

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Role of Institutional Official and Human Protections Administrator
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12
EFFECTIVE DATE: September 1, 2013	REFERENCE NUMBER: COG.RSH.009 (formerly CSG.RSH.009)
APPROVED BY: Ethics and Compliance Policy Committee	

<p>SCOPE: For all Company-affiliated facilities (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.) engaged in clinical research including exempt and non-exempt research with human subjects.</p>
<p>PURPOSE: This policy describes two (2) key oversight roles that a facility has when overseeing clinical research.</p>
<p>POLICY:</p> <p>A. Identifying The Key Roles</p> <ol style="list-style-type: none"> 1. If the facility is engaged in clinical research (including exempt and non-exempt research with human subjects), they shall define which person fills the roles of Institutional Official and Human Protection Administrator. 2. One person can fulfill both roles. <p>B. Institutional Official</p> <ol style="list-style-type: none"> 1. Purpose of Role <ol style="list-style-type: none"> a. Promotes the culture of conscience for the ethical conduct of human subject research at the highest level within the facility. b. Authorizes the necessary administrative or legal action pertaining to the protection of human subjects. c. Serves as, and/or appoints and (directly or indirectly) supervises, a Human Protections Administrator. 2. Criteria For Selection <ol style="list-style-type: none"> a. A high-level facility official who has the authority to represent the facility and oversee its human research protection program. This person is usually the Chief Executive Officer (CEO)/Administrator, Chief Operating Officer (COO), Chief Medical Officer (CMO), Ethics and Compliance Officer (ECO) or other high-ranking individual but OHRP recommends that it not be the chair or member of any IRB designated by the facility. b. The individual must have sufficient standing, authority, knowledge and independence to ensure implementation and maintenance of the human subject protection program. c. Unless otherwise designed in writing by the facility's CEO/Administrator, the facility's CEO/Administrator shall serve as the Institutional Official. 3. Role Responsibilities <ol style="list-style-type: none"> a. Assures compliance with federal and local laws/regulations and the corporate compliance policies relating to clinical research. This includes but is not limited to human research protections and other compliance functions such as billing compliance, contracting compliance, etc.

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- b. Continually evaluates the human subject protection program to assure it has adequate resources to fulfill its function. Adequate resources would include but are not limited to sufficient staff, consultants, IRBs (number and adequacy), equipment, finances, information technology systems, and space to store records securely, permit private conversations, accommodate computer and office equipment, and hold meetings.
 - c. In the absence of written policies to the contrary, appoints IRB members for any internal IRBs.
 - d. May make IRB exemption determinations according to federally regulated criteria.
 - e. Determines when audits are needed on third parties to which any functions falling under the facility’s compliance policies are outsourced to and either conducts such audits or assures such audits are conducted.
 - f. Develops and/or coordinates relationships with other required review committees.
 - i. Assists in the oversight of operations of any internal IRBs as well as develop and oversee relationships with external IRBs as needed.
 - 1. Helps assure that any internal IRB has meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.
 - ii. Develops, as may be needed, Institutional Biosafety Committees (IBC) and coordinate their relationship with the DHHS Recombinant DNA Advisory Council (RAC).
 - iii. Develops, as may be needed, a Radioactive Drug Research Committee (RDRC).
 - iv. Develops, as may be needed, a Data Safety Monitoring Board for facility-initiated studies.
 - g. Oversees compliance with Federal-Wide Assurance (FWA) with DHHS or other written assurances with other federal agencies, if applicable.
 - i. Determines if an FWA or other written assurance is needed.
 - ii. Assures any FWA or other assurance is updated timely (i.e., prior to expiration).
 - iii. Assures any FWA is updated within 90 days after changes occur regarding the legal name of the facility, the Human Protections Administrator, or the Signatory Official.
- C. Human Protections Administrator**
- 1. Purpose of Role
 - a. Serves as primary contact (for federal agencies, research participants, investigators, IRBs, the corporate office, etc.) for routine matters pertaining to human subject protections.
 - b. Performs other activities pertaining to human subject protection as delegated by the Institutional Official.

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<p>2. Criteria For Selection</p> <ul style="list-style-type: none"> a. Extensive knowledge and experience in the area of human subjects protection. b. Preferred certifications are Certified IRB Professional (CIP) or to a lesser extent Regulatory Affairs Certification (RAC). c. If the facility operates an Internal IRB, then the IRB administrator/coordinator will be the default person for this role unless otherwise determined by the Institutional Official. Absent any other appointment to the role (i.e., to the ECO, Vice President of Quality etc), the Institutional Official shall also serve in the role as Human Protections Administrator. <p>3. Potential Role Responsibilities</p> <ul style="list-style-type: none"> a. Conducts review of requests for determinations of whether an activity qualifies as research, research not involving human subjects, and research exempt from IRB oversight. b. Certifies IRB review (when required) by obtaining and/or maintaining copies of IRB approval letters. c. May make IRB exempt determinations according to federally regulated criteria as appointed by the Institutional Official. d. Verifies research proposed to be either 1) not with human subjects or 2) with human subjects but exempt from regulations; are indeed properly categorized. e. Maintains active and historical protocol database(s). f. Advises key leadership (i.e., the Institutional Official (IO), IRB Chair/Members, etc.) on key matters regarding research with human subjects. g. Provides “local context” and community attitudes information to external IRBs. h. In conjunction with the IO, ensures that requirements regarding reporting to federal agencies are satisfied (i.e., unanticipated problems involving risks to subjects or others, Internal IRB suspensions/terminations etc.). i. Submits, implements, and maintains Federal-Wide Assurance(s), if any, and any Internal IRB registrations. j. Coordinates and periodically evaluates activities to enhance the public’s understanding of research via outreach activities proportional to the size and complexity of the research program. This can be as simple as providing pamphlets/brochures/website-links but also can be health fairs, coordinating or performing presentations, etc.
<p>REFERENCES:</p> <ul style="list-style-type: none"> 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)