1. Purpose

The process for determining which one of three types of Investigational New Drug Application (IND) and Investigational Device Exemption (IDE) final clinical study reports required for Food and Drug Administration (FDA) submission is outlined.

2. Scope

2.1. The Office of Sponsor and Regulatory Oversight (OSRO) Regulatory determines the final clinical study report category and provides the decision to the Principal Investigator.

2.2. Limitation

2.2.1. OSRO provides this information for clinical studies conducted under a Center for Cancer Research (CCR)-held IND or IDE under OSRO oversight.

3. Responsibilities

3.1. OSRO Regulatory determines the type of final clinical study report needed to close a study.

3.2. The OSRO Director determines if a study may be exempt from the clinical study report requirement.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

4. References

4.1. 410 Final Clinical Study Reports for Studies under CCR-Held INDs/IDEs Policy

4.2. Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (FDA, August 1999)

4.3. IDE Reports: Suggested Format for an IDE Final Report (FDA)

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. OSRO Policy 410 Final Clinical Study Reports for Studies under CCR-Held INDs/IDEs delineates the different types of reports available.

6.2. At any time prior to communicating to the study team that the IND/IDE is active, OSRO Regulatory will assess the required report type.

6.2.1. The assessment will be communicated to the study team as part of the IND/IDE activation notice.

6.3. OSRO Regulatory may reassess the required report type if major design changes are part of a protocol amendment, or if the study is prematurely terminated or administratively closed.

6.3.1. If the new assessment finds that the a study was closed or terminated with no or low enrollment, then the OSRO Director may determine that no Clinical Study Report will be required.

6.3.1.1. The OSRO Director conveys the decision to SROS Monitoring and OSRO Regulatory.

6.3.2. The new assessment will be communicated to the study team by SROS staff.

7. Associated Documents

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	10JAN2020	New Document
2	04APR2022	Biennial Review Updated document language as required Step 1, text – added IDE Step 4 – updated hyperlinks Step 6.4 – removed
3	09JAN2024	Step 3.1 – updated Steps 3.2 & 3.3 – added Step 6.2.1 – removed Step 6.3 – revised to add administrative closure Step 6.3.1 – replaced Step 6.3.1.1 – added Step 6.3.2 – revised to remove promptly Step 7.1 – removed F01-410-S01 Selection of Final Clinical Study Report Type