

**PMHS Standard Operating Procedure  
FOOD & DRUG ADMINISTRATION**

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**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.

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- 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.

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**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.