APPLICATION FOR EXEMPTION

American Academy of Pediatrics Institutional Review Board (AAP IRB)

OFFICE USE	DATE RECEIVED:	PROTOCOL NUMBER:

1. PROJECT TITLE

Early Hearing Detection and Intervention Quality Improvement Project, Phase 2

2. PRINCIPAL INVESTIGATOR (PI)

Name (Last, First): _____ Degree(s): _____

Employer: _____

Mailing Address: _____

E-mail: _____ Fax: _____

Phone: _____

3. AAP STAFF CONTACT

Name: _____ E-mail: _____

Department: _____ Phone: _____

4. CO-PI(s), if applicable

Name (Last, First): _____ Degree(s): _____

Employer: _____

Mailing Address: _____

E-mail: _____ Fax: _____

Phone: _____

5. HUMAN SUBJECTS PROTECTION TRAINING REQUIREMENT

The AAP IRB encourages annual human subjects protection training but requires training every 3 years; this requirement must be satisfied prior to submitting the application for review.

Date and name of PI's most recent completion of human subjects protection training: _____

Have all project investigators and key research staff received human subjects training within the last 3 years? *Double click on the box to check.*

☐ Yes
☐ No

6. PROPOSED PROJECT DATES

Provide the estimated beginning and end dates of the project: December 2016-August 2017

7. FUNDING OR OTHER SUPPORT

Provide source(s) of funding: _____

8. SCREENING QUESTIONS *(See last page of this form for the list of categories and their description).*

a. Will the research risk expose participants to discomfort or distress beyond that normally encountered in daily life?
☐ Yes
☒ No

b. Could disclosure of participants' responses reasonably place participants at risk of criminal or civil liability or risk damaging participants' financial standing, employability, or reputation AND will information obtained be recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?
☐ Yes
☒ No

c. Does any part of the research require deception or incomplete disclosure of information to participants?
☐ Yes
☒ No

d. For research proposed under category 2, will the research involve surveys or interview procedures with children?
☐ Yes
☒ No or N/A

e. For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed?
☐ Yes
☒ No or N/A

f. For research proposed under category 4, will any of the data, documents, records, or biological specimens be collected or created <u>after</u> the date of this application for exemption?
☐ Yes
☒ No or N/A

g. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants?
☐ Yes
☒ No or N/A

If you checked YES to ANY of the questions above, your research is NOT EXEMPT. Do not complete this application. Submit an Application for Initial Review of Human Subjects Research. For more information on exempt research, see the AAP IRB Administrator.

9. EXEMPT CATEGORY *(See last page of this form for the list of categories and their description).*

Please check the categories of exemption for which you are applying. *You may check more than one box.*

☒ **1** ☒ **2** ☐ **3** ☒ **4** ☐ **5** ☐ **6**

10. LOCATION OF THE RESEARCH

List the specific site(s) at which the research will be conducted.

Location name(s), or description
5 pediatric primary care practices nationwide
American Academy of Pediatrics headquarters

11. PARTICIPANTS

a. Specify the participant population(s) to be included (check all that apply):

- ☒ AAP members
- ☒ Children (< 18 years)
- ☐ Pregnant women
- ☒ Other, specify: Pediatric practice staff; parent/caregiver partners

b. Provide the total number of participants (or number of participant records) for each category of human subjects (e.g., AAP members, children, parents):

Subject Category	Total number to be studied (for each category)
AAP members	5-20 (includes pediatrician champion and other pediatricians in the practice)
Children	1,595 medical records total (up to 22 medical records for 6 week olds and up to 22 medical records for 4 month olds x 5 practices x 6 months) (Baseline: up to 15 medical records for 6 week olds and 4 month olds at baseline who did not pass hearing screen over a 3-month period and 20 medical records for 6 week olds and 20 medical records for 4 month olds who did pass the hearing screen [275 total at baseline])
Parents/caregivers	5
Post-project feedback call with practice teams and parent/caregiver partners	15 (pediatrician champion, practice staff and parent/caregiver partner)
Pediatric practice staff (nurses/non-pediatrician clinical staff members, front desk/administrative staff)	5-10

c. Describe the characteristics of the population(s). *If requesting exemption under category 4 (see question #9 above), include the date range of records/specimens to be accessed (e.g., patients immunized between 01/01/2009 and 01/01/2012).*

Five practice teams, each consisting of a lead pediatrician, at least one other clinical or non-clinical practice staff, and a parent/caregiver partner will be recruited from the EHDI chapter champion network which spans 53 AAP US chapters and from other AAP communication outlets. Chapter champions also will be encouraged to recommend other pediatricians/pediatric practices. The goal is to obtain a diverse sample of practices, including practice geographical location, practice setting (urban, rural, suburban), practice size, and type of practice.

