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)

- Biologic
- Device
- Other Cell
- Cancer Stem Cell Targeting Therapy
- Gene Therapy
- Other: _____________
- Combination Therapy
- Immunotherapy
- Stem Cell, complete question 5A

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

- Cord Blood Stem Cell
- Hematopoietic Stem Cell
- Neural Stem Cell
- Embryonic Stem Cell
- Induced Pluripotent Stem Cell
- 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?

- Yes, complete questions 7A-D
- No, but pursuing
- No
- Not Applicable

7A. If yes, which CIRM funding?

- TRAN
- CLIN 1
- 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)
- [ ] Other: ____________
- [ ] 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)

- [ ] 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