1 PURPOSE
1.1 To establish an Institutional Review Board (IRB) with oversight responsibility for the protection of human subjects participating in research studies conducted within AMITA Health. This policy describes the requirements for membership and composition of the IRB.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 Composition:

3.1.1 The IRB shall have at least five (5) voting members with varying backgrounds to promote a complete review of research activities commonly conducted at AMITA Health.

3.1.2 Members will be sufficiently qualified through their experience and expertise as well as through their diversity of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, so as to promote respect for IRB advice and counsel in safeguarding the rights and welfare of human subjects.

3.1.3 Of the permanent members selected for IRB membership:

3.1.3.1 at least one must be from a scientific area of interest,

3.1.3.2 at least one must be from an area of interest that is primarily non-scientific (lawyer, clergy, ethicist), and

3.1.3.3 at least one must be independent of AMITA Health and not part of the immediate family of a person who is affiliated with AMITA Health (community member).

3.1.3.4 NOTE: One member may fulfill the requirements of both 3.1.3.2 & 3.1.3.3.

3.1.4 The total number of primary voting members shall include:

3.1.4.1 Chairperson who is a licensed physician;

3.1.4.2 Co-Chairperson, or Vice Chair

3.1.4.3 One or more Scientists;

3.1.4.4 One or more Non-scientists;

3.1.4.5 One or more Citizen Representatives;

3.1.4.6 Representative from AMITA Health Administration;

3.1.4.7 Nursing Representative.

3.1.5 Alternates shall be formally appointed for one or more primary members and listed in the membership roster. The roster will identify the primary member(s) for whom each alternate may substitute.

3.1.5.1 To ensure maintaining an appropriate diversity, the alternate’s qualifications should be comparable to the primary member to be replaced.

3.1.5.2 When an alternate substitutes for a primary member, the alternate member shall receive and review the same material that the primary member received or would have received prior to the meeting.
3.1.5.3 The attendance roster within the IRB meeting minutes will identify the voting member the alternate member is representing.

3.1.5.4 Alternate members are subject to all IRB policies governing voting members (e.g., qualifications, term etc.)

3.2 Institutional Support:

3.2.1 AMITA Health will provide the IRB with resources and professional and support staff sufficient to carry out their responsibilities under Adventist Midwest Health’s and Alexian Brothers Health System’s Federal Wide Assurances (FWAs) effectively for AMITA Health.

3.2.2 Educational training and oversight mechanisms will be established to ensure IRB members and staff maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP and FDA guidance, other applicable guidance, state and local laws, and IRB policies for the protection of human subjects.

3.3 Selection, Term, and Removal of IRB Members

3.3.1 The Signatory Official of AMITA Health IRB shall appoint IRB members. The term of appointment shall be indefinite. However, it can be terminated by resignation or by action of the AMITA Health Signatory Official with cause.

3.3.2 Excessive absences may result in the removal of a member from service on the IRB. In addition, a member may be removed for any of the following:

3.3.2.1 lack of participation in IRB meetings, including frequent abstention from voting activities;

3.3.2.2 ineffectiveness (as determined by the IRB Chairperson) due to a consistent lack of preparation or follow-up as necessary to ensure the objectives of the IRB are being met;

3.3.2.3 failure to attend training sessions as offered by AMITA Health;

3.3.2.4 except under emergency circumstances, failure to notify the IRB Administrative Coordinator or IRB Chairperson in advance of an absence thus preventing the use of a designated alternate; and,

3.3.2.5 frequent early departures from the meeting resulting in loss of quorum.

3.4 Membership Roster

3.4.1 A list of the current voting members, both primary and alternate will be maintained. The list will identify members by name, earned degrees, representative capacity, indications of experience (e.g., board certifications and licenses) sufficient to describe each member’s primary anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution.

3.4.2 Any changes in IRB membership or other authorized institutional officials listed on Adventist Midwest Health’s or Alexian Brothers Health System’s most recent Assurances on file with DHHS must be timely reported to the Office of Human Research Protections (OHRP).

3.5 Consultants may be engaged to assist the IRB however, they will be non-voting members. Consultants must be independent of the investigator and/or sponsor of the proposed research and cannot be counted towards quorum.
4 RESPONSIBILITIES
4.1 AMITA Administration, IRB Chairperson

5 PROCEDURE
5.1 Membership approval process

5.1.1 IRB Membership Applications will be completed to request to serve on the IRB panel. The application must include the following:

5.1.1.1 Current curricula vitae (CV) or resume that is signed and dated;

5.1.1.2 Contact information;

5.1.1.3 Description of research experience and/or IRB experience;

5.1.1.4 Documentation of willingness to comply with the IRB’s policies and applicable federal and state regulations; and

5.1.1.5 Commitment to receive continuing education on the responsible conduct of research and protection of human subjects, including the IRB process, changing regulations, and informed consent requirements.

5.1.2 Decisions will be communicated to the applicant in writing within a reasonable amount of time after receipt of the application.

5.2 The IRB Coordinator will be responsible for maintaining:

5.2.1 Member files including current CVs or resumes, training certificates and other relevant documentation; and

5.2.2 Membership rosters in accordance with policy provision 3.4.1, above.

5.3 The IRB Administrative Coordinator will be responsible for keeping the filing current and up-to-date with OHRP, including reporting any changes in IRB membership or other authorized institutional officials listed on Adventist Midwest Health’s or Alexian Brothers Health System’s most recent Assurances on file with DHHS.

6 MATERIALS
6.1 IRB Membership Roster
6.2 IRB Member Information  FRM-201
6.3 IRB Member Agreement  FRM-202
6.4 OHRP Federal Wide Assurance

7 OTHER RELATED POLICY/PROCEDURES
7.1 None

8 REFERENCES
8.1 21 CFR 50
8.2 21 CFR 56
8.3 45 CFR 46