In order to be selected as part of the project, the practice must:

- Be a pediatric primary care practice
- Currently be using an electronic health record (EHR) system and not planning to implement a new system during the project timeframe
- Enroll a minimum of 50 infants in their practice, each month

All completed project applications will be reviewed by a subset of the project's Expert Group including the chairperson, the QI advisor, one member and staff. Once practice teams are selected to participate in the project, the lead pediatrician and all other identified practice team member(s), except for the parent/caregiver partner, will be required to sign consent forms for participation in the project. Since the parent/caregiver partners will not have access to QIDA, they will not be required to sign a project consent form. Consent forms and additional project

materials will be distributed via email to practice teams by AAP staff upon selection into the project. Consent forms will be returned to AAP staff prior to completion of baseline data collection and pre-implementation survey. It is expected that practice teams will return the consent form primarily via email or fax.

Baseline/Prework (January 2017)

During the baseline/prework period, retrospective medical record reviews will be performed on a sample of patients within the practice who are at least 6 weeks and 4 months of age. Practice teams will review up to 55 patient records total. The practice teams will review medical records from the immediate past 3-months (mid-November 2016 through mid-January 2017) for all children at least 6 weeks old and 4 months old who they identify as having a "do not pass" newborn screening result. Expert group members expect that there will be less than 15 medical records total per practice over a 3-month period for children who did not pass the newborn hearing screening. The practice teams will also review up to 20 medical records from the immediate past 3-months (mid-November 2016 through mid-January 2017) for children at least 6 weeks old and 20 medical records from the past 3-months for children at least 4 months old who they identify as having passed the newborn hearing screening. The record reviews data will be submitted via the AAP QIDA.

Action Periods (February 2017-July 2017)

The number of patient records reviewed each month will depend on the number of new patients enrolled in a practice each month. This is due to the fact that statistically, 1-3% of newborns will receive a "do not pass" result following their newborn hearing screen. Practice teams will be asked to review the medical records of all infants ages 6 weeks and 4 months who they identify as having a "do not pass" newborn hearing screening result each month during the Action Period (mid-February 2017 through mid-July 2017). This will likely be no more than 4 patient medical records per month per practice. Circumstances may exist when practice teams do not have the requisite number of patients at the 6 week or 4-month age frame who have a "do not pass" result on their newborn hearing screen.

Practice teams will also be asked to review the randomly selected medical records of 20 infants ages 6 weeks and 4 months (40 medical records total) who they identify as having passed the newborn hearing screening each month during the Action Period (mid-February 2017 through mid-July 2017). These medical record reviews of newborns who have passed the newborn hearing screening will help ensure that the initial newborn hearing screening results are documented in the medical records of all infants, that the pediatrician discusses those results (whether the infant passed or did not pass the hearing screening) with all families, and that risk factors for late-onset hearing loss are discussed with families. All data will be submitted via the AAP QIDA.

12. SUMMARY OF THE RESEARCH

Briefly summarize the purpose and procedures of the proposed research.

The Early Hearing Detection and Intervention (EHDI) program within the American Academy of Pediatrics is dedicated to promoting the role of the medical home and the primary care provider in EHDI. The EHDI program supports a network of over 60 Chapter Champions, who provide ongoing EHDI education and resources to medical home providers, and play a vital role in coordinating health efforts between pediatricians, health care professionals, and state EHDI programs.

This quality improvement project will build on lessons learned from the previous iteration of the Early Hearing Detection and Intervention Quality Improvement Project, which was approved by the AAP IRB on May 22, 2015 (IRB # 15 CI 01). See Appendix A for study approval and details. This project will use the Learning Collaborative

model to test strategies that will enhance pediatrician knowledge and practice related to documentation of newborn hearing screening results, referrals to sub-specialists, documentation of risk factors for delayed or late-onset hearing loss, and communication of these results with families. The project will result in potential dissemination of best practices and education on topics of relevance to practicing pediatric primary care clinicians. Five practice teams will be recruited through the EHDI Chapter Champion network and other AAP member communications and each team will be led by a practicing primary care pediatrician. Each team will also work with a parent/caregiver partner to ensure that family-centered care and family feedback is incorporated into practice changes.

Data collection for quality improvement purposes will involve de-identified patient record reviews, completion/submission of monthly progress reports, and completion of pre- and post- project surveys completed by the participating teams. Teams will also participate in monthly educational webinars/conference calls to learn from experts and each other and to receiving coaching and mentorship from the project quality improvement advisor. At the end of the project, practice teams will participate in a post-project feedback call to gauge their experience participating in the project.

This quality improvement project is led by an Expert Group, which provides clinical expertise and insight regarding the focus area. Members include pediatric quality improvement (QI) experts, general pediatricians, neonatologists, an audiologist, a representative from the National Center for Hearing Assessment and Management (NCHAM) a QI Advisor, and a family representative (Appendix B). The role of the Expert Group is to help develop the project's overall educational approach as well as the quality improvement methodology and focus for the project. Expert Group members and the QI Advisor will be responsible for leading the monthly webinars/conference calls with the practice teams during each action period. AAP program staff also supports the Expert Group in its work.

Purpose

The AAP EHDI QI project utilized the results of the 2012 NCHAM physician survey to develop strategies for the project that focus on strengthening the role of the medical home within the EHDI system. The practice teams selected to participate in the project will likely consist of the state EHDI chapter champion or other primary care pediatrician, one individual from the practice based on focus area/priorities for the project (eg, nurses, care coordinators, office managers or other administrative staff, and/or other pediatricians), and a parent/caregiver partner.

