Children's Hospital LOS ANGELES
THE SABAN RESEARCH INSTITUTE

Updated 4/2022

For Office Use Only
PeopleSoft – Project #:

Extramural Project Intake Form

Project Information

Project Type	Proposal Type	Award Type	Funding Source	Applicable Research Theme (check all that apply)
☐ Training	☐ New	☐ Cooperative	☐ Federal	☐ Best Starts to Life
☐ Basic Research	☐ Continuation	☐ Grant	☐ State/Local/County	☐ From Discovery to Pediatric Care Innovation
☐ Service	☐ Renewal	☐ Subcontract	☐ Industry/For Profit	☐ Pediatric Disease Models and Mechanisms
☐ Clinical Research	☐ Resubmission	☐ Contract	☐ Foundation/Not for Profit	☐ Personalized Prevention and Care
☐ Clinical Trial	☐ Supplement		☐ International	
	☐ Transfer In/Out			

Project Title:

Select Primary Location:
☐ Anderson ☐Duque ☐McAllister ☐Outpatient Tower ☐Clinical Trials Unit
☐Saban Research Building ☐Smith Research Tower ☐5000 Sunset ☐Maubert
☐Community (various off campus locations) ☐Wilshire

☐ Other_____

Existing Grant/Award Number (if applicable):

Intellectual Property Information

Is Intellectual Property (discoveries with commercial potential) reasonable expected to result from this project?
☐ Yes ☐ No

Is there existing Intellectual Property, developed at or held by CHLA that is being used in this project?
☐ Yes ☐ No

Protocol Number (if applicable):

Protocol Developed By (if applicable): ☐PI ☐Sponsor ☐Joint

Export Control

Does this project include a foreign collaborator?
☐ Yes ☐ No

If yes, I confirm I have submitted a completed Export Control Questionnaire to the Research Compliance office, as required by CHLA Policy COMP 039.0 – Export Control.
☐Yes, I have submitted the required forms ☐ No, I have not yet submitted the required forms

CHLA Information

PI Name:	Dept:	Div:
Email:		Phone:
Div. Admin Name:	Email:	Phone:
Is this a multi PD/PI Application (if applicable)? ☐ Yes ☐ No		

Conflict of Interest (COI)

Does the PI or any individual responsible for the design, conduct, or reporting of the research (as determined by the PI) have a COI or potential COI as defined in CHLA's COMP – 021.0 Conflicts of Interest in Research policy (e.g., ownership interest, consulting activity, or management role in the sponsor, sub awardee, or licensee) related to this project? ☐ Yes ☐ No

If yes, list the names of the individuals below. Each individual with a conflict or appearance of conflict must complete the RESEARCH CONFLICT OF INTEREST CERTIFICATION FORM appended to the end this intake form. Please add additional pages if needed.

Name	Role	Department	Faculty (Y/N)	Completed COI (Y/N)

Sponsor Information

Funding Agency/Sponsor:		Due Date:
Contact Name:	Phone:	Email:
Funding Opportunity Number:		
Pass Through Entity (if sub to CHLA):		PTE Due Date:
Contact Name:	Phone:	Email:
After the Fact Proposal? ☐ Yes ☐ No		
CHLA Limited Submission? ☐ Yes ☐ No Please follow the CHLA Limited Submission Procedure		

Funding Agency Guidelines

☐ Sponsor does not have guidelines/solicitation/announcements

Please explain:

☐ Link to guidelines:

If no link, please send a PDF copy of guidelines to your Grants team analyst or to TSRIPreAward@chla.usc.edu.

