NCT Number: NCT02536963

Study Title: Improving Quality Vision Outcomes in Managed Care Setting While Reducing Cost by Use of Accurate, Automated Screening

Document: Informed Consent

Date Created: August 2015

I. Informed Consent Form

KAISER FOUNDATION HOSPITALS PATIENT'S NAME: _____

SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP M.R. #: _____

STUDY #: _____

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY:
Improving quality vision outcomes in the managed care setting while reducing cost by use of accurate, automated screening

SPONSOR: National Institutes of Health (NIH)

INVESTIGATOR:

TELEPHONE:

Your child is being invited to be in a research study. The purpose of this form is to give you detailed information about this study. Our goal is for you to understand:

- **that taking part in a research study is entirely voluntary,**
- **the reason we are doing the study,**
- **what will happen to you if you decide to be in the study, and**
- **what will happen to you if you decide not to be in the study.**

You can ask the study staff any questions at any time. You can take this form home to think about the study or talk to family and friends about it.

Participating in a research study is not the same as getting regular medical care. Therefore, it is important that you understand the difference between the regular care you get from your doctor and what is involved in this research study.

The purpose of regular medical care is to improve your child's health. The purpose of a research study is to gather information to advance medicine. There is no guarantee that your child will directly benefit from the research study. Your child's study doctor and the research staff assisting your child's study doctor must follow the requirements of the research study. Being in this study does not replace your child's regular medical care.

Kaiser Permanente is being paid by the study sponsor, National Eye Institute (a branch of the NIH), to conduct this research.

II. Enrollment Form

Vision Screening Study

Participant Enrollment Form

Form #1 Version: 12/5/2014

SECTION A: GENERAL INFORMATION

A1. Study ID number ___ ___ ___ - ___

A2. Visit Date: MM/DD/YYYY __ __ / __ __ / __ __ __ __

A3. Initials of person completing form: __ __ __

A4. Date Form Completed: MM/DD/YYYY __ __ / __ __ / __ __ __ __

SECTION B: Demographics

B1. Name _____

B2. KP# _____

B3. Date of Birth: ____Month ____Day ____Year

B4. Gender: ____Male ____Female

B5. Race: ____American Indian/Alaska Native
____Asian
____Native Hawaiian or Other Pacific Islander
____Black or African American
____White
____More than one race

B6. Ethnicity: ____Hispanic or Latino
____Not Hispanic of Latino

B7. Corrective Lens Use: ____Yes ____No

B8. History of Ocular Disease: ____Yes ____No

*Specify if yes:*_____

III. Eligibility Form

SECTION A: GENERAL INFORMATION

A1. Study ID number ___ ___ ___ - ___

A2. Visit Date: MM/DD/YYYY __ __ / __ __ / __ __ __ __

A3. Initials of person completing form: __ __ __

A4. Date Form Completed: MM/DD/YYYY __ __ / __ __ / __ __ __ __

SECTION B: ELIGIBILITY CHECKLIST

	Criteria	Yes	No
B1.	Is the subject older or equal to 2 years of age, and less than 6 years of age? *If yes, continue to B2.* *If no, subject is not eligible for study.*		
B2.	Does the subject have any apparent developmental delay or cognitive deficit? *If yes, subject is not eligible for study.* *If no, continue to B3.*		
B3.	Does the subject have any visually obvious ocular conditions (cosmetically obvious strabismus, ptosis, gross nystagmus, eye infection, etc.) that would warrant specialist referral? (Children wearing glasses are not to be excluded, unless they have the visually obvious conditions listed.) *If yes, subject is not eligible for study.* *If no, subject is eligible for study.*		
	Is subject eligible for study?		

Name of person conducting screening (first & last): _____

Signature: _____

Date: _____