Practice teams will focus on work related to pre-determined project aims and measures designed to improve follow up after newborn hearing screening. Areas of focus include: documentation of newborn hearing screening results, engaging in discussions with families about the results of the hearing screen and if the infant has risk factors for hearing loss, and ensuring all infants who do not pass the initial screen receive the needed diagnostic follow up.

The quality improvement project will occur over a period of eight months (including recruitment/orientation, baseline, and action periods), with three action periods. Repeated measurement of the practices' care processes, using patient record review and aggregate electronic health record data collection, will be used to track changes in practice. Initial measurement will be conducted at baseline and during the three action periods. The baseline period will take place over one month and each of the action periods will be two-months in length. Although action periods will be two-months in length, data will still be collected from practice teams on a monthly basis to ensure full practice team engagement in the project.

Specific aims of the project include:

By July 2017, five pediatric offices will make practice-based improvements that lead to enhanced care across the delivery system and strengthen the role of the medical home within the EHDI system. The participating pediatric practices will make improvements so that:

1. 97% or more of all newborns have documentation of the results of their final newborn hearing screening in their medical records by 6 weeks of age
2. 97% of newborns have documentation in their medical record that the results of the newborn hearing screening were discussed with the family no later than 6 weeks of age
3. 97% or more of all newborns identified to have risk factors associated with hearing loss will have documentation of those risk factors in their medical record by 6 weeks of age and will have an individualized care plan by the 4 months of age
4. 100% of children who do not pass their newborn hearing screening have completed an audiological evaluation by 3 months of age and documentation will be in their medical record by 4 months of age

The project's process and outcome measures are included in more detail in the table below and in Appendix C.

Process Measures

Measure	Numerator	Denominator	Goal
Screening Results – All	Number of newborn infants with hospital newborn hearing screening results documented in the medical record by 6 weeks of age	Number of newborn infants 6 weeks of age during the reporting period	97%
Outpatient Screening Results	Number of newborn infants who have the results of an outpatient screen documented in their medical record by 6 weeks of age	Number of newborn infants who have been referred for an outpatient hearing screen and are 6 weeks of age during the reporting period	97%
Risk Factors	Number of newborn infants who were documented to have an assessment of risk factors for hearing loss by 6 weeks of age	Number of newborn infants 6 weeks of age during the reporting period	97%
Referral to audiological exam	Number of newborn infants who do not pass their final hearing screen (hospital newborn or outpatient) who have a referral for an audiological exam documented in the medical record by 6 weeks of age	Number of newborn infants who do not pass their final hearing screen (hospital newborn or outpatient) who are 6 weeks of age during the reporting period	100%

Audiological exam conducted	Number of newborn infants who do not pass their final hearing screen (hospital newborn or outpatient) who have received an audiological exam	Number of newborn infants who do not pass their final hearing screen (hospital newborn or outpatient) who are 4 months of age during the reporting period	100%
Documentation of audiological exam results	Number of newborn infants who do not pass their final hearing screen (hospital newborn or outpatient) who have documentation of the audiological exam results in the medical record by 4 months of age	Number of infants who do not pass their final hearing screen (hospital newborn or outpatient) who are 4 months of age during the reporting period	100%

Outcome Measures

Measure	Numerator	Denominator	Goal
Results Conversation	Number of newborn infants with documentation in their medical record that the results of the final hearing screen (hospital newborn or outpatient) were discussed with the family by 6 weeks of age	Number of newborn infants who are 6 weeks of age during the reporting period	100%
Risk Factors Conversation	Number of newborn infants with documentation in their medical record that the assessment for risk factors for hearing loss were discussed with the family by 6 weeks of age	Number of newborn infants who are 6 weeks of age during the reporting period	100%
Risk Factors Care Plan	Number of newborn infants identified with risk factors for hearing loss with documentation in their medical record of an individualized care plan by 4 months of age	Number of newborn infants with identified risk factors who are 4 months of age during the reporting period	97%

Audiological Exam Completed By 3 Months	Number of newborn infants who do not pass their newborn hearing screen with documentation in their medical record of an audiological exam completed by 3 months of age	Number of newborn infants who do not pass their newborn hearing screen who are 4 months of age during the reporting period	100%
Audiological Results Conversation	Number of newborn infants who do not pass their newborn hearing screen that had the results of the audiological exam discussed with the family by 4 month well child visit	Number of newborn infants who do not pass their newborn hearing screen completing their 4 month well child visit during the reporting period	100%

Over the course of the project period, practice team members (specifically, pediatricians, nurses, and other non-pediatrician clinical staff, front desk/administrative staff) will:

