

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Use of and Relationship with Institutional Review Boards
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.004 (formerly CSG.RSH.004)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy pertains to all Company-affiliated Facilities (*i.e.*, hospitals, surgery centers, physician practices, administrative offices, etc.). This policy concerns the Facility’s use of Institutional Review Boards (IRBs) that can be “internal” or “external.” This is not a compliance policy that pertains to the operation of an IRB.

PURPOSE: This policy provides guidance on the Facility’s delineation of the requirements to certify IRB review by either running an internal IRB and/or deferring to external IRBs. This policy describes that the IRB should function independently of the Facility administration decisions regardless of whether it is internal or external. This policy also provides guidance on the Facility’s written requirements (not the IRB’s requirements) for use of one or more IRBs. Finally, it provides guidance on the process needed to assure that the Facility does not become engaged in non-exempt human subject research activity unless that research activity is under the oversight of an IRB.

POLICY:

1. Reliance on IRBs (Internal or External).
 - a. When the Facility is expected to be i) engaged in non-exempt research with human subjects; ii) administering a Humanitarian Use Device; and/or iii) dispensing a drug/device/biologic under the FDA’s Expanded Access Program (*i.e.*, “compassionate use”), the Facility shall certify IRB review by running its own internal IRB(s) and/or relying on external IRB(s). Certification of IRB review is not needed when the Facility is a “Second Institution” or if the research has been determined exempt through Facility policy per the Human Subject Protection Program Policy, COG.RSH.003.
 - b. At the discretion of the Institutional Official, the Facility can defer to external IRBs even if it runs an internal IRB.
 - c. The Facility will rely upon only IRBs registered with the FDA to review the clinical investigations subject to FDA regulations, Humanitarian Use Devices and drugs/devices/biologics dispensed under an Expanded Access Program. This applies to all IRBs, regardless of whether they are internal IRBs or external IRBs.
 - d. The Facility will rely upon only IRBs registered with OHRP to review the research to which its FWA applies. This applies to all IRBs, regardless of whether they are internal IRBs or external IRBs. The FWA applies to
 - research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.
 - e. Questions regarding evaluating the familiarity of an IRB may be forwarded to the Corporate Responsible Executive for Clinical Research.

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2. Agreements with External IRBs

- a. A written agreement should be executed between the Facility and any external IRBs. This can be a simple letter or form that most IRBs can provide or a written “IRB Authorization Agreement” (a sample of which is on the OHRP website).
- b. Whenever research applies to the Facility’s FWA, the written agreement is required and shall note that the IRB is reviewing the research under the Facility’s FWA.
- c. The Facility shall assist the IRB in their need to review under “local context” (*i.e.*, community attitudes, local laws, etc.). This can be accomplished in a wide variety of ways such as a site visit by a representative of the IRB, by appointing an IRB member from the Facility’s community, or by advising the IRB, either prior to or during the deliberations, of any local issues that the IRB should consider.
- d. A Business Associate Agreement is not necessary unless the rare circumstance occurs where the IRB is expected to perform a covered function (“covered function” as defined by HIPAA noting that the oversight of research is not a covered function of a Business Associate) on behalf of the facility (*i.e.*, creating de-identified datasets, etc.).

3. Facility’s Relationship with IRBs

- a. No Facility representative has the authority to approve (or offer continuing approval, waivers, extension, etc.) non-exempt research with human subjects, clinical investigations or the use of a Humanitarian Use Device or products under the FDA’s Expanded Access Program contrary to the decision by the appropriately registered IRB designated to provide oversight.
- b. Facility representatives may not use their authority to unduly influence how individual IRB members vote.
- c. Any violation of this policy should be immediately reported to the Institutional Official, the Facility Ethics and Compliance Officer (ECO), and the Corporate Responsible Executive for Clinical Research or the Ethics Line. Depending on the severity and circumstances, the outcome of such investigations could range from requiring education to disciplinary action.

4. Independent Authority of the IRB Granted by Facility: The Facility hereby grants independent authority to the IRB for the following purposes:

- a. To approve, require modifications to secure approval, or disapprove the research activities overseen and conducted by the Facility needing IRB oversight.
- b. To approve, require modifications to secure approval, or disapprove the use of a Humanitarian Use Device and or products under the FDA’s Expanded Access Program.
- c. To suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants.
- d. To observe, or have a third party observe, the consent process.

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5. Certifying IRB Approval Prior to Engagement in Research
 - a. The Facility cannot become engaged in non-exempt research with human subjects until (among other things outside of the scope of this policy) IRB review is certified by the Facility.
 - b. Records for an Internal IRB in the IRB files shall suffice for certifying IRB review. To certify External IRB approval:
 - i. Copies of paper or electronic IRB approval letter(s) (noting expiration dates) are to be kept by the Facility. The Facility must designate a place for these copies to be stored, preferably in a folder with all other protocol-related information.
 - ii. Verification that the IRB is appropriately registered with FDA and/or OHRP as required.
 - c. Upon receipt of each new study or the change of a previously approved study, the Facility shall assure that it maintains the most current IRB expiration date in their research database.
 - d. When IRB approval expires or is terminated, the Facility can no longer be engaged in research except to the extent to orderly withdraw subjects from the research.

6. Assurance of Continuing IRB Oversight
 - a. The Facility shall maintain on its active protocol list the most current IRB expiration date.
 - b. The Facility shall inquire of the investigator and/or IRB prior to expiration of any active protocol as to whether to expect continuance or closure.
 - c. In the event the IRB expiration date arrives and documentation of IRB continuing review is not obtained, the Facility may not continue to be engaged in the research. It is advised that a notification of such be sent to the investigator and, if needed, the IRB and/or study sponsor.

REFERENCES:

1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
2. Clinical Operations Group Research Policies in the COG.RSH series (COG.RSH.001 through COG.RSH.010)