

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Development of Local Standard Operating Procedures
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12
EFFECTIVE DATE: September 1, 2013	REFERENCE NUMBER: COG.IRB.005 (formerly CSG.IRB.005)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all Company-affiliated facility-run Institutional Review Boards (IRBs).
PURPOSE: To provide guidance for developing Standard Operating Procedures (SOP) required by regulation for the IRB oversight of non-exempt human subject research.
<p>POLICY: Federal regulations require each IRB to develop and follow local written procedures that address, at a minimum, the following:</p> <ol style="list-style-type: none"> 1. <u>Conducting initial and continuing reviews</u> This section is addressed in the IRB compliance policy pertaining to initial and continuing review, the IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects Policy, COG.IRB.007. 2. <u>Reporting findings and actions to investigators and institutions</u> <ol style="list-style-type: none"> a. The IRB is to communicate to investigators its actions regarding proposed research and any modifications or clarifications required by the IRB as a condition for IRB approval of proposed research in the form of notification letters. b. The Institutional Official is to be notified of IRB findings and actions in writing. This can be accomplished in a number of ways but usually by providing copies of meeting minutes to them (in paper form or electronically) or providing a copy of the correspondences to the investigator. Note, the mere attendance of the Institutional Official at an IRB meeting does not fulfill the regulatory requirement that they be notified in writing. Providing of copies of minutes and/or investigator correspondence does fulfill the regulatory requirement. c. Institution administration is responsible for further review and approval or disapproval of research that is approved by the IRB; however, no other institutional office or official may approve non-exempt human subject research that has not been approved by an IRB. 3. <u>Determining which protocols require review more often than annually</u> The IRB should consider the following in this determination: (a) high risk protocols, (b) complex projects involving unusual levels or types of risk to subjects; or (c) experience level of the investigator. 4. <u>Determining which protocols require verification from sources other than the investigator that no material changes have occurred since previous IRB review</u> The IRB should consider the following in this determination: (a) projects conducted by investigators who previously have failed to comply with regulations or requirements or determinations of the IRB; and (b) projects where concern about possible material changes occurring without IRB approval have been based upon information provided in continuing review reports or from other sources.

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Development of Local Standard Operating Procedures
PAGE: 2 of 3	REPLACES POLICY DATED: 3/1/12
EFFECTIVE DATE: September 1, 2013	REFERENCE NUMBER: COG.IRB.005 (formerly CSG.IRB.005)
APPROVED BY: Ethics and Compliance Policy Committee	

5. Prompt reporting to the IRB of proposed changes in approved research during the period IRB approval has already been given

Investigators shall have any of a combination of training programs and materials, specific directives included in approval letters, random audits of research records or other actions deemed appropriate by the IRB to assure prompt reporting to the IRB of proposed changes in approved research during the period IRB approval has already been given.

Requiring that changes in research not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects

Investigators shall have any of a combination of training programs and materials, specific directives included in approval letters, random audits of research records or other actions deemed appropriate by the IRB to assure that changes in research not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

6. Prompt reporting to the IRB, appropriate institutional officials and the FDA or OHRP

a. Prompt Reporting By The Investigator To The IRB

- i. The investigator is responsible for promptly reporting to the IRB of being notified of the following:
 - a) Unanticipated Problems Involving Risks to Subjects or Other (UPIRSOs).
 - b) Serious/Continuing noncompliance with regulations or IRB requirements
- ii. With the exception of Unanticipated Problems that are Unanticipated Device Adverse Effects (which by regulation requires the Investigator report to the IRB within 10 working days), the IRB shall define their reporting timeframes noting that federal guidance suggests one week for UPIRSOs that are Serious Adverse Events (i.e. a fatality) and two weeks for UPIRSOs that are not Serious Adverse Events (i.e. loss of a laptop with confidential data on it).

b. Prompt reporting by the IRB/Institution to Governmental Authorities: The Institutional Official is responsible for such reporting to governmental authorities, noting that other internal policies may have to be followed for government reporting. The institution shall develop its own timeframes for such reporting but in the absence of such timeframes, the default shall be in accordance with that suggested in federal guidance as stated below.

- i. Unanticipated Problems Involving Risks to Subjects or Others not resulting in suspension or termination is suggested by federal guidance to be reported within one month.
- ii. Serious/Continuing noncompliance with regulations or IRB requirements is suggested by federal guidance to be reported within 5 days of the IRB determination as such.
- iii. Suspensions and terminations is suggested by federal guidance to be reported within 5 days of the IRB's actions.

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Development of Local Standard Operating Procedures
PAGE: 3 of 3	REPLACES POLICY DATED: 3/1/12
EFFECTIVE DATE: September 1, 2013	REFERENCE NUMBER: COG.IRB.005 (formerly CSG.IRB.005)
APPROVED BY: Ethics and Compliance Policy Committee	

REFERENCES:

1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
2. Clinical Operations Group Research Policies in the COG.IRB series (COG.IRB.001 through COG.IRB.011)