- Devote necessary resources and time to testing and implementing changes in the practice over the specified quality improvement period and working to obtain buy-in from additional members of the practice.
- Test and implement appropriate changes in the structure of how newborn hearing screening results are accessed and utilized to identify infants who do not pass their initial screening and need diagnostic follow up, using QI methodology.
- Review records of **all** infants ages 6 weeks and 4 months who do not pass the newborn hearing screen (about 4 records per practice) as well as the records of 20 infants ages 6 weeks and 4 months who do pass the newborn hearing screen per practice (up to 44 medical records total), seen in the practice during the review month of the Action Period. Record review and data collection of clinical measurements pertinent to the aims of the project will be completed using the AAP Quality Improvement Data Aggregator (QIDA).
- During project pre-work/baseline, review records from the **past three months** of all infants ages 6 weeks to 4 months who did not pass the newborn hearing screen as well as the records of 20 infants ages 6 weeks and 4 months who did pass the newborn hearing screen per practice (up to 55 medical records total). Record review and data collection of clinical measurements pertinent to the aims of the project will be completed using the AAP Quality Improvement Data Aggregator (QIDA).
- As part of project pre-work, hold a brief interview/discussion using the provided interview/discussion guide with a family from each practice who has a child diagnosed with hearing loss or who has a child who failed the initial hearing screen to assess gaps in patient care and to develop change strategies based on these gaps. Please note: the qualitative data/information from family interviews will not be submitted as part of the project.
- Attend a one-day improvement workshop (in-person Learning Session) at the beginning of the action period. Identify a parent/caregiver partner to attend this workshop as a member of the practice quality improvement team.
- Complete monthly progress reports due at the end of each month from February 2017-July 2017.
- Test innovations in care delivery to improve newborn hearing screening follow up in the medical home.

- Share lessons learned and problem-solve with other participating practices during the monthly webinars/conference calls.
- Use the online password-protected Project Workspace in QIDA and dedicated project email group on a regular basis for ongoing support, information, and communication among practice teams.
- Complete a pre- and post- implementation survey(s).
- Decide how to best share learnings with other physicians and staff in the practice using the newborn hearing screening follow up tools and QI resources provided.
- Participate in one (1) one-on-one coaching call with the Quality Improvement Advisor during the project period.
- Participate in a post-project feedback call with the quality improvement advisor and other practice teams at the end of the project (optional).
- If necessary, seek local Institutional Review Board approval for participation prior to Expert Group selection as a practice team participant in the QI project.
- *Pediatrician leader only: serve as Local Leader in the attestation process required by the American Board of Pediatrics for Part 4 Maintenance of Certification (MOC) (if approved). Duties include providing each pediatrician in the practice interested in participating for MOC credit a document describing the requirements of their participation, monitoring pediatrician participation and attesting that eligible pediatrician completed the project's completion criteria.*

Practice teams will also choose a parent/caregiver partner as a team member to help implement change within the practice. The parent/caregiver partners will participate in the in-person learning session and monthly webinars/calls, but will not be involved in any record reviews or have access to any data in QIDA.

As a benefit of participation in this quality improvement project, if approved by the American Board of Pediatrics (ABP), pediatricians in the practice will be eligible for Part 4 (Performance in Practice) Maintenance of Certification (MOC) credits. This includes pediatricians represented on the practice team as well as other physicians in the project.

Practice teams will have the opportunity to learn and test strategies to improve early hearing detection and intervention. Participants will also have the opportunity to participate in collaborative learning and to share promising practices, challenges, successes, and lessons learned. If improvements in care are achieved, the benefits to families/caregivers and children are likely to be significant.

Methods and Procedures

The total time a practice and individual participants will be involved in the project, including the orientation webinar, baseline data collection, and post-feedback webinar is 8 months. During this period there will be a planning phase, baseline data collection, an in-person learning session, 5 educational webinar sessions/conference calls (will include education on EHDI topics from experts, QI coaching, and collaborative learning among practice teams), a post-implementation feedback webinar/call, and 3 two-month long action periods. The project will consist of the following:

Project Recruitment (December 2016)

- Recruit and enroll 5 practice teams

Prework Period (December 2016-January 2017)

- Orientation webinar/call
- Retrospective baseline medical record review (up to 55 medical records reviewed by each practice from the past 3 months)
- Pre-implementation practice survey
- Interview/discussion with family from practice who has a child diagnosed with hearing loss or has a child who did not pass the initial newborn hearing screening

Learning Session (February 11 or 12, 2017)

- Quality improvement and EHDI education

Action Periods (February-July 2017)

- Action Periods will be two-months in length, but practice teams will still be asked to submit data and participate in webinars on a monthly basis.
- Medical record review (up to 44 medical records entered per practice using QIDA)
- Monthly progress reports (1 report per practice, narrative)
- Monthly webinar/conference call participation
- Monthly webinar/conference call evaluation survey
- One-on-one QI coaching call (one call per practice team during the Action Period)

Post-Action Period (July-August 2017)

- Post-implementation survey
- Post- project feedback telephone call

Additional Project Components

- Expert Group
- Project Workspace and Email Group

Prework Period

After recruitment of practice teams, an orientation webinar will be held with all practice teams. The webinar will be utilized to facilitate a discussion about quality improvement methodology, as well as roles and responsibilities of practice team members throughout the project. Practice teams will also learn how to utilize the QIDA software and how to complete baseline data collection and pre-implementation surveys.

