1 PURPOSE
1.1 All of the Institution’s human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 AMITA Health holds two Federalwide Assurance (FWA) for the Protection of Human Subjects under the Alexian Brothers Network and Adventist Midwest Health. The FWA’s apply to research involving human subjects performed at or under the auspices of any AMITA Health system hospital or subsidiary ministry (Ministry) listed on the FWA. For the purposes of this and all SOPs under the AMITA Health Office Regulatory Affairs and Research Compliance, the term “research involving human subjects” shall be interpreted to include any research-related procedure conducted at the Ministry or any Ministry-controlled facility.

4 RESPONSIBILITIES
4.1 IRB Coordinator and office staff

5 PROCEDURE
5.1 The Office of Regulatory Affairs and Research Compliance:
   5.1.1 Prepares and maintains the Federalwide Assurance and all updates (e.g., membership changes, relationships with other IRBs) as required by the Assurance;
   5.1.2 Submits membership changes to the federal Office of Human Research Protection (OHRP)
   5.1.3 Submits assurance updates to OHRP whenever changes to the assurance are required, or every 3 years to prevent expiration;
   5.1.4 Maintains records of all IRB registration updates;
   5.1.5 Updates internal tracking systems of current assurance information, including expiration dates, and maintains accurate and up-to-date IRB membership lists.

6 MATERIALS
6.1 None

7 OTHER RELATED POLICY/PROCEDURES
7.1 None

8 REFERENCES
8.1 45 CFR 46.102(e); 45 CFR 46.103