

Statement of Consent Process for VERBAL CONSENT

Study Protocol #/Short Title: _____ PI: _____

Participant's Name/Initials: _____

IRB Approval Number/Date: _____

Current IRB approved ICF version: _____ Date: _____

Check if informed consent was given **verbally** by the participant/legally authorized representative (LAR).

Date of Verbal Consent: _____ Time: _____

Obtained Verbal consent via: phone email both Zoom/video conference

Name of Person giving Verbal Consent: _____

If Applicable relationship to Participant: _____

Impartial Witness Name: _____

During Verbal Consenting the following was discussed per approved verbal ICF Script:

Initial the following:

1. _____ Participant/legal representative was given a copy of **current** IRB approved consent via: mail email fax
2. _____ Time was given to allow the participant/LAR to read, review each page of the consent form, and participant/LAR was given the opportunity to ask questions.
3. _____ Consent was signed and dated by the participant/LAR and designated study associate(s).
4. _____ Copy of signed consent was given to participant via: mail email fax
5. _____ A copy of the informed consent form was placed in the participant's medical record as specified in IRB /HSP protocol.
6. _____ If a hard copy of the consent is signed at some point during the participant's time on the study, the original signed consent will be filed in the research chart.
7. _____ **Current** IRB approved consent form was read to participant/LAR, and all details related to study participation were explained.

8. _____ Consent was reviewed with participant/LAR, including, but not limited to risks and benefits, other options for treatment, and the participant's right to withdraw from the study at any time.
9. _____ 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 participant/LAR.
10. _____ Proper consent process was completed **prior** to beginning of all study procedures.
11. _____ If applicable, Assent was discussed and verbally assented to by child.
12. _____ When practicable, consent was obtained in person. Date: _____

Notes made during verbal consent discussion: _____

 Person Conducting Consent Discussion Signature

 Date

The verbal consent process was witnessed and the principles of ICH GCP (Section 4.8) were followed.

 Witness of Consent Discussion Signature

 Date