



# Standard Operating Procedures for the cIRB



# PETAL cIRB Operating Procedures

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## The cIRB Review Process

### **Initial Review:**

The PETAL cIRB will review initial applications for new studies in accordance with applicable federal regulations, the local context provided by each PETAL site, and its own operating procedures. As part of its responsibilities for conducting the initial review, the PETAL cIRB must:

- Take into consideration the “local context” information provided to it by the PETAL sites including site-specific information for any informed consent documents. This information will be provided to the PETAL cIRB upon reliance agreement execution.
- Act as a HIPAA Privacy Board and make any applicable HIPAA Privacy Rule determinations required on behalf of the PETAL sites relevant to the initial review (i.e., waivers or alterations of authorization). PETAL sites are responsible for their own accounting of disclosures.
- Confirm that study personnel have completed human subjects protection training at least every 3 years. Training can be completed via CITI or NIH human subjects protections training courses. The CCC will provide verification of study personnel training.

Unless an issue is discovered during the course of review that requires input from the PETAL sites, the PETAL cIRB will not provide any direct communication to the PETAL sites except approved documents and an approval letter.

When informed consent documents (ICDs) are required for a study, the ICD template(s) of the PETAL cIRB will be used for all PETAL sites for that study.

The PETAL cIRB will determine the content of ICDs except for sections for which the PETAL sites have provided their site-specific language, as applicable. The site-specific language includes but is not limited to:

- Compensation for injury
- Costs related to study participation
- Local study team contact(s) for questions about the study

Short form ICDs used for enrolling non-targeted, non-English speaking subjects are considered local context and will be reviewed and approved by the PETAL cIRB. PETAL sites are responsible for ensuring their site-specific language is current, including providing as a part of their local context, any non-English short form used at their site(s). The PETAL cIRB is responsible for

ensuring that the required site-specific language is incorporated into the ICDs for use at that site.

If a local study team or PETAL site requires changes to its local language after the PETAL cIRB has approved the ICD(s) for that site, notification must be given to the PETAL cIRB so that an amendment can be reviewed.

#### **Amendments:**

Amendments are submitted to the PETAL cIRB by the PETAL CCC (Clinical Coordinating Center). The PETAL cIRB will conduct protocol amendment reviews in accordance with applicable federal regulations, the local context provided by each PETAL site, and its own operating procedures. PETAL site teams will report changes in personnel and potential conflicts of interest as they change/occur to the PETAL CCC for submission to the PETAL cIRB.

- Study-wide amendments are submitted as a single submission for all sites;
- Local site amendments are submitted as single submissions for each site unless the change is exactly the same for all sites in which case, a single submission for multiple sites is preferred;
- Site additions can be submitted in bulk (i.e., more than 1 site).

#### **Continuing Review:**

The PETAL CCC will submit a continuing review progress report to the PETAL cIRB. PETAL CCC is responsible for obtaining information from each PETAL site so that the PETAL cIRB can review a comprehensive report regarding study progress, new information, and problems that have occurred.

The PETAL cIRB is responsible for reviewing all relevant information at the PETAL sites until the research is closed. The PETAL cIRB will conduct continuing reviews in accordance with applicable federal regulations, the local context provided by each PETAL site, and its own operating procedures.

The PETAL CCC, upon approval, provides all currently approved documents along with the approval letter to the PETAL sites. If the PETAL cIRB determines it cannot reapprove a study, the PETAL cIRB will notify the PETAL CCC and relevant PETAL site of its determination and the reasons for the determination.

In the event any continuing review information is submitted to the PETAL CCC after cIRB approval for the study expires or the study expires before the PETAL cIRB can reapprove the study, the PETAL cIRB will notify the PETAL site of the expiration.

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## **HIPAA Privacy Board**

### **The Privacy Rule**

The PETAL cIRB will serve as Privacy Board for Research for PETAL sites that are Covered Entities. As such, protected health information (PHI) will not be shared among collaborating institutions unless there is: (1) appropriate authorization to use and disclose such information for the purposes of research, or; (2) an appropriate waiver of such authorization has been granted by the PETAL cIRB in accordance with the HIPAA Privacy Rule, or; (3) the information constitutes a Limited Data Set shared pursuant to a Data Use Agreement as those terms are defined in HIPAA.

