IRB Office
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March 17, 2017

Tulio Valdez, MD
Otolaryngology
Connecticut Children's Medical Center
Hartford, CT 06106

CCMC IRB#: 15-115
Study Title: A Short Wave Infrared Otoscope For Objective Middle Ear Effusion Diagnosis

Review/Type: Expedited Review of Amendment

IRB Approval Date: March 17, 2017
IRB Approval Valid Thru: January 4, 2018
Continuation/Progress Report Due Date: December 04, 2017

On March 17, 2017, an Institutional Review Board of the Connecticut Children's Medical Center approved the above-referenced human subjects' research.

As the Principal Investigator, you are responsible for complying with reporting requirements as described in the HRPP Standard Operating Procedures that are posted on the HRPP website. For example, you are responsible for reporting unanticipated problems involving risk to subjects or others.

You are also responsible for obtaining IRB review and approval in writing before changes are made to approved protocols or consent forms unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).

Please note, when applicable, Principal Investigators are responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research.

IRB Determination(s):
Main Study: 45 CFR 46.404
45 CFR 46.110 (6)
45 CFR 46.110 (1)(b)
45 CFR 46.110 (5)

Overall Risk Level: Minimal risk
HIPAA: The Investigator is required to obtain Individual Authorization under 45 CFR 164.508.
Consent: The Investigator is required to obtain written Informed Consent from participants under 45 CFR 46.116.
Assent: Assent is required for all or some children given their maturity for this research, in accordance with the information provided in the Assent section of the IRB Application.
Parental Permission: Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This study was determined by the IRB to be an applicable clinical trial in which federal regulations require that applicable clinical trials and NIH-funded clinical trials be registered on clincialtrials.gov. The Responsible Party for a clinical trial must register the trial and submit results information. The lead sponsor should take responsibility for registering the trial. In cases where there is no sponsor, investigators involved in the research must work with each other to identify a responsible party and ensure the trial is registered only once for the entire project. Instructions for completing registration can be found here [https://clinicaltrials.gov/ct2/manage-recs/how-register]

Approved Study Personnel:

Name	Role
Principal Investigator	Dr. Tulio Valdez
Study Coordinator	Bridgette Carter, Danielle Blake

For reference, the amendment was described within the submission material as stated below:

Adding additional enrollment numbers from 50 patients to 100 patients

Currently the patients must be seen in Audiology to have a tympanogram/audiogram completed within 7 days +/- of the scheduled ENT visit. We will keep that language, but will add that patients who meet eligibility, but did not go to audiology have the option to receive a tympanogram in the ENT office by the PI.

IRB Office
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All IRB correspondence addressed to the IRB Office should include your IRB protocol #. Connecticut Children's DHHS Federal-Wide Assurance Number is: FWA00004706; *IRB# 00000703; IORG: 0000416*