Following the orientation webinar/call, all participating practice teams will collect baseline medical record review data. Up to 55 medical record reviews will be performed on a sample of patients within the practice who are 6 weeks and 4 months of age. The practice teams will review patient records from the past 3 months for all children 6 weeks and 4 months of age who did not pass their newborn hearing screening (up to 15 medical records total) and medical records for those infants who did pass their newborn hearing screening (up to 40 medical records total). See Appendix D for the medical record review tool.

Practice teams will complete a pre-implementation survey to assess existing practice-level care related to EHDI (Appendix E). The lead pediatrician, or designated practice team member will be responsible for compiling, entering and submitting the survey responses via Survey Monkey, but all team members will be encouraged to contribute to the survey.

Additionally, practice teams will be asked to hold a brief interview/discussion with a family from their practice who either has a child who has been diagnosed with hearing loss or who did not pass the initial newborn hearing screen. This discussion with the family will help the practice team potentially identify gaps in care and EHDI processes that they could work to improve throughout the duration of the quality improvement project. Practice teams will be provided with a discussion guide to help facilitate these discussions (Appendix F), but specific responses from families will not be submitted. During the learning session, practice teams will verbally report out one lesson learned or surprising finding from the family discussions that they plan to work to improve during the project.

Learning Session

All three members, including the parent/caregiver partners, of each of the five practice teams will attend an in-person learning session focusing on educating the practice teams on quality improvement and EHDI-specific topics, respectively. The learning session is scheduled to take place at the AAP headquarters in Elk Grove Village, Illinois on February 11 or 12, 2017, prior to the start of the first action period. All presentations at the learning session will be expert-led, and will focus on preparing the teams for the activities of the action periods.

Action Periods

The Expert Group will help practice teams review their current EHDI practice processes in terms of documenting newborn hearing results, identifying risk factors for late-onset or progressive hearing loss, making referrals for infants who receive a "do not pass" result for their newborn hearing screening and discussing same with families. This will assist the practice teams in identifying small tests of change that can be implemented to help achieve progress related to the specific measures outlined in the project aims and measures. Throughout the action period, the practice team will implement the small test of change in order to improve EHDI related care within the practice.

A simple time-series design will be used to measure progress over time for each of the project measures being addressed by participating practice teams. Practice team members will conduct monthly record reviews and the data will be entered into QIDA. Practice teams will review the medical records of all infants ages 6 weeks and 4 months who they identify as having a "do not pass" newborn hearing screening result each month during the Action Period. Practice teams will also be asked to review the randomly selected medical records of 20 infants ages 6 weeks and 4 months each who they identify as having passed the newborn hearing screening each month during the Action Period. These medical record reviews of newborns who have passed the newborn hearing screening will help ensure that the initial newborn hearing screening results are documented in the medical records of all infants, that the pediatrician discusses those results (whether the infant passed or did not pass the hearing screening) with all the families, and that risk factors for late-onset hearing loss are all discussed with families. The lead pediatrician or designated practice team member will, on a monthly basis, review run charts displaying data obtained from their record review. Run charts will help teams visualize change over time, as well as decide where to focus future efforts.

The lead pediatrician, or the designated team member will complete and submit a monthly progress report (Appendix G) to provide additional feedback about changes made in the practice during the action period(s).

The Expert Group, QI Advisor and staff will facilitate monthly webinars that will include an educational component as well as time to review data, share practice teams' successes and challenges and encourage collaborative learning. The calls will be offered on a monthly basis and will take place during pre-determined reserved times at the end of each month during the action period. All lead pediatricians and practice team members will attend the monthly educational webinar/conference call. The first portion of the webinar will consist of EHDI education provided by an expert in the field. The topic(s) and faculty for these will be determined in the near future. The second portion of the educational webinar will consist of QI coaching from the QI advisor and time for practice teams to share progress, best practices, and lessons learned throughout the last action period in a learning collaborative format. Practice team members will share the results of their improvement efforts with the Expert Group and other project participants. The Expert Group and staff will adapt and refine the tools, measures, and data collection instruments based on the monthly data and feedback collected from practice team and this analysis will inform small-scale plan-do-study-act (PDSA) cycles during the project. An evaluation (Appendix H) will be sent to individual team members to complete after the webinars. Evaluations will be anonymous and optional from each team member.

During the action period, each practice team will also participate on one (1) one-on-one quality improvement coaching call with the quality improvement advisor. These calls are designed to provide technical assistance and support to each practice team related to planning, testing, and sustaining changes in practice. Since these calls are held with only one practice team at a time, each team will receive individualized support tailored to their particular practice setting and situation. Project staff will participate on these calls and provide further technical assistance if necessary. Successes and challenges shared with the quality improvement advisor by practice teams during these calls will be shared with other practice teams as promising practices.

Post Action Period

At the end of the action period, the practice teams will be asked to complete a post-implementation survey. In order to compare results, the survey will be identical to the pre-implementation survey, and include questions on assessing

practice-level care systems for EHDI related topics. The procedure for dissemination and data collection will be identical to the pre-implementation survey procedures.

