1 PURPOSE
1.1 To authorize the AMITA Health Institutional Review Board (IRB) to accept IRB review and approval from another site’s IRB or a central IRB in lieu of full board review of multi-site studies by the AMITA Health IRB.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 Federal regulations do not prohibit a local IRB from delegating responsibility for initial and continuing review to a non-local IRB, provided that: (a) the non-local IRB is competent to understand the local context of the research, and (b) has entered into a written agreement with AMITA Health’s IRB delineating the roles and responsibilities of the respective IRBs. If the research is regulated by the Department of Health and Human Services’ (DHHS) Office of Human Research Protections (OHRP), Alexian Brothers Health System or Adventist Midwest Health must also amend its Federal-wide Assurance listing the non-local IRB as an IRB authorized to review and approve research taking place within Alexian Brothers Health System or Adventist Midwest Health.

3.2 The AMITA Health IRB will review and approve each request to use a non-local IRB on an individual basis. Principal investigators shall not be allowed to engage in research with a non-local IRB until the AMITA Health IRB office has signed a waiver of jurisdiction for the study. The AMITA Health IRB reserves the right to suspend and/or terminate, with or without cause, any research study approved by a non-local IRB in violation of this policy. Suspensions and/or terminations of research for violation of this policy will be reported.

3.3 Prior to submitting a waiver request to the AMITA Health IRB, the Clinical Research Office must acknowledge receipt of the contract, budget, and protocol for the proposed study.

3.4 Investigators shall submit a “Central IRB Submission” (HRPP-215) form to the AMITA Health IRB requesting use of a non-local IRB. The following information should be provided:
   3.4.1 How the research will utilize any property, facilities, equipment, services or employees or agents of AMITA Health.
   3.4.2 If the protocol requires access, use or disclosure of protected health information from human subjects that is held by AMITA Health.
   3.4.3 Contact information for the non-local IRB.
   3.4.4 The non-local IRB’s waiver form, signed by the investigator.

3.5 Prior to submitting an application for initial review to a non-local IRB, the IRB will ensure a written agreement is in place between the non-local IRB and the AMITA Health IRB delineating the specific roles and responsibilities of the respective IRBs and/or, in the case of research under the jurisdiction of OHRP, the Alexian Brothers Health System or Adventist Midwest Health FWA has been amended.

3.6 Investigators will be notified of the decision to accept or reject the non-local IRB review.

3.7 Once the non-local IRB is approved, the following information should be made available to the AMITA Health IRB for review:
   3.7.1 Continuing Reviews (Renewals)
   3.7.2 Local Unanticipated Problems (including Serious Adverse Events [SAEs] and Major Protocol Violations)
   3.7.3 Modifications (Amendments / Updates / Revisions)
   3.7.4 Study closure
3.8 All research studies accepted from non-local IRBs will be reported to the convened AMITA Health IRB through local agendas and meeting minutes.

4 RESPONSIBILITIES
4.1 Investigators, IRB Staff

5 PROCEDURE
5.1 This section has been intentionally left blank. Please refer to related policies for applicable procedures.

6 MATERIALS
6.1 Central IRB Submission (HRPP-215) form

7 OTHER RELATED POLICY/PROCEDURES
7.1 None

8 REFERENCES
8.1 45 CFR 46.114
8.2 21 CFR 56.114