1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Communications with the FDA (Food and Drug Administration) Policy.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, other departmental personnel, and external National Institutes of Health (NIH) collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), Non-Significant Risk Device (NSR) or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. Personnel are not bound to this procedure when working on non-IND/IDE/NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

2.3.2. Nothing in this policy will supersede NCI, NIH or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. CCR Management is committed to providing resources to meet the requirements for implementing a Communications with the FDA Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding the Communications with the FDA Policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Communications with the FDA Policy.

3.4. The OSRO Director is responsible for establishing and maintaining the Communications with the FDA Policy.

4. References

4.1. Best Practices for Communication Between IND Sponsors and FDA During Drug Development: Guidance for Industry and Review Staff, December 2017

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. The Office designation of OSRO shall refer both to the Office of Sponsor and Regulatory Oversight staff and the OSRO Sponsor and Regulatory Oversight Support contractor staff.

6.2. OSRO Regulatory will control any communication with the FDA.

6.3. The FDA review division regulatory project managers are the primary point of contact for communications between the Sponsor (OSRO) and the FDA.

6.4. OSRO Regulatory will establish secure email with the FDA to allow for informal communications that may include confidential information.

6.5. Facsimile may be used when secure email has not been established with the FDA.

6.6. Prior to providing information or documents to the FDA, the information or documents must be approved by the appropriate Subject Matter Expert (SME). In addition to the Principal Investigator, SMEs will include, as appropriate:

6.6.1. For manufacturing – OSRO CMC Regulatory personnel.

6.6.2. For protocol or consent documents – OSRO Safety personnel and/or OSRO Operations personnel.

6.6.3. For subject safety issues – OSRO Safety personnel.

6.6.4. OSRO Regulatory, at its discretion, may request the OSRO Director to approve the information or documents.

6.7. The information or documents will be reviewed by the OSRO SME, and approval or request for changes in the information or documents will be provided to OSRO Regulatory:

6.7.1. For CCR-generated information or documents – within 8 business days from receipt of information or documents.

6.7.2. For responses to FDA query – within 1 business day from receipt of information or documents. For urgent responses, the timeline will be shortened.

6.8. The information or documents will either be submitted to the FDA or returned to the originator with comments in the following time frame:

6.8.1. For CCR-generated information or documents – within 10 business days from receipt of information or documents.

6.8.2. For responses to FDA query – within 2 business day from receipt of information or documents. For urgent responses, the timeline will be shortened.

6.9. OSRO Regulatory will acknowledge receipt of FDA's information requests and provide the FDA project manager with an estimated response time.

6.9.1. Responses will be complete and prompt.

6.10. Information may be provided to the FDA project manager via email; the e-mail will be promptly followed by an official submission.

6.11. Formal submissions must be made via the Electronic Submission Gateway or other form of electronic media.

6.12. Telephone calls are suitable for informal communications covering general or administrative questions between Sponsors and FDA project managers.

6.12.1. When complex, regulatory, or technical issues are discussed during a telephone conversation, the caller should follow-up with a written communication (e.g., email, sponsor submission, FDA correspondence) to document the discussion and/or respond to information requested during the conversation.

6.13. Copies of all communications will be posted to the electronic Trial Master File.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	24OCT2019	New Document
2	14JAN2022	Biennial Review Step 2.2 – added Non-Significant Risk Device (NSR) Step 3.3 – added Step 4.1 – updated reference text and added hyperlink Step 6.1 – added Updated document language as required