Statement of Consent Process

Study Protocol #/Short Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Approval Number/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject’s Name/Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Initial the following:

\_\_\_\_\_Subject identity verified (use at least 2 identifiers)

 [ ]  Full name \_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  DOB \_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  EMR photo verified \_\_\_\_\_

\_\_\_\_\_Legal representative identity verified

 [ ]  Full name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Relation to subject \_\_\_\_\_\_\_\_\_\_\_\_\_

* Spouse
* Parent
* Adult Child (18 years of age or over) for his or her parent
* Adult Sibling (18 years of age or over)
* Grandparent
* Adult Grandchild
* Guardian appointed to make medical decisions for individuals who are incapacitated

 [ ]  Written confirmation of LAR status provided (if applicable)

\_\_\_\_\_ Subject/legal representative was given a copy of **current** IRB approved consent. **Version: \_**\_\_\_\_\_

\_\_\_\_\_ Time was given to allow the subject/legal representative to read, review each page of the consent form, and was given the opportunity to ask questions.

\_\_\_\_\_ Consent was reviewed with subject/legal representative, including, but not limited to risks and benefits, other options for treatment, and the subject’s right to withdraw from the study at any time.

\_\_\_\_\_ All questions were answered by the trial coordinator and/or study physician.

\_\_\_\_\_ Contact information for study related questions, general research questions and HIPAA issues were provided to the subject/legal representative.

\_\_\_\_\_ Consent was signed and dated by the subject/legal representative and designated study associates.

\_\_\_\_\_ Copy of signed consent was given to subject.

\_\_\_\_\_ Copy of the informed consent form was placed in the subject’s medical record per IRB protocol.

\_\_\_\_\_ Proper consent process was completed **prior** to beginning of all study procedures.

\_\_\_\_\_ Original signed consent filed in research chart.

\_\_\_\_\_ If applicable, Assent discussed and signed by child.

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Person Conducting Consent Discussion Signature Date