Improving COVID-19 Vaccine Uptake Among Black and Latino Youth

NCT 05293392

June 7, 2021

Nemours

Institutional Review Board

Application for Waiver of Consent and / or HIPPA Authorization

Version April 2016

A waiver of the requirement for Informed Consent, or to document Informed Consent and/or Authorization for Research Use of Protected Health Information can be granted by the IRB for human subjects research that meets certain Federal requirements. The investigator should be aware that while the Parental Permission/Informed Consent templates include the elements of an Authorization that are required by HIPAA, that the two are not the same. The IRB must review and approve these separately. *Informed Consent must always be sought when practical to do so, however in certain circumstances, it may be appropriate to request waiver of the requirement to document that process (see below).*

When applying for these waivers:

- Provide the information requested below
- Although not required, it would be prudent to include an informed consent form with the waiver request. If the waiver is disapproved, the informed consent form can be reviewed at that meeting, thus avoiding delay of approval of the project. If an informed consent/assent form has been prepared, attach it.
- Attach the completed Application for IRB Review of a new protocol.
- Attach the complete research protocol.
- Explain how the attached research protocol fulfills each of the criteria below.

Date: June 6, 2021 **Principal Investigator's Name**: Thao-Ly Phan, MD, MPH; Paul Enlow, PhD

Protocol Title Improving Pediatric COVID-19 Vaccine Awareness, Access, and Accountability in Underrepresented Communities

Section A: REQUEST TO WAIVE THE REQUIREMENT FOR INFORMED CONSENT / PARENTAL PERMISSION FOR RESEARCH

Is this a research or demonstration project, not subject to FDA regulations, to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; ***and*** the research could not practicably be carried out without the waiver or alteration?

☐ Yes ☒ No. **If yes**, this must be verified in the attached protocol.
If no, is this research subject to FDA regulations?
☐ Yes ☒ No.
If yes, stop. Waiver is not permitted.
If no, continue.

Explain how *each* of the four criteria below apply to this research (*if seeking only a waiver of the requirement to DOCUMENT parental permission / informed consent, leave this section blank*).

1. The research involves no more than minimal risk to participants.
   Explain: A request to waive the requirement for informed consent/parental permission fis being requested for Aim 3 of this study, which is a practice-level cluster randomized controlled trial of an intervention to increase awareness of and access to the COVID-19 vaccine (e.g. materials like flyers or posts in the Nemours App, community healthcare worker outreach, vaccine clinics). 4 primary care practices will be randomized to receive the intervention or not and all patients of the 2 practices randomized to receive the intervention may be exposed to the intervention. Data will be collected on all patients at each of the 4 clinics as part of routine clinical care in the EHR about

intention to vaccinate and registration for vaccination. Because the intervention is primarily educational in nature and data collected requires minimal effort (two questions) and will be collected as part of routine clinical care, we believe this represents a minimal risk study for participants.

2. The rights and welfare of participants will not be adversely affected by the waiver.
   Explain: This is a minimal risk study, as noted above. If the participant is a patient of one of the primary care practices randomized to receive the educational intervention they will have exposure to the intervention but will be able choose whether or not to engage with the intervention. Data collected in the EHR about intention to vaccinate and registration for vaccination will be part of routine clinical care at all the practices. Confidentiality of data extracted from the EHR will be protected and data will be de-identified as described in the new study application.
3. It is impractical to carry out the research without the waiver.
   Explain: Approximately 19,000 patients are seen at the 4 practices involved in the cluster randomized controlled trial. Since the study is being implemented at the practice level, all patients in the 2 primary care practices randomized to receive the intervention will potentially have exposure to the intervention (e.g. flyers in clinic or vaccine clinics in the community) and patients in all 4 practices will have data collected in the EHR. It would be impractical to consent all 19,000 patients.
4. If possible, participants will be fully informed after the project is completed.
   Explain how this will be done and if not, explain why: As noted above, approximately 19,000 patients are see at the 4 practices involved in the cluster ranomized controlled trial. It will not be feasible to inform all participants individually of the trial. However, we will inform the practices when the trial is complete and will encourage the practices to share information about the trial and practice-level findings from the trial with their patients to continue to encourage vaccination awareness and access.

