

UCSD 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 Track (FDA)
- ☐ Breakthrough Therapy ☐ Priority Review
- ☐ Fast Lane (Moore's 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