The practice teams will also be asked to participate in a post-project feedback conference call to review data and practice team progress from the QI project, share lessons learned, and provide feedback on the overall QI project process (Appendix I). This conference call will provide an opportunity for practice teams to provide feedback that can be used to evaluate the QI project.

Additional Project Components
The EHDI QI Expert Group has overseen the design of the project and assisted staff in its implementation. The Expert Group consists of content experts, pediatric quality improvement experts, a family representative, and a QI Advisor. The Expert Group will be available to answer clinical and process-related questions and the QI Advisor will provide coaching to the teams. Expert Group members will participate in the webinars/conference calls, and will have viewing access to the Project Workspace.

To assist in information sharing and provision of educational materials, technology tools will be used throughout the project. The AAP Quality Improvement Data Aggregator (QIDA) will be used for data collection and will also serve as the password-protected project workspace. It will house resources and tools related to the project, and include practice-level and project-level data (an aggregate of all participating practices' data). This will allow a point of comparison for teams over the course of the project and has been helpful in previous quality improvement projects.

The project email group will include all practice team members, except for parent/caregiver partners. The group will provide a forum for communication among team members, as well as serve as the main method for communication from the Expert Group and AAP staff to the practices regarding project information.

13. RESEARCH METHODS & ACTIVITIES

Check all research activities that apply. *Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.).*

- ☒ Audio, video, digital, or image recordings
- ☒ Existing data, not publicly available
- ☐ Existing data, publicly available
- ☐ Focus groups
- ☐ Internet or e-mail data collection
- ☒ Record review
- ☒ Surveys, questionnaires, or interviews (one-on-one)
- ☒ Surveys, questionnaires, or interviews (group)
- ☐ Other, specify: _____

14. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

Five practice teams will be recruited from the AAP EHDI Chapter Champion network and other AAP communication outlets; a requirement for participation is that the pediatrician be in pediatric primary care practice. The goal is to obtain a diverse sample of practices, including practices that differ by geographical location, practice setting (urban, rural, suburban), practice size, and type of organization. The lead pediatricians on each of the five practice teams will be practicing primary care pediatricians.

Patients ages 6 weeks and 4 months of age who have passed and have not passed their newborn hearing screening will be identified via medical record review by each participating practice. No identifiable Protected Health Information is being collected on patients in this quality improvement project.

In addition, practice teams will recruit a parent/caregiver partner to join their practice team. Project Expert Group members have provided a document to guide practice teams in choosing a parent/caregiver partner (Appendix J).

b. **Describe the recruitment process, including the setting in which recruitment will take place.** *Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters/e-mails, and oral/written scripts).*

Five practice teams, each consisting of a lead pediatrician, at least one other clinical or non-clinical practice staff, and a parent/caregiver partner will be recruited from the EHDI chapter champion network which spans 53 AAP US chapters and from other AAP communication outlets. Chapter champions also will be encouraged to recommend other pediatricians/pediatric practices. The goal is to obtain a diverse sample of practices, including practice geographical location, practice setting (urban, rural, suburban), practice size, and type of practice.

Recruitment materials, an application for participation, and an acceptance letter will be used for practice team recruitment and selection (Appendix K). The packet includes a cover letter signed by the project Principal Investigator (PI), Robert Cicco, MD, FAAP; a project overview that describes the project and provides specific responsibilities of the practice/individual team members; and a link to the application to be completed via Survey Monkey. The application will ask for basic practice information, patient and practice demographics, quality improvement experience and will provide an overview of project requirements.

The application packet will be emailed to EHDI Chapter Champions and to other practicing primary care pediatricians via AAP communication outlets by AAP program staff. All recruitment materials and communications will contain AAP staff contact information.

Among those that respond and complete an application, five practices teams will be selected to participate in the project after the applications are reviewed by a subset of the QI Expert Group and AAP staff. All applicant information will be downloaded by project staff, imported into an Excel spread sheet, and shared with the subset of the QI Expert Group who will make recommendations about selecting practice teams for participation in the project.

Upon selection into the project, all identified participants will receive additional information about project participation, including consent forms for practice team members to complete (Appendix L) and will be invited to attend an orientation webinar/conference call. Parent/caregiver partners will be given a separate consent form to complete at the time of the post-project feedback calls (Appendix M). AAP project staff will email participants these materials, along with their acceptance letter. In addition to these selection materials and the consent form that are emailed to participants, the orientation webinar/conference call will provide practice teams with specific expectations related to participation in the project and allow for teams to ask questions regarding the project before the in-person learning session.

15. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., cash payments, gift certificates, parking) to participate in the research study?

☐ Yes
☒ No

If Yes → Describe the incentives, including the amount and timing of all payments.

16. INFORMED CONSENT

Will you obtain informed consent? ☒ Yes ☐ No

If Yes → Provide copies of documents, as applicable, and describe the consent process.

