| LSU Health NEW ORLEANS Human Research Protection Program | RELYING ON THE PETAL CIRB | | | |
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| | P & P | VERSION DATE | REPLACES P & P | PREVIOUS VERSION DATE |
| | 8.03 | 12.06.2022 | 5.29 | 02.07.2020 |

## Introduction

Louisiana State University Health Sciences Center–New Orleans (LSUHSC–NO also referred to as the Institution) and the Vanderbilt University IRB have initiated an authorization agreement whereby LSUHSC–NO will defer to the Vanderbilt University IRB, acting as the central IRB (CIRB) for PETAL Network clinical trials. The PETAL Network conducts cooperative group trials funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

The CIRB will conduct reviews of the following: initial and continuing reviews, amendments, non-local serious adverse events, local serious adverse events that are not listed in the protocol or that meet the criteria of unanticipated problems, all unanticipated problems, and all instances of noncompliance. The CIRB will also address local context issues via the PETAL Network, Site Local Context information document.

## Review Process for CIRB-Approved Protocols

As the Signatory Institution, LSUHSC-NO will monitor the conduct of the research locally. Monitoring will be accomplished by the LSUHSC-NO IRB staff with the cooperation of the local PETAL Network, LSUHSC-NO Principal Investigator (PI) and study teams.

## Reviews of CIRB-approved protocols will be performed as follows

A PI who wishes to enroll subjects in a CIRB-approved protocol must submit a request to the Institution using the LSUHSC-NO IRB PETAL Abbreviated Application. In addition, the PI must submit the approved CIRB informed consent form (ICF) modified for local site use and the LSUHSC-NO HIPAA Authorization document. All study related documents must be made available to the LSUHSC-NO IRB through the PETAL Clinical Coordinating Center website or supplied to the LSUHSC-NO IRB as electronic versions of the documents.

The PI must submit to the LSUHSC-NO IRB the CIRB approval of the study in question.

## Further Review Procedures

The Institution will perform reviews of further documentation as follows:

1. The local PETAL PI must provide the LSUHSC-NO IRB a brief summary of all significant amendments reviewed by the full Board CIRB along with notification of CIRB approval. If amendments resulted in changes to the ICF, a copy of the newly approved ICF, that includes local context issues, must be submitted to the LSUHSC-NO IRB.

2. For continuing reviews that were approved by the full board CIRB, the local PETAL PI will submit copies of the continuing review application and the CIRB's continuing review approval documentation to the LSUHSC-NO IRB staff.

3. The local PETAL PI must provide any approved advertisements that will appear locally for enrollment into the study the LSUHSC-NO IRB staff.

4. The local PETAL PI will submit notification of any expedited CIRB activity related to the study to the LSUHSC-NO IRB staff.

5. The local PETAL PI must report local serious adverse events (SAEs), local unanticipated problems, protocol deviations and local instances of noncompliance to the CIRB as required by the CIRB Standard Operating Procedures, and must simultaneously report to the LSUHSC-NO IRB all such events. The principal investigator must inform the LSUHSC-NO IRB staff of any actions taken by the CIRB that result from problems identified in these areas.

6. Note that the Institution retains the right to expand on or to create its own corrective action plan related to issues of non-compliance with CIRB or LSUHSC-NO IRB policies, or pertinent federal regulations. Further actions by the Institution's administration may vary depending on the significance of issues involved but may include withholding of permission to conduct further human subjects research at LSUHSC-NO or termination of employment at LSUHSC-NO.

7. LSUHSC-NO retains the right to not accept determinations of the CIRB. In such a case, the study must be closed at the Institution with due consideration of the safety and welfare of enrolled subjects.

## Further Responsibilities of Institution

LSUHSC-NO will:

1. Comply with the CIRB's requirements and directives

2. Report to the CIRB the names of any Component or Affiliate Institutions that rely on LSUHSC-NO IRB

3. Maintain a Federal Wide Assurance (FWA) and designate the Vanderbilt IRB under its FWA

4. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects

5. Ensure that local investigators receive proper initial and continuing education on the requirements related to human subjects protections

6. Perform oversight of the local conduct of the study, monitoring study compliance, thereby ensuring the safe and appropriate performance of the research at this institution. There will also be the provision of a mechanism by which complaints about the research can be made by local study participants or others

7. Review all local SAEs, unanticipated problems, and issues of non-compliance as submitted to the CIRB and evaluate whether Institutional actions in addition to those taken by the CIRB may be required

8. Provide updates to the CIRB whenever a PI is no longer the responsible party for a study under the purview of the CIRB

9. Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the Institution, such as the local IRB administrator

10. Notify the CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the CIRB was responsible for study review

11. Maintain a regulatory file for each study under CIRB purview as per local institution and Cooperative Group policy.