

Industry 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. Individual completing this form

☐ Industry Representative ☐ CRO Representative

2. Your Information

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

3. Project Information

Project Title:	
Mechanism of Action:	
Disease Indication:	

4. Trial Phase (check all that apply)

☐ Pilot ☐ Combination: Phase I/II ☐ Other: _____

☐ Phase I ☐ Phase III

☐ Phase II ☐ 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

- | | |
|--|--|
| <input type="checkbox"/> Application Preparation | <input type="checkbox"/> Grant Approval |
| <input type="checkbox"/> GWG Review | <input type="checkbox"/> Notice of Award |
| <input type="checkbox"/> ICOC Review | <input type="checkbox"/> 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

- | | | |
|--|--|-------------------------------------|
| <input type="checkbox"/> Pre-IND | <input type="checkbox"/> Pre-IDE | <input type="checkbox"/> IDE-Exempt |
| <input type="checkbox"/> IND-Submitted | <input type="checkbox"/> IDE-Submitted | |
| <input type="checkbox"/> IND-Active | <input type="checkbox"/> IDE-Active | |

9. Special Designation (if applicable)

- | | | |
|---|--|---------------------------------------|
| <input type="checkbox"/> Accelerated Approval | <input type="checkbox"/> Fast Track (FDA) | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Breakthrough Therapy | <input type="checkbox"/> Priority Review | |
| <input type="checkbox"/> Fast Lane (Moores Cancer Center) | <input type="checkbox"/> Regenerative Medicine Advanced Therapy (RMAT) | |

10.

Clinicaltrials.gov identifier NCT # (if applicable):	
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11.

Anticipated start date of trial:	
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12. Services being requested (check all that apply)

- ☐ Identification of a UC San Diego Principal Investigator
- ☐ A confidentiality or non-disclosure agreement with UC San Diego
- ☐ Information on UC San Diego infrastructure available for Regenerative Medicine Clinical Trials
- ☐ Support for Diversity, Equity, and Inclusion (DEI)

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