DEPARTMENT: Clinical Operations Group Research	**POLICY DESCRIPTION:** Human Subject Protection Program
PAGE: 1 of 2	**REPLACES POLICY DATED:** 3/1/12
EFFECTIVE DATE: September 1, 2013	**REFERENCE NUMBER:** COG.RSH.003 (formerly CSG.RSH.003)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all research with human subjects in which Company-affiliated Facility (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.) employees become engaged.

PURPOSE: To provide guidance on protecting the rights and well-being of human subjects in clinical research.

POLICY:

1. The Facility shall have a human subject protection infrastructure that oversees research with human subjects they engage in. Such a program contains the minimum following designations:
    a. The name of the Institutional Official who is ultimately responsible for all components of research compliance (See Policy COG.RSH.009, Role of Institutional Official and Human Protections Administrator).
    b. The name of the Human Protections Administrator who is the contact person for any research-related issues pertaining to human subject protection (this person may be the same as the Institutional Official) (See Policy COG.RSH.009, Role of Institutional Official and Human Protections Administrator).
    c. Arrangements (formal or informal) with one or more Institutional Review Boards (IRBs).

2. Obtaining a Federal-Wide Assurance (FWA) For DHHS Supported Studies
    a. When the Facility is engaged (or expected to be engaged) in non-exempt research with human subjects conducted or supported by DHHS, the Facility shall obtain a Federal-Wide Assurance (FWA) through the Office of Human Research Protections.
    b. The Institutional/Signatory Official and the Human Protections Administrator must take any required OHRP online course(s) and review the “Terms of Assurance” as posted on the OHRP website.
    c. The FWA must be updated per OHRP policy, usually the sooner of:
        i. The expiration of the FWA (3-5 year cycle); or
        ii. Upon any material changes such as turnover in the roles of Institutional/Signatory Official or Human Protections Administrator.
    d. A paper (or printable) copy of the FWA shall be available for auditors to review.

3. Determination Of Research that is Subject to Human Subject Protection Program
    a. Criteria
        i. For studies subject to oversight by the DHHS Office of Human Research Protections (OHRP) the Facility must use 45 CFR 46 (of DHHS regulations) in making this determination.
        ii. For studies subject to oversight by the Food and Drug Administration (FDA) the Facility must use 21 CFR 56 (of FDA Regulations) in making this determination.
        iii. For studies subject to the oversight of both OHRP and FDA, the Facility must use both 45 CFR 46 AND 21 CFR 56 in making this determination.
        iv. For studies subject to none of the above, the Facility uses the OHRP regulations as guidance in making this determination.

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b. Persons Eligible to Make this Determination
   i. The Institutional Official or Human Protections Administrator may make this determination.
   ii. The Institutional Official may designate other individuals (*i.e.*, the IRB Chair) or entities (*i.e.*, an external IRB) to make this decision.
   iii. The Facility may rely on the determination made by the Corporate Responsible Executive for Clinical Research.
   iv. No one with a conflict of interest may make this determination.

c. Upon request, the Principal Investigator and/or Sponsor may obtain this determination in writing. The determination should be justified by the relevant criteria.

d. Research subject to the human research protection program may still be exempt from certifying IRB review. See the Research Activities Not Needing IRB Oversight or Certification of IRB Review Policy, COG.RSH.005.

e. The suggested, but not required, targeted turnaround time for a decision by the facility is five (5) working days.

4. Human subjects in research do not surrender any rights or benefits to which they would otherwise be entitled. Research subjects (current, former or prospective) must have access to the same mechanisms as all other patients (current, former or prospective) to discuss problems, bring up concerns, ask questions, obtain information, and offer input.

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)