DEPARTMENT: Clinical Operations Group – Research	**POLICY DESCRIPTION:** IRB Membership and Training
PAGE: 1 of 2	**REPLACES POLICY DATED:** 3/1/12, 9/1/2013, 11/1/16
EFFECTIVE DATE: February 22, 2019	**REFERENCE NUMBER:** COG.IRB.002 (formerly CSG.IRB.002)
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 for adequate representation for proper IRB decision making.

POLICY:

1. Each IRB run by the facility must be appropriately constituted according to federal law.
    a. Each IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research commonly reviewed by the organization.
    b. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the Institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender..
    c. Each IRB shall have members who represent different professions.
    d. Each IRB shall have at least one member whose primary concerns are in scientific areas.
    e. Each IRB shall have at least one member whose primary concerns are in non-scientific areas.
    f. Each IRB shall have at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.
    g. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
    h. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB unless they are members of the IRB.

2. Appointment, Evaluation and Removal of Members
    a. Absent other self-derived mechanisms for appointment, the chair, members and alternates will be appointed by the CEO or his/her designee (such as the Institutional Official).
    b. The facility adjusts the membership and composition of the IRB to meet regulatory and organizational requirements.
    c. Absent other pre-determined mechanisms for removal of the chair, members and alternates, these members may be removed by the CEO or his/her designee during their appointed term.
    d. Any addition, expiration or termination of members (voluntary or involuntary) shall result in a prompt updating of the IRB roster.

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3. Training of IRB Members
    a. Training shall be customized to the needs of the IRB. There is no regulatory prescribed training for IRB members. Those that have obtained Certified IRB Professional (CIP) designation by the *Council for Certification of IRB Professionals* need only produce their certificate to demonstrate adequate training. For all others, any of the following will suffice:
        i. Courses from HCA's IRB Podcast Channel
        ii. Any IRB courses put forth by Public Responsibility in Medicine and Research
        iii. National Institute of Health (NIH's) Computer–Based Training for NIH IRB Members
        iv. NIH's Protecting Human Research Participants
        v. Collaborative Institutional Training Initiative
        vi. Other training in human subject protection deemed acceptable by the Facility.
    b. The facility shall document any training of IRB members in either member folders or in minutes (if training was performed or validated during an IRB meeting).

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