Evaluation of Cellphone Based Otoscopy in Pediatric Patients

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ORAL CONSENT SCRIPT (for subjects)

Protocol Title: Evaluation of Cellphone Based Otoscopy in Pediatric Patients.

PURPOSE:

You are being asked to take part in a research study. The purpose of this study is to evaluate whether a smartphone otoscope (ear examination tool) improves patient care and trainee education.

PROCEDURES:

You will be asked to have yours/your child's ears examined with the Cellscope, an iPhone-based otoscope that uses the iPhone camera and light source to capture HIPAA compliant images and video recordings of the ear structures. No identifying information will be collected from or about your child.

RISKS/DISCOMFORTS:

Few risks or discomforts are anticipated. The risk of needing to repeat the otoscopic examination due to failure of the Cellscope is expected to be exceedingly rare. As mentioned above, this will be at the discretion of the primary team caring of the patient and will be reported as a secondary outcome. The risk of infection from the use of a shared device (Cellscope) among multiple subjects is very low and would be equal to that of or regular exam techniques. The risks associated with recording images and videos of your/your child's ear is very low. Your doctor has been instructed to record only the external and middle ear, both of which are non-traceable to you/your child.

BENEFITS:

The potential to improve your doctors confidence and skill in the ear exam, have better agreement with their supervisor, decrease the number of times your/your child's ear needs to be examined, and improve your doctors ability to use antibiotics the correct way.

VOLUNTARY PARTICIPATION:

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins.

If you have any questions about your rights as a research participant please do not hesitate to ask your doctor or call The Johns Hopkins Institutional Review Board at 410-955-3008.

Date: September 6, 2018

ORAL CONSENT SCRIPT (for providers)

Protocol Title: Evaluation of Cellphone Based Otoscopy in Pediatric Patients.

PURPOSE:

You are being asked to take part in a research study. The purpose of this study is to evaluate whether a smartphone otoscope improves patient care and trainee education.

PROCEDURES:

You will be asked to evaluate the Cellscope, an iPhone-based otoscope that uses the iPhone camera and light source to capture HIPAA compliant images and video recordings of the external and middle ear structures. You will then be asked to complete a short survey and record non-patient identifying information to help with data analysis.

RISKS/DISCOMFORTS:

Few risks or discomforts are anticipated. The risk of needing to repeat the otoscopic examination due to failure of the Cellscope is expected to be exceedingly rare. As mentioned above, this will be at the discretion of the primary team caring of the patient and will be reported as a secondary outcome.

The risks associated with recording images and videos of deidentified non-sensitive area anatomy is exceedingly low. You, as providers, will be instructed to record only the external and middle ear of patients, both of which are non-traceable to a given patient.

BENEFITS:

The potential to improve your clinical confidence in the otoscopic exam, have better agreement with your supervisor, and improve your diagnostic accuracy and thus improve your antibiotic prescribing behavior.

VOLUNTARY PARTICIPATION:

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your standing at Johns Hopkins. You may refuse to answer any question(s) that you do not wish to answer. Your employment will not be jeopardized if you decide not to participate.

If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Johns Hopkins Institutional Review Board (IRB) at 410-955-3008.