed and product specifications. Attach a process flow diagram if available.

D. Facilities/Equipment Needs

Mention any special facilities/equipment requirements for this project.

6. Clinical Service Information

Mention where patients will be treated (UCSD and/or elsewhere). What hospital and/or clinical services are likely to be involved?

7. Timeline

Expected start of GMP cell production	
Start Date of Clinical Trial	
Duration of Clinical Trial	
Anticipated Number of Patients to be enrolled	

8. Funding Information

What is the status of funding (check one):

Budget is complete and funded ☐ Budget is estimated and under review ☐

Budget is in development ☐

List funding source/s (e.g. NIH, CIRM, Foundations, Industry or Corporate Sponsor)

9. Publications

Provide a list of references and attach pdf of prior publications.

For questions and/or additional information please contact **Holly Young** (Facility Director; hyyoung@ucsd.edu) or **Dr. Dan Kaufman** (Scientific/Medical Director; dskaufman@ucsd.edu).