

UC San Diego Intake Form

Directions: To receive an estimate, please complete this form and email it to ASCCDataManager@ucsd.edu.

For product manufacturing or inquiries about product storage capabilities, contact Advanced Cell therapy Laboratory (ACTL) at 858-249-0244 or actl@ucsd.edu.

If regulatory consult for Pre-IND or IND application needs, email Vickie Sheckler at vsheckler@ucsd.edu.

For database management, email team at ASCCDataManager@ucsd.edu.

1. Your Information

Name:	
Company:	
Title/Role	
Phone Number:	
Email Address:	

2. Project Information

Primary Investigator Name:	
Primary Investigator Email:	
Project Title:	
Mechanism of Action:	
Disease Indication:	

3. Trial Sponsor (provide name of Sponsor)

Investigator Initiated:	
Industry Sponsored:	

4. Trial Phase (check all that apply)

- | | | |
|-----------------------------------|--|---------------------------------------|
| <input type="checkbox"/> Pilot | <input type="checkbox"/> Combination: Phase I/II | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Phase I | <input type="checkbox"/> Phase III | |
| <input type="checkbox"/> Phase II | <input type="checkbox"/> Not Applicable | |

5. Product Type (check all that apply)

- | | | |
|---|--|---------------------------------------|
| <input type="checkbox"/> Biologic | <input type="checkbox"/> Device | <input type="checkbox"/> Other Cell |
| <input type="checkbox"/> Cancer Stem Cell Targeting Therapy | <input type="checkbox"/> Gene Therapy | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Combination Therapy | <input type="checkbox"/> Immunotherapy | |
| <input type="checkbox"/> Stem Cell (complete question 5A) | | |

5A. If stem cell, what type of stem cell?

- | | | |
|---|--|---|
| <input type="checkbox"/> Cord Blood Stem Cell | <input type="checkbox"/> Hematopoietic Stem Cell | <input type="checkbox"/> Neural Stem Cell |
| <input type="checkbox"/> Embryonic Stem Cell | <input type="checkbox"/> Induced Pluripotent Stem Cell | <input type="checkbox"/> Other: _____ |

6. Financial Source

- Industry Sponsored
- Funding secured, list funding source: _____
- Funding secured and plans for additional funding. List funding source: _____
- No funding yet, but have a funding plan.

7. Have you applied for CIRM funding?

- | | | | |
|--|---|-----------------------------|---|
| <input type="checkbox"/> Yes (complete questions 7A-D) | <input type="checkbox"/> No, but pursuing | <input type="checkbox"/> No | <input type="checkbox"/> Not Applicable |
|--|---|-----------------------------|---|

7A. If yes, which CIRM funding?

- | | | |
|-------------------------------|---------------------------------|---------------------------------|
| <input type="checkbox"/> TRAN | <input type="checkbox"/> CLIN 1 | <input type="checkbox"/> CLIN 2 |
|-------------------------------|---------------------------------|---------------------------------|

7B. Please select CIRM funding status

- Application Preparation Grant Approval
 GWG Review Notice of Award
 ICOC Review Other: _____

7C. Please provide CIRM information

Grant Number (if applicable):	
CIRM funding amount:	

7D. List the CIRM representative(s) contact information you have been in discussions with

CIRM Rep Full Name:	
CIRM Rep Email:	

8. Select Current FDA Status

- Pre-IND Pre-IDE IDE-Exempt
 IND-Submitted IDE-Submitted
 IND-Active IDE-Active

9. Special Designation (if applicable)

- Accelerated Approval Fast Tack (FDA)
 Breakthrough Therapy Priority Review
 Fast Lane (Moores Cancer Center) Regenerative Medicine Advanced Therapy (RMAT)

10.

Clinicaltrials.gov identifier NCT # (if applicable):	
--	--

11.

Anticipated start date of trial:	
----------------------------------	--

12. Services being requested (check all that apply)

- Diversity, Equity, and Inclusion (DEI) Support
- Operational Support
- Reconciliation of Coverage Analysis from OCAA
- Study Coordination

- Data Management
- Project Management
- Regulatory Support
- Trial Budget Creation

13. Source of Referral: How did you learn about us?

- CIRM Representative
- UCSD Employee (not at Sanford Stem Cell Institute)
- UCSD Sanford Stem Cell Institute Employee
- Colleague/Friend
- Other: _____

- Patient Advocate
- Internet Search/Website
- Social Media
- News Article