Subrecipient Information (If Applicable) Please submit for each recipient: SOW, Subrecipient Commitment Form or FDP LOI, Budget and Budget Justification Please attach additional pages if needed.		
Subrecipient Institution	**Contact Name/Email**	**Estimated Project Amount (All Years)**

Budget Information					
Is this project non-monetary? ☐ Yes ☐ No					
Does the budget cover all costs associated with this project? ☐ Yes ☐ No					
If no, this cost share (including PI/Co-I salary) must be approved in advance. Please send a Cost Share Form to TSRIPreAward@chla.usc.edu in accordance with Cost Sharing/Cost Matching Policy FIN – 043.0.					
Check applicable IDC recovery box below:					
☐ 69.5 % Federal or Non-Clinical/Lab	☐ 35% CTA-Industry Sponsored	☐ 35% Off Campus	☐ 40% Other Sponsor Activity	☐ Sponsor State Rate: _____ *No IDC allowed*	☐ Modified Total Direct Cost ☐ Total Direct Cost ☐ Salary & Wages
If IDC is not being recovered in accordance with Indirect Cost Policy FIN – 048.0, including if IDC is only applied to certain costs such as salary/fringe, an IDC waiver request must be submitted prior to proposal submission to TSRIPreAward@chla.usc.edu.					

Budget Information for Non-Clinical Trial Projects					
Year	**Estimated Start Date**	**Estimated End Date**	**Estimated Direct Cost**	**Estimated Indirect Cost**	**Estimated Total Cost**
Initial Budget Period					
Overall Project Period					

Budget Information for Clinical Trials	
Project Start Date:	Project End Date:
Number of Anticipated Participants:	Estimated Division Start-Up Cost:
Estimated Sponsor Advance (if applicable):	Estimated Total Costs Based on Anticipated Enrollment:
Consortium? ☐ Yes ☐ No	Consortium Organization:

Institutional Compliance

When marking "approved" for questions 1-7, you must provide approval documentation with this intake packet. If an item is "pending" please provide the approval documentation when it's available to TSRIPreaward@chla.usc.edu.

1) Are human subjects (material or data from human subjects) involved?
☐ IRB Approved ☐Pending
☐N/A If yes, please provide
IRB number:

2) Commercially-Available Cell-Line: ☐Yes (if yes, No IRB approval needed) ☐No

a) Is CHLA receiving or providing the data? ☐Receiving ☐Providing ☐Both

b) Nature of the Data Set: ☐De-identified Data ☐Limited Data Set ☐PHI

c) Use of Human Induced Pluripotent Stem Cells, Human Totipotent Stem Cells, Human Gametes or Human embryos? ☐Approved ☐Pending ☐N/A

d) Use of Human Adult Stem Cells? (needed for state reporting): ☐Approved ☐Pending ☐N/A

e) Use of Human Embryonic Stem Cells? ☐Approved ☐Pending ☐N/A

3) Use of Vertebrate Animals? ☐Approved ☐Pending
☐N/A IACUC Number:

4) Use of biological agenda, infectious agents, recombinant or synthetic nucleic acid molecules? (IBC)
☐ Approved ☐Pending ☐N/A

5) Use of radioactive materials or radiation devices?
☐ Approved ☐Pending ☐N/A

6) Use of designated acutely toxic or physically dangerous chemicals? Please contact the Lab Safety Office at labsafety@chla.usc.edu
☐ Approved ☐Pending ☐N/A

7) Use of carbon or silica-based nanochemistry (particles sized from 1-100 nm)? Please contact the Lab Safety Office at labsafety@chla.usc.edu.
☐ Approved ☐Pending ☐N/A

Resource Library (Grants Only)

Should this proposal result in a successful award, may Research Operations include it in an internal CHLA resource archive, available to other investigators who are applying for similar awards?

☐ Yes, entire ■ ☐ Yes, a portion ☐No

**If not comfortable sharing the entire application, check "Yes, a portion of the application" and someone from the Research Operations team will work with you on including the portions you are comfortable sharing.*

TSRI Intramural Awards/Support Programs

If any intramural awards or programs supported the submission of this application, please check all that apply below:

☐ 2nd RO1 Pilot Grant ☐Bridge Funding ☐CHLA Core Pilot Program Grant ☐Donnell Society ☐Pre-Doctoral Award

☐ Research Career Development Award ☐Research Career Development Fellowship ☐Research Success Teams

☐ Team Science Grant ☐Grant Application Mock Review ☐HP-RCDA ☐Training & Travel Award ☐OTC Innovation Fund

☐ Start Up Funding ☐Other:_____

Core Facilities

Please check any and all Cores that supported the submission of this application:

☐ Biostatistics & Data Management ☐Cellular Imaging ☐ExtraCellular Vesicle ☐FACS ☐Human Imaging ☐Neuropsychology

☐ Metabolic ☐Spatial Biology & Genomics ☐Small Animal Imaging ☐Stem Cell Analytics ☐TBIL

Space and Facilities

Should this proposal result in a successful award, will current assigned space meet the needs of the award?

