1 PURPOSE
This procedure describes the process and requirements for preparing, distributing, and maintaining FDA-required reports on the conduct of FDA-regulated human subject research for investigator initiated studies.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
a) The Investigator or designee will develop, review and approve FDA-required Progress Reports and Annual Reports.

b) The designee will label all written reports predominantly and clearly with IND or IDE number, protocol title, date of report and any other pertinent information for clear report identification.

3 SPECIFIC PROCEDURES
3.1 Preparation of Reports
3.1.1 Preparing the Investigational New Drug Annual Report
In preparing the IND Annual Report, the Investigator will do the following:

a) Compile all information identified in 21 CFR 312.33 for the IND Annual Report.


c) Submit the IND Annual Report to the FDA within 60 days of the anniversary of the date the IND was put into effect or approved.

d) Cease submitting IND Annual Reports when the IND is withdrawn, closed, or placed on inactive status.

3.1.2 Preparing the IND Safety Report
Investigator Standard Operating Procedures

In preparing an IND Safety Report, the Investigator will do the following:

a) Compile and review all available information upon receipt from any sources (e.g. interim study reports, published literature, reports from other investigations) regarding safety and effectiveness of the investigational drug/biologic to ensure timely reporting.

b) Report all unexpected, life-threatening, or fatal adverse events associated with the use of the drug/biologic to the FDA by telephone or facsimile within 7 days of the Investigator's becoming aware of the event, and concurrently notify the IRB of record and any other participating investigators.

c) Notify the FDA and the IRB of any relevant information regarding serious or unexpected adverse events associated with the use of the drug/biologic in a written IND Safety Report within 15 days of receiving the information.

d) Label all such reports prominently as "IND Safety Report".

e) The Investigator may submit IND Safety Reports using the FDA MedWatch Form 3500A rather than a narrative report (Attachment D, FDA MedWatch Form 3500A).

f) For any newly submitted IND Safety Report, include a summary of previously filed IND Safety Reports having the same or similar adverse events and include an analysis of the reports to date.

g) Report the subject's use of any marketed drug(s) when an adverse event occurs that is associated with concomitant use of an investigational drug/biologic.

h) Promptly investigate all safety information and submit relevant follow-up information to the FDA when available.

i) For an IND that is placed on clinical hold and/or withdrawn for safety reasons, report the withdrawal and its reason(s) to the FDA and the IRB immediately (within one business day).

3.1.3 Preparing Other Required Reports

For other required reports, the Investigator or designee will do the following:

a) To initiate withdrawal of an IND (not withdrawn for safety reasons), submit request to the FDA and notify the IRB.

b) For any IND placed on inactive status, report to the IRB and all other participating Investigators.

3.2 Device Study Reporting

All investigational medical device reports that must be submitted to the FDA are submitted as IDE.

3.2.1 Preparing Investigational Device Exemption Reports

In preparing the Investigational Device Exemption (IDE) Progress or Annual Reports, the Investigator or designee will do the following:

a) Review and compile all information from any sources (e.g. interim study reports, published literature, reports from other investigations) regarding safety and effectiveness of the investigational device for use in the preparation of progress or annual reports.
Investigator Standard Operating Procedures


c) For significant risk (SR) devices, submit Progress Reports to the FDA and IRB at time intervals specified but at least annually.

3.2.2 Preparing IDE Final Report

In preparing IDE Final Reports, the Investigator or designee will do the following:

a) Notify the FDA within 30 days of completion or termination of a SR device study.

b) Submit a Final Report to the IRB and the FDA within 6 months of termination or completion of the significant risk (SR) device study.


3.2.3 Preparing Required Progress and Final Reports for Non-Significant Risk Device (NSR)

Required progress and final reports for non-significant risk (NSR) devices will be prepared by the Investigator as follows:

a) Submit Progress Reports to the IRB only (not FDA), at time intervals specified by the IRB, but at least once a year.

b) Submit a Final Report to the IRB only (not FDA) within six months of termination or completion of the NSR device study.

3.2.3 Preparing Other Required Reports

For other required reports, the Investigator or designee will do the following:

a) Submit unanticipated adverse device effect reports (and investigations of reports) to the FDA and the IRB within 10 working days for the first report, or as specified by the FDA.

b) Report any IRB withdrawal of approval within five (5) working days of the withdrawal to the FDA.

c) Report FDA's withdrawal of IDE approval to the IRB within five (5) working days of receiving the FDA notification.

d) Notify the FDA and the IRB of any recall, repair, or removal of a device from an investigation within 30 days of request.

e) Provide the FDA a copy of any Investigator report of an investigational device’s use where a subject’s informed consent was not obtained, within five (5) working days of the learning of the event.

f) Notify FDA of any IRB decision to change a preliminary non-significant risk (NSR) determination made by the Investigator to a significant risk (SR) determination, within five (5) working days of receiving the IRB's decision.

4 REFERENCES TO OTHER APPLICABLE SOPS

- 102 Document Development and Change Control
Investigator Standard Operating Procedures

- 104 Study Team Training
- 105 Prohibition of Financial Conflicts
- 201 Contacts and Submissions for FDA
- 402 Initiation Visit and Site Training
- 501 Communications
- 505 Study Closeout Visit
- 605 Adverse Event Recognition and Reporting

5 ATTACHMENTS
A. IND Annual Report Guidelines
B. IDE Progress Report Guidelines
C. IDE Final Report Guidelines
D. FDA MedWatch Form 3500A

6 APPLICABLE REGULATIONS AND GUIDELINES
- Information Amendments (21 CFR 312.31)
- IND Safety Reports (21 CFR 312.32)
- Annual Reports (21 CFR 312.33)
- Withdrawal of an IND (21 CFR 312.38)
- Inactive Status (21 CFR 312.45)
- Selecting Investigators and Monitors (21 CFR 312.53)
- Investigator Reports (21 CFR 312.45)
- Supplemental Applications (21 CFR 812.35)
- Reports (21 CFR 812.150)
- FDA Investigational Device Exemption (IDE) Manual (June 1996)
- Communication with IRB/IEC (ICH E6, Section 4.4)
- Compliance with Protocol (ICH E6, Section 4.5)
- Records and Reports (ICH E6, Section 4.9)
- Progress Reports (ICH E6, Section 4.10)
- Safety Reporting (ICH E6, Section 4.11)
- Trial Management, Data Handling, and Record Keeping (ICH E6, Section 5.5)
- Notification/Submission to Regulatory Authority (tas) (ICH E6, Section 5.10)
- Safety Information (ICH E6, Section 5.16)
- Adverse Drug Reaction Reporting (ICH E6, Section 5.17)
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- Noncompliance (ICH E6, Section 5.20)
- Premature Termination or Suspension of a Trial (ICH E6, Section 5.21)
- Clinical Trial/Study Reports (ICH E6, Section 5.21)
- Structure and Content of Clinical Study Reports (ICH E3, July 1996)
- Clinical Study Data Management: Definitions and Standards for Expedited Reporting (ICH E2A, March 1995)