1 PURPOSE
1.1 To ensure that there are adequate provisions for soliciting and documenting the assent of prospective subjects capable of some degree of understanding prior to participation in a research study within AMITA Health.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 Obtaining Assent
3.1.1 The Institutional Review Board (IRB) shall determine that adequate provisions are made for soliciting the assent of children. When in the judgement of the IRB the children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. This judgement may be made for all subjects to the involved research under a particular protocol, or for each subject, as the IRB deems appropriate.

3.1.2 The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

3.1.2.1 For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus conveying an accurate picture of what the actual experience of participation in the study is likely to be (e.g., what the experience will be, how long it will take, whether it might involve any pain or discomfort).

3.1.2.2 For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission.

3.2 Waiver of Assent
3.2.1 If the IRB determines the capacity of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, assent is not a necessary condition proceeding with the research.

3.2.2 Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent can be waived.

3.3 Consent after 18 years of age or Emancipated Minor: When a subject who was enrolled in research with parental permission subsequently reaches the legal age of consent, the investigator must seek and obtain the legally effective informed consent for the now adult subject for any ongoing interactions or interventions with the subjects.

4 RESPONSIBILITIES
4.1 Investigators, IRB members, & staff
5  PROCEDURE
   5.1 Investigator must submit a completed form(s) along with the initial study application if he/she feels obtaining assent is appropriate. If the investigator does not feel obtaining assent is appropriate, he/she should state this on the application along with the reason(s) on which the determination is based.
   5.2 The IRB shall make the final determination on whether assent will be required and document its findings in the meeting minutes. The IRB shall not approve a research study that requires assent for which an assent form has not been submitted. Investigators will receive prompt written notification of the IRB’s decision to require assent.
   5.3 The investigator is responsible for determining if/when a subject reaches the legal age of consent. If the investigator needs to make any changes to the currently IRB-approved informed consent document, the modified form must be submitted to the IRB for review and approval as an amendment before it is used.

6  MATERIALS
   6.1 Initial Review form (HRPP-211)
   6.2 Request Alteration or Waiver of Informed Consent (Appendix I)

7  OTHER RELATED POLICY/PROCEDURES
   7.1 None

8  REFERENCES
   8.1 45 CFR 46.408