

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Registration with, and Mandated Reports to, FDA and/or DHHS
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.IRB.003 (formerly CSG.IRB.003)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy pertains to all Company-affiliated facility-run Institutional Review Boards (IRBs).
PURPOSE: To provide guidance to Internal IRBs on the appropriate registration and reporting to/with the United States Government in accordance with federal law.
<p>POLICY:</p> <ol style="list-style-type: none"> 1. All facilities that operate IRBs located in the United States that meet certain criteria listed in 45 CFR 46.501 or 21 CFR 56.106 are required to register with the respective government agency. All other registration is voluntary. <ol style="list-style-type: none"> a. The criteria as of the approval date of this policy is that the IRB is located in the United States and reviews any of the following: <ol style="list-style-type: none"> i. For registration with the Office of Human Research Protections (OHRP) (45 CFR 46.501) <ol style="list-style-type: none"> 1. An IRB that is designated to review under a facility’s Federal-Wide Assurance (FWA) 2. IRBs that review research with human subjects that is conducted or supported by U.S. Department of Health and Human Services (DHHS). ii. For registration with FDA (21 CFR 56.106) <ol style="list-style-type: none"> 1. IRBs that review research of investigational FDA-regulated products, regardless if they are intended to be submitted for marketing approval (i.e., Investigational New Drugs (INDs) or Investigational Device Exemptions (IDEs)). (21 CFR 56.106(a)). 2. IRBs that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated product. b. IRB registration is required prior to reviewing research that would require registration. c. Registration is considered complete only when formally accepted by the DHHS, not when the information is submitted. DHHS acceptance is usually identified in the form of an email or other written communication from DHHS or a confirmation page from the internet registration system. d. IRB Registration must be renewed prior to the expiration date given (usually three years) regardless of any changes. Should certain changes occur that require more frequent updates (i.e., change of chairman, change of contact person, change of type of FDA products reviewed), the facility shall submit those changes within the designated timelines determined by this policy and federal guidance. 2. The IRB shall perform all required reporting (i.e., suspensions, terminations, unanticipated problems involving risks to subjects or others, serious or continuing noncompliance etc.) to the relevant governmental agencies as required and within the established timeframes.

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PROCEDURE:

Procedure for Registering IRBs

1. Initial Registration
 - a. The facility shall determine if the IRB meets the criteria for registering with either OHRP or FDA (or both) per this policy and federal guidelines.
 - b. Prior to reviewing research that would require registration with one or both governmental agencies, the IRB shall complete the online registration.
2. Registration Updates
 - a. Any changes of the below information shall be submitted within the below timeframes:
 - i. Change of contact information for IRB Contact: Any change of the submitted information of the IRB contact person, including the contact person him/herself, must be updated within 90 days of the change.
 - ii. Change of contact information for IRB Chairperson: Any change of the submitted information of the Chairperson, including the Chairperson him/herself, must be updated within 90 days of the change.
 - iii. Change of status regarding reviewing DHHS-conducted or DHHS-supported studies:
 1. Beginning Review of DHHS-conducted or DHHS-supported Studies: Should the IRB decide to begin reviewing DHHS-conducted or DHHS-supported studies and it was not previously registered to do so, the IRB must update its registration prior to reviewing the first DHHS-conducted or DHHS-supported study.
 2. Ceasing Review of DHHS-conducted or DHHS-supported Studies: Should an IRB cease review of DHHS-conducted or DHHS-supported studies, such update must be given within 30 days of ceasing such activity.
 - iv. Change of Status Regarding Reviewing FDA-governed Studies:
 1. Beginning Review of FDA-Governed Studies: Should the IRB decide to begin reviewing FDA regulated studies and it was not previously registered to do so, the IRB must update its registration prior to reviewing the first FDA-Governed study.
 2. Adding New Types of FDA-Regulated Products: Should an IRB begin reviewing types of FDA-regulated products not currently on their registration (e.g., reviewing “medical devices” when they initially checked “human drugs” only), the deadline to update their registration is within 30 days of the activity.
 3. Ceasing Review of FDA Governed Studies: Should an IRB cease review of FDA-regulated clinical investigations, such update must be given within 30 days of ceasing such activity.
 - v. Disbanding IRB: Should the IRB determine to cease review of registration-required activities altogether, the IRB must update its registration within 30 days of ceasing such activity.

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- b. All other information: All other updated information should be submitted with the next submitted update. This update will be submitted either pursuant to the expiration of the three (3) year registration period or upon one of the special circumstances listed above requiring more proximal update. For example, changing the number of active protocols only needs updating at the three years registration update; however, if during that three-year registration period the IRB Chairperson's contact information changed, then the updated number of active protocols must be submitted at the time the Chairperson's update is submitted (*i.e.*, within ninety (90) days instead of at the three (3) year expiration).
- c. A copy of the registration information and any updates are to be sent to the Responsible Executive for Clinical Research in the Clinical Services Group in the corporate office in Nashville, TN. The address is One Park Plaza, Building 2-4W Nashville, Tennessee 37203.

Required Reporting

1. Under federal law, the IRB must report the following to the FDA (for clinical investigations), OHRP (for research that applies to an institution's FWA) or DHHS Institution Official head (for federally-funded studies):
 - a. Any suspensions of previously-approved research for any reason (suspension meaning the IRB mandated temporary stoppage of some or all previously approved research activity)
 - b. Any termination of previously-approved research for any reason (termination meaning the IRB mandated a permanent cease of all research activity)
 - c. Serious or continuing noncompliance with regulations or IRB requirements.
2. Note that a protocol reaching its expiration date without an extension being requested by the investigator or processed by the IRB in time is not a suspension or termination that needs to be reported. It is the natural expiration of the research which must then stop according to such policy. However, continuing to perform research activity after the expiration may be considered reportable under the "serious or continuing noncompliance" provision.
3. The government agency websites (links are in the Reference Section) have the addresses and instructions for reporting.
4. Reporting must occur promptly (usually within 5 days) of the IRB decision.

REFERENCES:

1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
2. Clinical Services Group Research policies in the COG.IRB series, COG.IRB.001 through COG.IRB.011
3. Government Agency websites:
 - <http://ohrp.cit.nih.gov/efile/IrbRnwStart.aspx>
 - <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm>
 - http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html