1. Purpose

To describe the procedures for preparing and submitting Investigational New Drug Application (IND) Annual Reports to the Food and Drug Administration (FDA).

2. Scope

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The Office of Sponsor and Regulatory Oversight (OSRO) prepares Annual Reports for protocols in OSRO's portfolio and submits the reports to the FDA within due dates.

2.2. Limitations

2.2.1. OSRO prepares Annual Reports only for protocols overseen by OSRO.

3. Responsibilities

3.1. OSRO IND Managers are responsible for preparing Annual Reports.

3.2. The OSRO IND team lead is responsible for reviewing Annual Reports.

3.3. The Principal Investigator (PI) is responsible for reviewing the Annual Report.

4. References

4.1. 402 Regulatory Compliance & File Management

4.2. 21 CFR Section 312.33: Investigational New Drug Application – Annual reports

4.3. FDA: IND Application Reporting: Annual Reports

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. Annual Reports must be submitted to the FDA no more than 60 calendar days after the IND anniversary date.

6.1.1. IND Annual Reports are prepared by an IND Manager using information provided by the study team(s), from the OSRO Regulatory IND files, the Center for Cancer Research (CCR) Patient Registration and Enrollment System (PRES), and the Integrated Research Information System (iRIS).

6.2. The IND Manager drafts the Annual Report

6.2.1. If a previous IND Annual Report is available, the IND Manager will use this as a starting point for the next IND Annual Report.

6.2.1.1. For initial IND Annual Reports, the current FDA Annual Report template will be used.

6.2.2. The reporting period starts on the anniversary date in the previous year and ends the day before the anniversary date in the current year.

6.3. The IND Manager obtains additional information required for the Annual Report.

6.3.1. Study enrollment information is obtained from CCR PRES.

6.3.2. Adverse Event (AE) information is requested from the study team(s).

6.3.2.1. An initial draft of the Annual Report is provided.

6.3.2.2. The data cutoff date is provided.

6.3.2.3. A deadline of approximately 3 calendar weeks for return of the information is provided.

6.3.3. Certificates of Analysis (CoAs) are requested from the National Institutes of Health, Clinical Center, Department of Transfusion Medicine (DTM) or the CCR Surgery Branch, if applicable.

6.3.3.1. If the IND involves a cellular or vaccine product that is manufactured individually for each subject, a CoA for each product is required.

6.3.3.1.1. The CoAs must be redacted against Personally Identifiable Information (PII).

6.4. Preparation of the Final Draft of the Annual Report

6.4.1. The IND Manager reviews and reconciles all information obtained from the different sources.

6.4.1.1. If there are any discrepancies, the study team(s) may be contacted for clarification.

6.5. Review and Approval of Final Draft Annual Report

6.5.1. The IND Manager provides the final draft of the Annual Report to the Principal Investigator(s), copying the research nurse(s)/study coordinator(s), for their review.

6.5.1.1. The IND Manager provides a due date for any comments/changes (typically $\leq$ 5 days from receipt).

6.5.2. The final draft of the Annual Report is revised based on input received from the Principal Investigator(s) and research nurse (s)/study coordinator(s).

6.5.3. The IND Team Lead reviews and approves the final version of the Annual Report and supporting submission documents.

6.6. Filing Annual Reports to IND

6.6.1. The Annual Report along with the IND submission cover letter and Form FDA 1571 Investigational New Drug Application should be submitted to the FDA before the due date.

6.7. Provide Annual Reports to Collaborators

6.7.1. A copy of the Annual Report is provided to collaborator(s) as an Adobe PDF with a "confidential" watermark.

6.7.1.1. The IND submission cover letter and Form FDA 1571 are not included.

6.7.2. Annual Reports should be provided to collaborator(s) promptly, via email.

6.7.2.1. A request for an updated version of the Investigator's Brochure(s) is included in the email, as applicable.

7. Associated Documents

7.1. FDA Annual Report template (stored on OSRO Regulatory Drive)

8. Change Summary

Revision Number	Effective Date	Description of Change
1	09AUG2022	New Document