AAP staff will obtain consent from each individual participating on the practice team(s), which includes, at minimum, the lead pediatrician from all five participating practices and the additional team member on each practice team (eg, physicians, nurses, care coordinators, medical assistants, office managers). AAP staff will also obtain separate consent from parents/caregivers who wish to participate in the post-project feedback call prior to the call (See Appendix N and O for the invitation for parent/caregiver partners to participate in the post-project feedback call, information about completing the consent form, and the consent form respectively).

Upon selection into the project, practice teams will receive additional information about project participation, including the consent form, via email. This email will be sent to each identified participant's email address on the team (contact information for each individual on the team will be required in the application), except for the parent/caregiver partner. Ample time (approximately one week) will be provided for team members to individually review these materials. Included in the consent to participate form is information regarding the voluntary nature of the QI project. Participants may refuse to participate, or stop participating at any time and for any reason, without any penalty or impact.

Specific expectations related to participation will be presented on an orientation webinar/conference call that will take place in December or January. During the orientation webinar/conference call, participating practices will be provided an open forum to have all their questions and concerns related to participation in the project addressed by AAP project staff, the Expert Group chairperson, and the QI Advisor. AAP staff contact information will be provided during this call and it will be announced to all individual participants that they may contact staff privately with any concerns or hesitations regarding their involvement. Consent forms will be submitted from individuals directly (on their own accord) rather than submitted in compiled format from the entire practice team.

17. CONFIDENTIALITY OF DATA

When answering a, b, and c, please address both paper and electronic data.

a. Does the research require access to the individually identifiable private information (e.g., name, contact information)? ☒ Yes ☐ No

If Yes → Describe the individually identifiable private information involved in the research. List the information source(s) (e.g., Netforum, surveys, medical records, etc.).

No identifiable Protected Health Information is being collected on patients and practices in this quality improvement project; therefore, no HIPAA-specific measures are employed within the protocol.

Names and contact information (eg, address, email address, telephone numbers) will be requested on the application for all identified practice improvement team members and parent/caregiver partners. This information will only be available to AAP staff and Expert Group members. To encourage collaborative learning among practice teams, a roster with practice name, address, phone number and team member names and email addresses will be shared during the in-person learning session and on the Project Workspace.

b. Explain how participants' data is retained, including storage, security measures (as necessary), and who will have access to the information.

Comprehensive measures will be implemented to maintain subject confidentiality as appropriate (details provided below). The practice team will be provided with a username and password to access the secure online Project Workspace/QIDA. Each practice team will have a unique username/password that will not be shared with any other practice teams, project staff, consultants, or Expert Work Group members. Additional provisions for maintaining confidentiality for each specific type of data collection tool are described in the sections below.

Pre- and Post-Implementation Survey (Appendix E)
Each team will submit one practice survey at pre- and post-implementation of the quality improvement project. The practice team will be asked to complete the survey together. Data from the survey will be collected directly through Survey Monkey and stored on the Survey Monkey server under the password protected account of the AAP Division of Children with Special Needs. The data will be downloaded by project staff via Survey Monkey, which uses which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. Data will be shared with the project's QI Advisor, Amanda Norton, MSW, via email for analysis. Any reports resulting from the pre- and post-implementation surveys will be in aggregate format without any participant or practice names. Practice teams will be provided with their individual pre-implementation survey results at the in-person learning session at the beginning of the project and with their post-implementation results via email at the end of the project. These individual practice-level results will not be shared with other practice teams.

Learning Session Evaluation Survey (Appendix P)
At the end of the in-person learning session, attendees (practice team members) will be asked to complete optional anonymous evaluation surveys. These paper-based surveys will be utilized to gather feedback from learning session attendees about their experience participating in the learning session. Feedback received from the surveys will be collected, entered into an Excel spreadsheet and analyzed by project staff. Anonymous results from the learning session evaluation surveys will be shared with the Expert Group and quality improvement advisor.

Medical Record Review Data (Appendix D)
Data entered into the QIDA system is without patient identifiers and will be entered by a designated member of the practice team through the use of the online data collection tool. One designated team member will have access to enter data into the QIDA system. The data will be transmitted electronically and securely to the AAP without any patient identifiers. For this reason, no parental informed consent for data collection will be sought, and parents/caregivers will not have access to the QIDA Project Workspace or data entry tool. Practice teams will be given one month to enter data into QIDA. Project staff will pull reports from QIDA using the practice names as identifiers.

Practice teams will have access to performance data for quality improvement purposes. The de-identified data elements from the online data collection tool, aggregated by practice, will be presented by measure on a monthly basis to participating practice teams. Data is collated by practice and not by individual pediatrician, so no individual pediatrician data will be identified or known to others involved in the project. Data will be presented by practice, therefore no patient or pediatrician-level identifiers will be shared. (Note: in the case that a participating practice has only one pediatrician, practice-level data will dually serve as pediatrician-level data. This risk will be discussed on a one-on-one basis with the affected pediatrician(s) and the practice team members by the Expert Work Group, quality improvement consultant, and project staff.) Data will be reported by practice name, and practice teams will be able to see the aggregate of other practices' data, as well as an aggregate of the entire 5 practices' data through the password protected QIDA module.

