

Intake Form for UC San Diego

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

1. Person completing this form:

- PI Study coordinator Project manager
 Other: _____

2. Contact information:

Name: _____
Department: _____
Phone: _____
Email: _____

3. Trial PI Contact information (leave blank if PI is completing this form):

Name: _____
Department: _____
Phone: _____
Email: _____

4. Trial Sponsor:

- Investigator sponsor: _____
 Industry sponsor: _____

5. Product type (check all that apply):

- Stem cell Other cell Gene therapy
 Biologic Device Cancer stem cell targeting therapy
 Small molecule Immunotherapy Combination therapy
 Other: _____

6. Trial phase (check all that apply):

- Phase I Phase II Phase III
 Combination Pilot Not applicable
 Other: _____

7. Current FDA status:

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

8. Special designation:

- Fast track
- Breakthrough therapy
- Priority review
- Accelerated approval
- Regenerative Medicine Advanced Therapy (RMAT)

9. ClinicalTrials.gov identifier or NCT # (if applicable): _____

10. Anticipated trial start date (mm/dd/yy): _____

11. Funding status:

- Funding secured – Indicate funding source here: _____
- No funding yet but have a funding plan

12. Services being requested (check all that apply):

- Study coordination
- Regulatory support
- Project management
- Operational support
- Trial budget creation
- Reconciliation of coverage analysis from OCAA

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

For IND guidance, email Vickie Sheckler at vsheckler@ucsd.edu.

For database or registry creation email the data management team at ASCCDataManager@ucsd.edu.

13. Disease indication: _____

14. Project title (optional): _____