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| --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB Number:** | | |  | | | | |
| **Study Title:** | | |  | | | | |
| **Principal Investigator:** | | |  | | | | |
| **Version Date:** | | |  | | | | |
| **Section 1. Who will be perform safety assessments at CHLA?** | | | | | | | |
| Identify who on the CHLA study team will be performing safety assessments of individual subjects at CHLA. (add rows as needed) | | | | | | | |
| **Name** | | | | | | **Role on Project** | |
|  | | | | | |  | |
|  | | | | | |  | |
|  | | | | | |  | |
| **Section 2. What safety Assessments will be conducted at CHLA?** | | | | | | | |
| Identify what type of safety assessments will be performed on individual research subjects at CHLA and how frequently these assessments will be conducted. You may refer to relevant sections or tables of the protocol if applicable | | | | | | | |
| Age specific intervention(s) | | | | |  | | |
| Clinical and/or research tests | | | | |  | | |
| Subject interview and/or contact | | | | |  | | |
| Subject’s physical exam and/or vital signs | | | | |  | | |
| Subject’s symptoms or performance status | | | | |  | | |
| Review/follow-up of adverse events | | | | |  | | |
| Other study parameter(s), please specify: | | | | |  | | |
| **Section 3. Who will review the data from all study subjects for safety and efficacy?** | | | | | | | |
|  | **The Principal Investigator (or designee) at CHLA will perform the safety monitoring for a single-site study.** This may only be selected where: 1) the protocol has been determined to pose only a slight increase over minimal risk to human subjects, 2) the study does not require an internal or external Data and Safety Monitoring Committee/Board, and 3) the research is only being conducted at CHLA. | | | | | | |
|  | **The PI/study chair or designee (at CHLA or elsewhere) will perform the safety monitoring for a multi-site study.** This may only be selected where: 1) the protocol has been determined to pose only a slight increase over minimal risk to human subjects, and 2) the study does not require an internal or external Data and Safety Monitoring Committee/Board. | | | | | | |
|  | **A DSMC/DSMB/DMC established at CHLA/USC will perform the safety monitoring for the study.** The protocol has been determined to pose moderate or “significant” risk to human subjects. This type of DSMC need not be independent of the study team and may make determinations in consultation with the CHLA/USC PI. | | | | | | |
|  | **A DSMC/DSMB/DMC established at an outside institution (university, hospital, pharmaceutical company, etc…) will perform the safety monitoring for the study.** The protocol has been determined to pose moderate or “significant” risk to human subjects. This type of DSMC need not be independent of the study team and may make determinations in consultation with the study Chair(s)/pharmaceutical sponsor. | | | | | | |
|  | **An independent DSMB/DSMC/DMC will perform the safety monitoring for the study.** A DSMB acts independently from the study sponsor/coordinating center. | | | | | | |
| **Section 4. DSMB/DSMC/DMC Information** | | | | | | | |
|  | Not applicable – this study does not include a DSMC/DSMB/DMC | | | | | | |
|  | This study includes a DSMC/DSMB/DMC. Provide the DSMB/DSMC/DMC information below (add rows as needed) | | | | | | |
|  | **Name** | | | **Institutional Affiliation and Specialty** | | | **Role** |
|  | | |  | | | Chair Contact Person Voting Member Non-Voting Member |
|  | | |  | | | Chair Contact Person Voting Member Non-Voting Member |
|  | | |  | | | Chair Contact Person Voting Member Non-Voting Member |
|  | | |  | | | Chair Contact Person Voting Member Non-Voting Member |
|  | | |  | | | Chair Contact Person Voting Member Non-Voting Member |
|  | Only the contact person is provided as the sponsor has determined that the members must be kept confidential | | | | | |
| How often will the DSMB/DSMC/DMC meet? | | | | | | |
|  | Once a year | | | | | |
|  | Once every 6 months/Twice per year | | | | | |
|  | Other frequency (please specify): | | | | | |
| Please check the box to agree with the following statement: | | | | | | |
|  | The PI will promptly submit all DSMB/DSMC/DMC reports as soon as received | | | | | |
| **Section 5. How will adverse events be graded?** | | | | | | | |
|  | The National Cancer Institute’s “Common Terminology Criteria for Adverse Events” (CTCAE) | | | | | | |
|  | The FDA Grading system | | | | | | |
|  | The Common Grading Scale | | | | | | |
|  | Other (Specify or refer to relevant sections of the protocol): | | | | | | |
| **Section 6. How will adverse events be attributed?** | | | | | | | |
| The investigator will determine the relatedness of the adverse event to the research (test procedure/device/agent/etc.) using which of the following scales | | | | | | | |
|  | Using the National Cancer Institute’s Cancer Therapy Evaluation Program (CTEP/NCI) guidelines | | | | | | |
|  | Using the FDA’s common attribution scale | | | | | | |
|  | The PI will determine the relationship of AEs to the research using an alternate attribution scale (describe or refer to relevant sections of the protocol): | | | | | | |
| **Section 7. To what groups will CHLA adverse events be reported?** | | | | | | | |
| All adverse events meeting the reporting criteria at CHLA must be reported to the IRB. These should be reported via iSTAR, using the “reportable event application.” For some studies, adverse events at CHLA must also be directly reported to additional agencies. To which additional agencies will CHLA adverse events be reported (select all that apply)? | | | | | | | |
|  | None | | | | | | |
|  | The study sponsor/coordinating center | | | | | | |
|  | Collaborating investigators at participating sites (when CHLA is the coordinating center) | | | | | | |
|  | The National Institutes of Health (NIH) | | | | | | |
|  | The Centers for Disease Control and Prevention (CDC) | | | | | | |
|  | The Food and Drug Administration (FDA) | | | | | | |
|  | Other (specify): | | | | | | |
| **Section 8. Are there any decision-making criteria for this protocol?** | | | | | | | |
|  | There are **no** decision-making criteria for this protocol. | | | | | | |
|  | There **are** decision-making criteria for this protocol. (check and describe all that apply): | | | | | | |
|  |  | Regarding study continuation for individual subjects (describe or refer to relevant sections of the protocol): | | | | | |
|  | Regarding modification/suspension/termination of the study as a whole (describe or refer to relevant sections of the protocol): | | | | | |
| **Section 9. Does this plan include interim monitoring?** | | | | | | | |
|  | This study does **not** include interim monitoring | | | | | | |
|  | This study **does** include interim monitoring. The plans for interim monitoring are based on (check and describe all that apply) | | | | | | |
|  |  | Number of subjects enrolled (Describe at what accrual point(s) analyses will be conducted or refer to relevant sections of the protocol) | | | | | |
|  | Time. (Describe at what interval(s) analyses will be conducted or refer to relevant sections of the protocol) | | | | | |
|  | Other (Describe) | | | | | |