Practice team members designated to enter information into QIDA using the medical record review tool may encounter subjects who have not received recommended health services. If this occurs, project staff and leadership will ask practice teams to follow their usual procedures when noting patients who have not received

needed services.

Monthly Progress Reports (Appendix G)
During the action period, each practice team will submit a monthly progress report which describes tests of change, assesses team progress, describes barriers encountered, strategies used, and other qualitative measures. Each team will submit their monthly progress report through Survey Monkey. The practice name will be collected on this report. Data from the report will be collected and stored through Survey Monkey under the password protected account of the AAP Division of Children with Special Needs. Project staff will download each report via Survey Monkey, which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. The report (identified by practice name only) will be shared with the quality improvement advisor and the Expert Group via email. These reports will also be posted on the Project Workspace/QIDA, so that practice teams can learn from each other's experiences.

Monthly Educational Webinar/Conference Call Evaluations (Appendix H)
During the action period five monthly educational webinars will take place (February-June 2017). Although January is the beginning of the action period, an educational webinar will not be held that month, since the in-person learning session will be held in early January. Participants on the calls/webinars will be asked to complete evaluation surveys to assess the effectiveness of each webinar/call. These surveys are optional, and will be collected using Survey Monkey. Individual practice team members have the option to submit individual surveys. The surveys will be completely anonymous. Data from the survey will be collected directly through Survey Monkey and stored on the Survey Monkey server under the password protected account of the AAP Division of Children with Special Needs. The data will be downloaded and analyzed by project staff via Survey Monkey which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. Aggregate reports of survey results (anonymous, no identifiers), will be shared with the quality improvement advisor and Expert Group.

Post-Project Feedback Call (Appendix I)
Each practice team will participate in a post-project feedback call following the last action period. Parent/caregiver partners will be given the option to participate in the call along with their practice teams, but they will not be required to participate. Parent/caregiver partners who express interest in participating will be emailed a consent form to complete in advance of the call. The questions to be posed during the conference call will be sent to the practice teams prior to the call. The call will be facilitated by the QI advisor. This webinar/conference call will be audiotaped for record keeping purposes, will not be transcribed, and will be stored on AAP staff password protected computer. The feedback given during the call will be de-identified (contact/identifiable information) and aggregated across all the five practices and included in project final report.

Sharing and Reporting Data
AAP staff, the QI Advisor, and Expert Group members will have access to see data from the record review, monthly progress report, and pre- and post-implementation survey.

Each participating team will be able to securely view reports of their practice's aggregate data, as well as aggregate data from other practices.

Parents/caregivers who are part of the practice team will be present for the learning session and may be present on monthly educational conference calls and, as such, will have access to aggregate data presented during these times (eg, run charts, no patient identifiers). Parents/caregivers will not have access to the Project Workspace.

Faculty who participate on monthly educational conference calls and at the learning session will have access to aggregate data presented at these times. Any sharing of additional data is at the discretion of the practice teams. Faculty will not have access to the Project Workspace.

For research and publications that may result from this work, all data will be reported in aggregate, and individual and practice data will not be identifiable. If practice data is presented, each practice will receive an ID number in the report. Potential publications may include a conceptual model of key barriers and potentially useful strategies that emerged from this project. No patients or practice staff will be identified in any report or publication about this study. Practice names will only be used in the acknowledgement section of any potential publication.

Data Storage

Any electronic data will be maintained on secure networks or as files on password-protected desktops for at least 3 years following completion of the quality improvement project and analysis and reporting of the data. Raw data will only be available on AAP computers/networks and will be secure via individual staff member's password-protected access to the computers and data storage areas. Any project data, information, and resources accessed outside the AAP server will be only through the secure, password-protected project workspace in QIDA. It is expected that hard copy materials (eg, paper consent forms submitted via fax) and data will be minimal, however they will be kept in locked file cabinets by AAP project staff, Christina Boothby. Hard copies of data will eventually be shredded after 3 years following the completion of the project.

c. Describe what will happen to participants' data at the end of the study (e.g., identifiers will be permanently removed, identifiable/coded data will be retained and stored confidentially for x years).

Any electronic data will be maintained on secure networks or as files on password-protected desktops for at least 3 years following the completion of the quality improvement project and analysis and reporting of the data.

After the three-year period, electronic data will be destroyed with guidance and assistance from the AAP Department of Information Technology. Paper documents will be shredded.

19. ASSURANCES

Principal Investigator:

I agree to follow all applicable federal regulations, guidance, state and local laws related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Application for Exemption is accurate and complete. I will initiate this research only after having received notification of an exemption determination.

Principal Investigator	Date
AAP Department Director	Date
AAP Senior Vice President	Date
AAP Chief Compliance Officer	Date

Research activities in which all involvement of human subjects will be in one or more of the following categories are EXEMPT from human subjects review (45 CFR 46.101). [NOTE: Under Subpart D – Additional Protections for Children Involved as Subjects in Research, there are modifications to this section. For example, surveys of children are not exempt.]

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects: and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i)The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.