### **Authorization Language**

HIPAA authorization language will be incorporated into the informed consent document (ICD). The PETAL sites are responsible for providing to the PETAL cIRB their entity approved language as a part of their local context. The PETAL cIRB will ensure the appropriate authorization language is incorporated into the ICD for use at their site.

### **Waivers and Alterations of Authorization**

The PETAL cIRB will review requests for waiver or alteration of authorization to the extent it is compliant with the local PETAL site's HIPAA policies and procedures. The PETAL cIRB will notify all affected PETAL sites of the rationale for the waiver so that the PETAL sites can accomplish accounting of disclosures.

### **Breach Notifications**

PETAL sites are responsible for investigating and reporting to appropriate authorities, including Privacy Officers, breaches of PHI in accordance with institutional policies. PETAL sites must promptly notify the PETAL cIRB of any PHI breaches that occur as well as to any individuals or offices required by local institutional policy (e.g., their local Privacy Officer). The PETAL cIRB will evaluate the breach as a potential unanticipated problem. Reporting will occur according to the PETAL cIRB reporting procedure.

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## HRPP/IRB Reporting

### **Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)**

All unanticipated problems (UP) should be reported by the site investigator to the CCC within 24 hours of discovery. The CCC will report the UP to the cIRB within 7 days. Unanticipated problems are events that are:

- Serious, and
- Unanticipated, and
- Related to the study, OR
- Any event that in the opinion of the Investigator, puts the subject at greater risk than previously known.

The PETAL cIRB will report to the appropriate regulatory authorities any event in which the CCC agrees meets the definitions above. Consultation with the investigators at research sites where the event occurred, the local IRB if applicable, and the PETAL CCC will occur prior to any report.

Events that are not described above will be reported by the investigators in the electronic CRFs as outlined in each study protocol. The CCC will aggregate adverse event reports for the PETAL cIRB review during annual continuing review.

### **Definitions:**

- 1. Non-compliance:** Failure to follow the determinations or requirements of the cIRB, including the cIRB-approved protocol.
- 2. Allegation of Non-compliance:** An unapproved assertion of non-compliance.
- 3. Finding of Non-Compliance:** A proven or obvious incident of non-compliance.
- 4. Serious Non-compliance:** An action or omission taken by an Investigator that any other reasonable Investigator would have reasonably and clearly seen as compromising the rights and welfare of a participant or the integrity of the resultant data.
- 3. Continuing Non-compliance:** A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, HRPP Policy, or determinations or requirements of the cIRB.

**Reports of Non-compliance:**

Any deviation (or violations) from the protocol that involves risk to the subjects or others must be reported to the CCC immediately. After being notified by the site investigators, the CCC will report these protocol deviations or violations to the cIRB within 7 days. Events that do not involve risk are reported by the CCC in aggregate at the time of continuing review unless there is an apparent Any noncompliance that is determined by the cIRB to constitute serious or continuing noncompliance are reported as described below.

**Serious or Continuing Non-Compliance:**

The PETAL cIRB will review any allegations of serious and continuing non-compliance of which it becomes aware. The PETAL cIRB will work closely with the local site to gather information that can assist in its determination. The PETAL cIRB will report to the appropriate federal agencies once the PETAL cIRB and the PETAL site agree on the language to be included in the report. The PETAL local site is responsible for reporting to any institutional offices and officials according to their institutional policy.

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## **Conflicts of Interest**

### **COI Review**

Reporting: PETAL sites must disclose any potential conflicts of interest to the PETAL Network as outlined in the PETAL Network COI Policy Document. The PETAL Network through the CCC will forward conflict of interest disclosures to the PETAL Ethics/COI Committee for development of management plans. The CCC will forward any documentation that affects human subjects protections to the PETAL cIRB for review.

Local Context, if applicable: The PETAL cIRB will contact the local IRBs/sites to discuss any plans and to assure the plans meet local requirements prior to the PETAL cIRB review. Once a mutually agreed upon plan has been identified by both the local IRB/site and the PETAL cIRB, the PETAL cIRB will review the management plan for that site.

Review/Approval: Management plans may then be accepted as written or modified to impose additional protection by the PETAL cIRB. Any modified management plans will then be shared with the PETAL sites to ensure they still meet the PETAL site's policies.

Initial Approval of Network Protocols: Upon agreement to COI management plans, the PETAL cIRB will conduct the IRB review of the study.