CHLA INSTRUCTIONS FOR SUBMITTING CLINICAL TRIALS TO THE WESTERN INSTITUTIONAL REVIEW BOARD (WIRB) - INITIAL SUBMISSION

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BACKGROUND

CHLA has a reliance agreement with WIRB-Copernicus Group (WCG) for review of clinical trials by WIRB. **This agreement is limited to industry initiated and sponsored, multi-center clinical trials**. Study team members who will be responsible for submitting to WIRB should participate in the Web-Ex training session called, "How to Use Connexus for Submission to WIRB." This session is offered several times each month, and session details are sent via email to the iStar and TSRI lists. If study teams are uncertain whether a study is eligible for WIRB review, or have questions about these instructions, please contact the HSPP office at irbreliance@chla.usc.edu, or 323-361-2265. Before getting started with a submission, refer to the Investigator Guidance for Reliance on Another IRB, and the CHLA-WIRB Consent Form Checklist on the HSPP website.

INSTRUCTIONS

All the following steps are required for submission to WIRB:

Communicate with the Sponsor/Contract Research Organization (CRO)

1. When a study team is contacted by the Sponsor to join a study, inform the Sponsor that CHLA relies on WIRB for industry initiated and sponsored, multi-center clinical trials. Inquire with WIRB whether the study has been or will be reviewed by WIRB. If not, contact the HSPP office at irbreliance@chla.usc.edu for additional instructions.

Communicate with WIRB

2. Contact WIRB Client Services to verify if the study has been reviewed by WIRB or Single Review Solution (SRS) WIRB/CGIRB via email to clientservices@wirb.com, via LiveChat in Connexus, or (800) 562-4789.
    a. The website for Connexus is: https://connexus.wcgclinical.com/
        i. First time users will need to "Create a New Account" by completing the registration process. Once registered, an activation link will be emailed, please click on that link to Activate your account.
            1. Use your CHLA email account; no personal email accounts may be used.
        ii. Existing users can log in using the credentials used to register for their account.
    b. If the study has been approved by WIRB:
        i. Request Connexus access from Client Services for submission via Connexus
        ii. Obtain WIRB approved templates from Connexus

iii. Obtain from the Sponsor all WIRB approved study documents, i.e., protocol and protocol support documents not included in the protocol, Investigator Brochure, all documents to be used or provided to subjects and recruitment materials.

c. If the study has not yet been approved by WIRB:
    i. Communicate with the sponsor/CRO and request the sponsor's consent template(s) and all other study documents that require WIRB review, i.e., protocol and protocol support documents not included in the protocol, Investigator Brochure, all documents to be used or provided to subjects and recruitment materials.

<u>Submit to the CHLA HSPP Office for Clearance</u>

3. Submit a request for CHLA HSPP clearance in iStar to rely on WIRB.
    a. Submit a ceded review application through iStar, and upload the protocol documents provided by the Sponsor, any CHLA specific documents, and a completed CHLA-WIRB Consent Form Checklist.
    b. Unlike other ceded review submissions, the Sponsor template consent form(s) does not need to be customized by the CHLA study team. WIRB will create the CHLA consent form(s) using the completed CHLA-WIRB Consent Form Checklist.
    c. All department/division and ancillary reviews must be completed before a submission may be cleared.
    d. The CHLA HSPP will issue a clearance notice to the Principal Investigator (PI).
    e. After receiving the clearance notice, the study team can submit for WIRB review.

<u>Submit to WIRB for Review</u>

4. If the study has been approved by WIRB, submit to WIRB via Connexus by selecting, "Submit New Investigator" under My Studies view. Include the following materials with the submission:
    a. Initial Review Submission Form (IRSF)
    b. Attachments as directed during the completion of the IRSF
    c. CHLA HSPP Clearance Notice
    d. CHLA-WIRB Consent Form Checklist
    e. Any CHLA specific recruitment or subject materials
    f. PI medical license (for PIs who have not previously submitted to WIRB)
    g. PI CV (for PIs who have not previously submitted to WIRB)

5. If the study has not been approved by WIRB, submit to WIRB via Connexus by selecting "Make a Submission to the IRB" from the Quick Access Links. Then select "Initial Review Submission", then "Review of New Research Protocol." In addition to the materials in #4 above, include the following materials with the submission (these documents must be obtained from the Sponsor):
        a. Protocol and protocol support documents not included in the protocol
        b. Additional Protocol document(s) provided by the Sponsor that require IRB review
        c. All documents to be used or provided to subjects provided by the Sponsor

d. All recruitment materials provided by the Sponsor
e. Investigator brochure(s) provided by the Sponsor

6. You will receive a Connexus Acknowledgment Receipt of submission. WIRB will begin processing your submission as follows:
    a. The submission will be reviewed by WIRB for completeness.
    b. The consent form will be prepared from CHLA-WIRB Consent Form Checklist for Board review.
    c. The submission will be sent for pre-review to the sponsor/CRO **if** the sponsor/CRO requires this step.
    d. The submission will be sent to Board for review and action.
    e. After approval, outcome documents are emailed with a hyperlink to all study contacts and posted to Connexus.
        i. The email is sent only to the study contact(s) listed on the IRSF, sponsor/CRO contacts, and CHLA HSPP office.
        ii. All site contacts with access to the site workspace in Connexus have access to view documents in Connexus.

7. Once approval is received, the CHLA study team will need to file an amendment in iStar to upload the following approved documents: Final Sponsor protocol, WIRB certificate of action (approval letter), CHLA consent form(s), CHLA flyers/ads, etc.