



# Project Initiation Form

Email completed form as a Word file to [research@rchsd.org](mailto:research@rchsd.org). Please do not send a PDF file.

|  |   | Principal Investigator <i>(Cannot be a trainee)</i>  | Coordinator or PI Contact <i>(Cannot be a trainee)</i> |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|--|---|--|--|--|---|---|------------------------------------|------------------------------------|-------------------------------------|--|--------------------------------|--|--|---|--|
| Name   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Employer   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Division   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Email <i>(use RCHSD or UCSD address; no personal addresses)</i>  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Project Title  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Sponsor Protocol # <i>(if there is one)</i>  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| UCSD IRB # <i>(leave blank if IRB application not submitted yet)</i>   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| What is the study design? <i>(e.g., Phase 2 clinical trial; retrospective review; observational study; registry)</i>   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| ClinicalTrials.gov NCT # <i>(if there is one)</i>  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| YES  | NO  |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | Is this an investigator-initiated study by either an RCHSD PI or a UCSD PI? <i>(If a PI at another institution initiated the study, it is not investigator-initiated)</i>  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | Is this an industry-initiated study (written and funded by a for-profit company)?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | Is this a clinical trial involving drug administration? If YES, add names and IND #s of investigational drugs? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | Is this a device clinical trial? If YES, add name and IDE # of the device. →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | Does your study involve the use of written consent?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| SPONSOR INFORMATION  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Sponsor <i>(list all prime &amp; flowdown sponsors, even if no research dollars will flow to RCHSD, e.g., NIH→USC→UCSD)</i>  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Contact <i>(if UCSD PI, this is the fiscal contact at UCSD)</i>  |   | Name   | Email  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| RESOURCE UTILIZATION   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| YES  | NO  |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will patient records, clinic schedules, or patient lists be accessed?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Does this project <b>utilize any RCHSD resources</b> including, but not limited to: <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> Investigational Pharmacy: If YES, will this require services on weekends; holidays; or after hours (3pm – 6:30am)? <input type="checkbox"/> YES <input type="checkbox"/> NO</td> <td><input type="checkbox"/> Lab, Pathology</td> <td><input type="checkbox"/> Research Informatics</td> <td><input type="checkbox"/> Radiology</td> </tr> <tr> <td><input type="checkbox"/> Personnel</td> <td><input type="checkbox"/> Cardiology</td> <td><input type="checkbox"/> Biostatistician</td> <td><input type="checkbox"/> Other</td> </tr> <tr> <td></td> <td><input type="checkbox"/> Develop. Services</td> <td><input type="checkbox"/> Health Information</td> <td></td> </tr> </table> • If YES to any of the above, describe, even if no costs will be incurred: → |  | <input type="checkbox"/> Investigational Pharmacy: If YES, will this require services on weekends; holidays; or after hours (3pm – 6:30am)? <input type="checkbox"/> YES <input type="checkbox"/> NO | <input type="checkbox"/> Lab, Pathology | <input type="checkbox"/> Research Informatics | <input type="checkbox"/> Radiology | <input type="checkbox"/> Personnel | <input type="checkbox"/> Cardiology | <input type="checkbox"/> Biostatistician | <input type="checkbox"/> Other |  | <input type="checkbox"/> Develop. Services | <input type="checkbox"/> Health Information |  |
| <input type="checkbox"/> Investigational Pharmacy: If YES, will this require services on weekends; holidays; or after hours (3pm – 6:30am)? <input type="checkbox"/> YES <input type="checkbox"/> NO | <input type="checkbox"/> Lab, Pathology   | <input type="checkbox"/> Research Informatics  | <input type="checkbox"/> Radiology                     |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/> Personnel   | <input type="checkbox"/> Cardiology   | <input type="checkbox"/> Biostatistician   | <input type="checkbox"/> Other                         |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  | <input type="checkbox"/> Develop. Services  | <input type="checkbox"/> Health Information  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | List all areas where research will be done involving subjects (e.g., Ortho Clinic, NICU, Emergency Care Center, Hem/Onc, Surgical Services) →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will any per-patient items be charged to the study? (e.g., Labs; Xrays; EKGs; Echos)   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, what items will be charged to the study? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will any per-patient items be charged to insurance?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, what items will be charged to insurance? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will any RCHSD personnel time be charged to the study?   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, list the personnel →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Would the RCHSD PI like an <b>RCHSD-employed coordinator</b> to begin working on this project prior to when the award is made from the sponsor? If the answer is YES, by checking off the YES box to the left, the PI agrees to pay RCHSD for the coordinator's personnel effort.  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will any study procedures add time to: Clinic; OR; Endoscopy suite; Cath Lab; Anesthesia; Inpatient/Outpatient stay; ED; Radiology; MRI?   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, provide details →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will <b>patient data, including dates of any kind</b> , be shared outside of RCHSD?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, to which entities will patient data be provided? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Will <b>body fluid, solid tissues or other materials</b> be transferred to another institution (includes UCSD) that is engaged in the research?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, what biological materials will be transferred? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, to which institution will the materials be transferred? →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Are you using <b>non-RCHSD-owned equipment/devices</b> ? (e.g., personal laptop, tablet, smart phone, ECG machine)   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, describe the equipment. →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, who owns the equipment? →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, will PHI, including dates of any kind, be recorded/transmitted? →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | <input type="checkbox"/>  | ← Does your study involve <b>photography or videotaping</b> ?  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, what devices are involved? →   |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
|  |   | • If YES, who owns the devices? →  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| ADDITIONAL INFORMATION   |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| Please provide any additional information you would like Research Administration to know:  |   |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |
| <input type="checkbox"/>   | The person submitting this form certifies that the information above is accurate and complete. If the PI is not the person submitting the form, the submitter certifies that the PI has reviewed and approved the information on this form. |  |  |  |   |   |                                    |                                    |                                     |  |                                |  |  |   |  |