Clinical Research (Clinical Trials) Intake Form

For Office Use Only
PeopleSoft - Cost Center #: ____________________
Project #: ____________________

Project Title:

Lead PI:	Protocol Number:
Division/Department:	Protocol Developed By: ☐ PI ☐ Sponsor ☐ Joint

Sponsor/CRO/Prime Information

Organization Type	Organization Name	Contact Name	E-mail	Phone Number	Notes

Project Type: ☐ Clinical Study (includes study drug) ☐ Device Study ☐ Service ☐ Other:

Subcontract/Subaward? ☐ Y ☐ N

Core Facilities Assisting with the Project (Check all that apply):

☐ Biostatistics ☐ FACS ☐ Human Imaging ☐ Neuropsychology ☐ Washing Core
☐ Cellular Imaging ☐ My Next Generation Sequencing (MiNGS) ☐ Stem Cell Analytics ☐ Translational Biomedical Imaging Laboratory (TBIL)

Project Start Date:	Project End Date (if known):	Number of Anticipated Patients:

Estimated Division Start-up Cost: $	Estimated Sponsor Advance (if applicable): $
Estimated Total Costs: $ or ☐ Based on enrollment	F&A Rate:
Consortium? ☐ Y ☐ N	Consortium Organization:

Human Subject Research:

☐ Approved ☐ Pending ☐ Exempt

IRB Number: ____________________

Additional Space Required?	☐ Y ☐ N
Stem Cells:	☐ Y ☐ N
Custom Antibodies:	☐ Y ☐ N
Biohazards: *If Yes, attach IBC Form.*	☐ Y ☐ N
Are staff Requirements met? *If no, explain in Comments below.*	☐ Y ☐ N

In the previous 12 months preceding the date of your signature below, have you, your spouse/domestic partner, or dependent child(ren): (1) received any payments from, including reimbursement for travel, (2) held stock, stock options, or other equity interest in (excluding stocks held through mutual funds), and/or (3) held a managerial position with an organization other than CHLA, CHLA Medical Group, or USC? ☐ Y ☐ N *If Yes, complete COI Disclosure Form.*

Comments:

Print Name ____________________ Signature ____________________ Date ____________________

Department/Division Head

Print Name ____________________ Signature ____________________ Date ____________________

Department/Division Administrator

Principal Investigator

I certify that the statements made in the above referenced project are true, complete and accurate to the best of my knowledge. I agree to accept the obligation to comply with all sponsor terms and conditions, to accept responsibility for the scientific and technical conduct of this project, and for the timely provision of all required reports. I also agree to administer the project in accordance with the policies and procedures of the sponsor and CHLA. I will ensure that all project personnel complete the required training programs, which may be mandated by the sponsor and/or CHLA. Until new project staff members have been trained, I will ensure that their work is closely supervised for compliance with regulations and policies of the sponsor and CHLA, and applicable law. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Print Name ____________________ Signature ____________________ Date ____________________