Study Coordinator Checklist

PI: Sponsor: Protocol #:

Study Title:

Number of Anticipated Study Subjects:

| **Steps** | **Check (√)****When Completed**  | **Comments** |
| --- | --- | --- |
| **1** |  | Send the following to CHLAclinicalresearch@chla.usc.edu:1. Draft CTA
2. Draft Budget
3. Protocol
4. Draft ICF/Assents
5. IB (Investigator Brochure)
6. Lab Manual
 |
| **2** |  | Please indicate which IRB will be used for this study?1. Western IRB (WIRB) \_\_\_\_\_\_\_\_\_
2. Advarra \_\_\_\_\_\_\_\_
3. Sterling \_\_\_\_\_\_\_\_
4. CHLA Local IRB (Single site, Investigator Initiated) \_\_\_\_\_\_\_

If not sure, please contact HSPP@chla.usc.edu  |
| **3** |  | If there will be any fees associated with the groups below, please submit the protocol to the person listed to determine the appropriate fees, and forward their fee quote to us.

|  |  |  |  |
| --- | --- | --- | --- |
| **Department** | **Contact** |  **Phone**  |  **Email** |
| Pharmacy | John Pech |  Ext. 15989 | jpech@chla.usc.edu |
| CRSP | Flora Luu | - | fluu@chla.usc.edu |
| CTU | CTU | - | CTU@chla.usc.edu |
| Radiology | Elizabeth Kim |  -  | Elizakim@chla.usc.edu |
| EKG/ECHOs | Jennifer Teh | Ext. 16009 | jteh@chla.usc.edu |
| Infusion Center | HemOncBMT Clinic Management | - | HemOncBMTClinicManagement@chla.usc.edu |

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| **4** |  | Review the draft budget and complete the following information concerning time and effort. Upon completion, send to CHLAclinicalresearch@chla.usc.edu, so this information can be added to the budget.

|  |  |  |  |
| --- | --- | --- | --- |
| **Category** | **Answer Question** | **Commonly Used Amount** | **Notes** |
| Informed Consent Form (ICF) | PI Time:\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 hour PI time at $200/HR  | $200/hour is non-negotiable and the same rate is used for all PIs at CHLA. |
| PI Oversight Fee (for each visit) | PI Time:\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 hour PI time at $200/HR | $200/hour is non-negotiable and the same rate is used for all PIs at CHLA. |
| **Category** | **Answer Question** | **Commonly Used Amount** | **Notes** |
| Clinical Research Coordinator Oversight Fee (for each visit) | CRC Time:\_\_\_\_\_\_\_\_\_\_\_\_\_ | 2 hours CRC time at $80/HR | $80/hour is non-negotiable and the same rate is used for all CRCs at CHLA. |
| Data Entry Fee For Each Visit (only if additional data entry is required) | Data Entry Time:\_\_\_\_\_\_\_\_\_\_\_\_\_ | 2 Hours CRC time at $80/HR | Only if additional data entry is required for on the project. |
| Patient Stipend | Are we accepting the offered Patient stipend amount?Yes or No*(Circle one)*If no, what is the amount we would like to propose for each visit? \_\_\_\_\_\_\_ | Typical Patient Stipend ranges from $25-$100 per visit | Patient Stipend is for the time & effort involved in participating in the study. It is separate from the travel or meal reimbursement. CHLA also adds its ClinCard processing fee to the stipend amount. This additional fee is to use the ClinCard debit card, instead of cash or gift cards.Make sure the final stipend amount matches the amount listed in the final Informed Consent Form. |
| Division Start-up Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$2,000-$5,000  | Example of how a $2,000 start-up fee is calculated: 4 hrs. PI time at $200/hr. = $80015 Hrs. SC time at $80/hr. = $1,200Total: $2000 |
| **Category** | **Answer Question** | **Commonly Used Amount** | **Notes** |
| Division Annual Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$500  | This is for time and effort involved in submitting the Study to the IRB for renewal.  |
| Division Close-out Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$1,000  | This is for time and effort involved in closing down the study - answer queries, the study close-out monitoring visit, reconciliation of study documents and materials. |
| Archiving/Document Storage Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$500  | Note: This amount may be higher ONLY if there are a large number of study participants or if the retention period is longer than 10 years.  |
| IRB Amendment Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$500 per protocol amendment | This is for time and effort involved in submitting the Study to the IRB when there is a protocol amendment. |
| Serious Adverse Event Reporting Fee | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$200 per SAE |  |
| Safety Reports | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$25 per IND Safety Report |  |
| **Category** | **Answer Question** | **Commonly Used Amount** | **Notes** |
| Screen Failure | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:Full screening visit cost  |  |
| Unscheduled Visit | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$1,000 per occurrence or pay-per-procedure + 35% | During an unscheduled visit, this amount will not require pre-approval from the Sponsor.  |
| Monitoring Visit (in excess of 5 per year) | Amount:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Typical Amount:$500 per monitoring visit |  |
|  Please note, CHLA’s 35% indirect cost rate will be added to all costs.  |
|  |  |  |  |

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| **5** |  | Submit the Protocol to CHLA’s IRB for initial review at <https://istar.usc.edu>  |

Prepared by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Information (email and/or extension): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Addendum 1**

Roles and Responsibilites



 Responsible Party:

 Study Team

 TSRI CCR Team

 IRB