☐ Yes, current research space will meet the needs of this award.

☐ No, we will need to assess space to ensure the space needs are met for this award. If no, please complete and submit the Request for Research Space form.

Signature

For Grants Only: All proposals must be received five business days prior to the agency deadline per Policy FIN – 049.0.

For any questions about the form, please email TSRIpreaward@chla.usc.edu. Upon appropriate execute, a copy of this form will be sent to the Grants team.

Principal Investigator

I certify that the statements made in the above are true, complete and accurate to the best of my knowledge. I agree to accept the obligation to comply with terms and conditions of any potential agreement, 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 CHLA. I will ensure that all project personnel complete the required training programs. Until new project staff members have been trained, I will ensure that their work is closely supervised for compliance with regulations and policies 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.

PI Name:_____

PI Signature: _____

Date: _____

Division Head Name:_____

Division Head Signature:_____

Date: _____

Division Administrator Name:_____

Division Administrator Signature:_____

Date: _____

Research Conflict of Interest Certification Form

In accordance with CHLA's Policy, Conflict of Interest Policy in Research COMP – 021.0 all investigators and other covered individuals (as defined below) are responsible for identifying and disclosing all potential conflicts of interests to CHLA. Complete only if you answered "Yes" to any of the questions in section titled *Conflict of Interest* in the Intake Form.

Name:_____

Job Title/Department:_____

Outside Organization:_____

Research Project Title:_____

COVERED INDIVIDUALS: Personnel who have independent decisional roles in conducting a specific covered research protocol. These individuals are influential in the design, direction, or conduct of a covered research protocol, or engaged in the analysis or interpretation of data. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research of many protocols through the performance of routine patient care tasks are not covered individuals. Covered Individuals include the principal investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on the FDA 1572 Form, and personnel who obtain informed consent or who make decisions about research eligibility. Others who have decisional responsibilities that meet the definition of a covered individual, e.g. as co-investigator, research nurse, associate investigators, or an individual who interprets or analyzes research data, are also covered individuals.

All Covered Individuals designated by the PI as responsible for the design, conduct, or reporting of this research **must certify** whether they or their family members hold any Significant Financial Interests related to the proposed research.

FAMILY MEMBERS include spouse, dependent children/step-children, any person financially dependent upon you regardless of legal/biological relationship, and any person with whom you have joint financial interests.

DEFINITION OF Significant Financial Interest

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the

Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education."

Do you or your family member(s) have any significant financial interests related to this research?

☐ Yes ☐ No

Please describe the financial interest briefly:

FINANCIAL DISCLOSURES

- Remember that a current, completed COI questionnaire MUST be on file for all covered individuals when research is proposed. Any financial conflict of interest involving a covered person must be reported to the project sponsor prior to the expenditure of any funds under the award. If a covered individual is not a CHLA employee or trainee, and they have not completed a financial disclosure statement at their home institution, they must contact the Office of Compliance Privacy compliance@chla.usc.edu.
- If you have any questions about significant financial interests related to research, please contact the Office of Compliance Privacy at compliance@chla.usc.edu.

CERTIFICATION

I certify that I have read and understand the CHLA Conflict of Interest Policy in Research COMP – 021.0 and will comply with all applicable laws and CHLA rules and policies governing conflicts of interest. I understand that I am required to notify CHLA within 30 days if there are any changes in my disclosure. I certify that to the best of my knowledge the foregoing information is true and correct.

PI Name:_____

PI Signature:_____

Date:_____