

SOP: CO 602 Version No: Effective Date: 01/01/07	OTHER ENTITIES	Supercedes Document Dated:
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1. POLICY

The IRB is required by federal regulation and institutional policy to communicate certain actions to entities that may have an interest in the status of the research being conducted.

Specific Policies

1.1 Communications to Others

The purpose of this policy is to ensure prompt reporting to appropriate Institutional Officials, funding sources, agency heads, regulatory agencies and any other appropriate entity of:

- Any unanticipated problems involving risks to human subjects or others
- Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB
- Any suspension or termination of IRB approval for cause, and
- Any research that the IRB cannot approve under the terms of 21 CFR 50.24.

1.1.1 Prospective emergency research: If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in 21 CFR 50.24 Exemption from Informed Consent Requirements for Emergency Research, notification of disapproval will be conveyed to the Sponsor as well as the Investigator.

1.1.2 Device studies: If the IRB determines that a study submitted as a non-significant risk presents significant risk, the IRB must notify the Sponsor, FDA, and Investigator.

1.1.3 Unexpected or serious adverse events: The Investigator must notify the IRB and other entities as stipulated in the Investigator's SOPs (SOP RI 801).

1.1.4 Suspension of a study for cause: The IRB will notify the Institutional Official, FDA when the study involves an FDA regulated product, OHRP if cause is noncompliance, and federal Agency Head if the research is federally funded, as appropriate. Notification of sponsor should suffice as sponsor is required to notify FDA.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

IRB Administrator is responsible for corresponding with other interested entities concerning the status of research under review by the IRB.

IRB Chairperson (or designee) is responsible for ensuring appropriate discussion and IRB decision-making regarding unapprovable emergency research, risk assessment of investigational device, adverse event assessments and Investigator non-compliance, where communication with outside external entities is necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

- 21 CFR 50.24
- 21 CFR 56.113
- 45 CFR 46. 113
- 21 CFR 812.66

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

- CO 601-C Notice of Disapproved Study
- CO 601-H Notice of Study Termination (for Cause)

7. PROCESS OVERVIEW

The IRB will report any instances of noncompliance (adverse/unexpected events, renewal suspension, termination) to the applicable agency and appropriate institutional officials or committees. Unapproved prospective emergency research and changes to patient risk are report to the FDA, Sponsor, and regulatory agency as appropriate.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator and IRB Chairperson</i>	If the IRB terminates a study for cause, notify the Institutional Official(s), FDA, and when appropriate, funding Agency Heads and/or Sponsors.	CO 601-H Notice of Study Termination (for Cause)
<i>IRB Administrator and IRB Chairperson</i>	If the IRB determines that it cannot approve a clinical investigation that is being conducted under an IND or IDE for emergency research conducted under 21 CFR 50.24, send a copy of the Investigator's disapproval letter to the sponsoring company.	CO 601-C Notice of Disapproved Study
<i>IRB Administrator and IRB Chairperson</i>	If the IRB determines that a device protocol submitted as a Non-Significant Risk study presents significant risk of harm to study subjects, in addition to the Investigator, the IRB must notify the Sponsor and FDA.	
<i>IRB Administrator and IRB Chairperson</i>	Contact FDA for guidance on SR/NSR device determinations when necessary.	
	If the IRB terminates a study for cause, notify the appropriate Institutional Officials, FDA (when appropriate), appropriate funding Agency Heads and/or Sponsors.	
	Monitor reports of serious adverse events from Sponsors to ensure all reportable events are being reported to the IRB by the Investigators.	
<i>IRB Coordinator</i>	Prepare and distribute all relevant correspondence to other entities in a timely manner.	Communication File and Study File