DEPARTMENT: Clinical Operations Group – Research	**POLICY DESCRIPTION:** IRB Records (Rosters, Minutes and Protocol Information) Content and Retention
PAGE: 1 of 3	**REPLACES POLICY DATED:** 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	**REFERENCE NUMBER:** COG.IRB.004 (formerly CSG.IRB.004) MARKED
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all Company-affiliated facility-run Institutional Review Boards (IRBs).

PURPOSE: To provide guidance on the proper documentation of IRB activity for validation and audits.

POLICY:

IRB Roster and Member Information:

1. Member Documentation: The IRB coordinator must maintain (*i.e.*, in a paper folder or in an adequate electronic system) or have immediate access to (*e.g.* if any of the below are kept elsewhere such as in Human Resources or Medical Affairs/Credentialing) the following for each member:
    a. Any appointment notifications (*i.e.*, Letter, email, etc.);
    b. Curriculum Vitae;
    c. Documentation of any IRB related training/certificates.
2. The written IRB rosters are to be dated with month, day and year and include the following fields:
    a. First and Last Name;
    b. Earned degree(s) if any;
    c. Representative capacities in terms of the vulnerable populations, if any, each member is knowledgeable about or experienced in working with.
    d. Scientific/non-scientific status;
    e. Affiliation status (whether the member or an immediate family member of the member is affiliated with the organization);
    f. Employment or other relationship between each IRB member and the organization.
    g. Indications of experience sufficient to describe each IRB member's chief anticipated contributions;
    h. Officer Status (*i.e.*, Chair, Vice Chair, etc.);
    i. Membership status (*i.e.*, voting member, alternate members, non-voting, etc.); and
    j. The voting members or class of voting members for whom each alternate member can substitute.
3. The Roster is to be promptly updated with any change of membership.

Meeting Minutes:

1. IRB minutes must document the following:
    a. Date of meeting;
    b. Voting members in attendance at meeting;
    c. When an alternate member replaces a primary member;
    d. A list of all expedited reviews since the last meeting (unless documentation shows that members were notified via other means);
    e. Separate deliberations, action and voting for each protocol;
    f. Exactly what activity was discussed (*i.e.*, protocol, consent, advertisement - all with version numbers and dates)
    g. The rationale for Significant Risk/Non-Significant Risk device determinations;

h. Unless documented in the IRB records determinations required by the regulations and protocol-specific findings justifying those determinations for:
    i. OHRP governed research involving pregnant women, fetuses, and neonates.
    ii. OHRP governed research involving prisoners.
    iii. FDA or OHRP governed research involving children.
i. A written summary of the discussion of controversial issues and their resolution;
j. Unless documented elsewhere, how various criteria for actions were met (*i.e.*, Non-Significant Risk Device, waiver of elements of consent, waiver of documentation of consent, waiver of HIPAA authorization etc.);
k. Actions taken by the IRB;
l. The basis for requiring changes in research;
m. The basis for disapproving research;
n. For initial and continuing reviews, the approval period;
o. For contingent approvals, how will the contingencies be verified and by whom;
p. The names of IRB members who left the meeting because of a conflict of interest along with the fact that a conflict of interest was the reason for the absence;
q. Votes for each protocol as # for, # against, and # abstaining; and
r. Any training or other activity that took place.

2. It is suggested that some form of quality assurance be performed on each set of minutes prior to ratification at the next meeting to assure regulatory compliance. This can be accomplished by peer review through the Corporate Responsible Executive for Clinical Research or using a checklist.
3. Training on documenting meeting minutes is available on the HCA IRB Podcast Channel.

Protocol Records:

1. IRB records for research protocols are to be stored (suggested in a protocol-centric manner, meaning a folder labeled with the unique identifier of the protocol containing all information).
2. All protocol-related information must be available for review by IRB members and auditors. This includes but is not limited to:
    a. Protocols;
    b. Consent forms (or justifications for waiver of documentation of consent);
    c. All correspondence to and from the investigator (including applications/progress reports and approval/denial letters);
    d. Any advertisements;
    e. Any scientific evaluations;
    f. Any reports of injuries to participants;
    g. Any information pertaining to any investigator conflicts of interest;
    h. Any statements of significant new findings provided to participants;
    i. For initial and continuing review of research by the expedited/exemption procedure:
        i. The specific permissible category for expedited review or exemption;
        ii. Description of action taken by the reviewer; and
        iii. Any other findings required under the regulations.

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j. Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
   i. OHRP governed research involving pregnant women, fetuses, and neonates;
   ii. OHRP governed research involving prisoners; and
   iii. FDA or OHRP governed research involving children.

Written Procedures:

1. The IRB shall maintain their current and previous sets of written procedures in accordance with the record retention policy.
2. The written procedures shall be dated (month, date and year) as to easily determine which procedures were in place at any given point in time.

Record Retention and Accessibility:

1. The current and legacy rosters should be housed in the same location (paper and/or electronically).
2. Minutes should be archived in the same location (paper and/or electronically).
3. IRB records relating to research are retained for at least three years after completion of the research (even if no subjects were enrolled).
4. IRB records are to be accessible for inspection and copying/printing by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.
5. Records are to be stored in a way that maintains confidentiality.
6. IRB records for a protocol are to be organized to allow a reconstruction of a complete history of IRB actions related to the review and approval of the research protocol.
7. The records required by this policy and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. This retention guidance is included in the State specific records retention schedules, pursuant to the Records Management Policy, EC.014. All records shall be accessible for inspection and copying by authorized representatives of the governing agency (FDA and/or OHRP) at reasonable times and in a reasonable manner.

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
3. Records Management Policy, EC.014