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:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
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________________________________________________________________________
________________________________________________________________________

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

Statement of Consent Process Checklist, Version 3.0
04/15/2020