Title: PMHS Standard Operating Procedure (SOP) for Review of Pediatric Study Plans (PSPs) and Written Requests by the Pediatric Review Committee (PeRC)

Purpose: To outline procedures and timelines for review of PSPs and Written Requests by the PeRC

PeRC Review of the Initial PSP, Amended PSP, and Agreed Initial PSP

**Timeline for Review of Initial PSP**

- The review division and the PeRC must review initial PSP within 90 days.
  - Sponsor should submit both a PDF and Word version of the PSP to facilitate PeRC review.
- The review division must either provide written comments to the sponsor or meet with the sponsor by day 90 to provide feedback on the initial PSP.

**PeRC Review of Initial PSP**

- Ideally, PeRC review should occur before Day 75.
- The review division project manager (PM) should contact the PeRC PM as soon as the PSP arrives in order to schedule PeRC review.
- PeRC review will include tracked changes to the initial PSP submitted by the sponsor. The PeRC will provide any recommended tracked changes to the review division.
- The review division will finalize its comments and provide recommended changes to the PSP to the sponsor in tracked changes for ease of review.

**Timeline for Review of Agreed Initial PSP**

- The sponsor should review and negotiate any further edits to the PSP with the review division within 90 days of the meeting or receipt of written comments.
- The sponsor must submit an Agreed Initial PSP within 90 days of the meeting or receipt of written comments.
- Prior to the review division responding to the agreed initial PSP, it must consult the PeRC and the PeRC must review.
- The review division must confirm agreement with agreed initial PSP within 30 days of submission of the Agreed Initial PSP.

**PeRC Review of Agreed Initial PSP**

- Ideally, PeRC review should occur before Day 25.
- The review division PM should contact the PeRC PM as soon as the agreed initial PSP arrives to schedule PeRC review.
The PeRC will review the materials provided by the sponsor and the review division to make a final recommendation of agreement or no agreement with the agreed initial PSP.

**Timeline for Review of Amended PSP**

- The review division must review the amended PSP.
- If the proposed changes are significant, the PeRC must also review the amended PSP during that timeframe.
  - Examples of significant changes to a PSP include, but are not limited to:
    - Removal or addition of one or more entire study(ies)
    - A change in the nonclinical program
    - A change in plans for formulation development
  - The sponsor should submit both a PDF and Word version of the amended PSP to facilitate PeRC review.
- The review division must provide written comments to the Sponsor or meet with the Sponsor by day 90 to provide feedback on the amended PSP.

**PeRC Review of Amended PSP**

- Ideally, PeRC review of the amended PSP, if needed, should occur before Day 75.
- The review division PM should contact the PeRC PM as soon as the amended PSP arrives to schedule PeRC review.
- PeRC review will include tracked changes in the actual sponsor-amended PSP (provided to PeRC by the review division). The PeRC will provide any recommended tracked changes to the review division.
- The review division will finalize its comments and provide recommended changes to the amended PSP to the sponsor in tracked changes for ease of review.

**Timeline for Review of Agreed Amended PSP**

- The sponsor must incorporate recommendations and submit the agreed amended PSP within 90 days of the meeting or receipt of written comments.
- Prior to the review division responding to the agreed amended PSP, it must consult the PeRC and the PeRC must review if the changes are significant.
- The review division must confirm agreement with the agreed amended PSP within 30 days of submission of the agreed amended PSP.

**PeRC Review of Agreed Amended PSP**

- Ideally, PeRC review of the agreed amended PSP, if needed, should occur before Day 25.
- The review division PM should contact the PeRC PM as soon as the agreed amended PSP arrives to schedule PeRC review.
- The PeRC will review the materials provided by the sponsor and the review division to make a final recommendation of agreement or no agreement with the agreed amended PSP.
PeRC Review of Written Requests

Timeline for Review of Written Requests

- The internal FDA goal is to respond to the Proposed Pediatric Study Request (PPSR) from the sponsor within 120 days.
- The response to a PPSR may be either a Written Request or an Inadequate Letter.
- The PeRC must review all Written Requests before they are issued.

PeRC Review of Written Requests

- As soon as the review division has decided that it will issue a Written Request, the review division PM should contact the PeRC PM to schedule PeRC review of the Written Request.
- The PeRC will review the Written Request and make recommendations.
- The PeRC considers the public health benefit of the studies when making recommendations.