1. **Purpose**

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

2. **Scope**

   2.1. 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 Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) application under OSRO oversight.

3. **Responsibilities**

   3.1. OSRO Regulatory determines the type of final clinical study report needed to close a study and provides the decision to the Principal Investigator.

4. **References**

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


   4.3. [IDE Reports: Suggested Format for an IDE Final Report (FDA)](https://www.fda.gov/)

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 documented on F01-410-S01 Selection of Final Clinical Study Report Type.

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

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

      6.3.1. The new assessment will be documented on F01-410-S01 Selection of Final Clinical Study Report Type.
6.3.2. The new assessment will be promptly communicated to the study team.

6.4. This SOP shall be reviewed periodically and updated as necessary.

7. **Associated Documents**

7.1. F01-410-S01 Selection of Final Clinical Study Report Type

8. **Change Summary**

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<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<tbody>
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<td>1</td>
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<td>New Document</td>
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