1. Purpose

To define the process by which the Office of Sponsor and Regulatory Oversight (OSRO) manages requests for information received from the Food and Drug Administration (FDA).

2. Scope

2.1. This procedure outlines the course of action for when requests for information are received from the FDA. Examples include requests arising from routine IND/IDE submissions and unsolicited requests for clinical safety information.

2.2. The procedure may be applied to information requests from other regulatory agencies.

3. Responsibilities

3.1. Office of Sponsor and Regulatory Oversight (OSRO) personnel shall follow this procedure.

3.2. OSRO Regulatory manages all communications with regulatory authorities.

3.3. OSRO Sponsor and Regulatory Oversight Support contractor staff assist OSRO functional groups as required.

4. References

4.1. 407 Communications with the FDA Policy

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. FDA requests may be received by the OSRO Director or OSRO Regulatory Head.

6.2. The OSRO Regulatory Head assesses the request to determine the response strategy.

6.2.1. The response strategy is documented in the eTMF.

6.3. The OSRO Regulatory Head provides a receipt acknowledgement to the FDA requestor (typically the regulatory project manager) and copies the OSRO Director.

6.4. If deemed necessary, the OSRO Regulatory Head immediately convenes an internal meeting with the OSRO Director, key OSRO personnel (task area managers (TAMs) and/or Subject Matter Experts (SMEs) to determine a response strategy.

6.4.1. The response team may include SMEs from outside OSRO (e.g., the Principal Investigator or product manufacturer).

6.4.2. The strategy decided by the response team is documented in the eTMF.

6.5. Information and/or documents supporting the response to the FDA request for information are requested from owners of the information.

6.6. The OSRO TAMs and/or SMEs review and approve the submitted information/documentation.

6.7. If additional information/documentation or corrections to the current material are needed, then a request is sent to the owner of the information.

6.8. The OSRO TAM/SME review cycle continues until the information/documentation is approved.

6.9. OSRO Regulatory Head, at their discretion, may request the OSRO Director to approve the information/documents.

6.10. OSRO Regulatory drafts the response to the FDA request for information.

6.10.1. The response is approved by the OSRO Regulatory Head or OSRO Director.

6.11. OSRO Regulatory submits the response to the FDA.

6.12. Emails, documents, and any other information-containing media received from or provided to the FDA are filed in the OSRO Regulatory electronic Trial Master File.

7. Associated Documents

7.1. 407-S01-W01 Processing FDA Requests for Information

8. Change Summary

Revision Number	Effective Date	Description of Change
1	28NOV2022	New Document