If the above criteria do not apply and you are seeking a waiver of Parental Permission under 45 CFR 46.408, explain how each of the criteria below applies to the research:

1. The research is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).
   Explain:

2. An appropriate mechanism is in place to protect the children, e.g., appointing a child advocate or an assent monitor, depending upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
   Explain:

3. The waiver is not subject to FDA regulations and is not inconsistent with federal, state, or local law. ☐ Yes ☐ No Comment:

Section B: REQUEST TO WAIVE THE REQUIREMENT FOR DOCUMENTATION OF INFORMED CONSENT

Select the condition that applies to this research from the two below and explain the specific applicability to your study and the proposed process of parental permission / informed consent. Skip section if not applicable.

1. ☒ The only record linking research participants to the research would be the consent document and the principle risk is potential harm resulting from a breach of confidentiality.

   AND:

   ☐ Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

Explain:

2. ☒ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
Explain: We are requesting waiver of documentation of informed consent for Aim 2 of the study, which involves enrolling 60 participants (30 caregivers, 30 youth) to participate in the cross-sectional mixed methods study. Participants will provide qualtiative feedback about the intervention through a crowdsourcing platform and quantaitive feedback about the intervention acceptability through a brief REDCap survey. The activities are purely observational and represent no more than minimal risk to participants.

AND:

Describe the proposed process of parental permission and/or informed consent. Eligible participants will be identified by a report generated from the EHR. The research coordinator will contact eligible participants (via text, e-mail, patient portal, or phone using the preferred mode of contact designated in the EHR) to assess interest in participation. If not enough participants are able to be recruited via remote methods, the research coordinator will recruit eligible participants in person at the primary care clinic sites. If someone is interested in participating, the coordinator will send a secure link to an e-consent via REDCap to the potential participant (if recruited remotely) or will pull up the REDCap e-consent on a password-protected research-only tablet computer (if recruited in person). The research coordinator will explain the purpose of the study, the voluntary nature of the study, procedures, and anticipated risks to the participant over the phone (if recruited remotely) or in person (if recruited in person). Participants will be allowed as much time as needed to read the e-consent. Participants will also be able to ask questions of the research coordinator. After ample time to read the e-consent and ask questions, the participant and research coordinator will sign the e-consent.

If caregivers are participating alone, they will sign the electronic version of the ICF. If caregivers are participating with their child, they will sign the electronic version of the PPF/ICF and the child will sign the electronic version of the assent. If the child is participating alone, the caregiver will sign the electronic version of the PPF and the child will sign the electronic version of the assent.

The e-consent will include direct images of the full consent documents uploaded to this package in order to detail all aspects of the study, including description of the voluntary nature of the study, study procedures, risks and benefits of participation, and provision of contact information if the participant has any questions. Interested participants will be able to electronically sign the survey per DHHS requirements. We believe that an e-consent process is important in this study, which employs remote/electronic methodology in its implemention (electronic surveys and online crowdsourcing platforms) during the time of the COVID-19 pandemic. This same process has successfully been used by this research team in previous studies, with no participants objecting to the electronic informed consent process.

Attach proposed script or written information that will be provided to the participant.

Section C: REQUEST FOR WAIVER OR ALTERATION OF THE REQUIREMENT FOR OBTAINING AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Explain how *each* of the criteria below apply to this research.

1. The use of PHI for this purpose involves no more than minimal risk of harm to participants.
    a. Explain: A request to waive the requirement for obtaining authorization for the use and dislcosure of PHI is being requested for Aim 3 of this study, which is a practice-level cluster randomized controlled trial of an intervention to increase awareness of and access to the COVID-19 vaccine (e.g. materials like flyers or posts in the Nemours App, community healthcare worker outreach, vaccine clinics). 4 primary care practices will be randomized to receive the intervention or not and all patients of the 2 practices randomized to receive the intervention may be exposed to the intervention. Data will be

collected on all patients at each of the 4 clinics as part of routine clinical care in the EHR about intention to vaccinate and registration for vaccination. Because the intervention is primarily educational in nature and data collected requires minimal effort (two questions) and will be collected as part of routine clinical care, we believe this represents a minimal risk study for participants.

2. Appropriate safeguards are in place regarding the use and/or disclosure of Protected Health information, based on, at least, the presence of the following elements:

    a. An adequate plan to protect protected health information (PHI) from improper use and disclosure;
    Explain: PHI will only be collected for the purposes stated in the protocol. Only research team members with HIPAA training will review the medical records to collect demographic data, health history data, and data about vaccination.

    b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;
    Explain: All data extracted from the EHR will be de-identified and all participants will be given a unique study ID number. Any identifiers (for example ZIP code or date of birth) extracted from the EHR to generate variables like rurality (for ZIP code) or age (for date of birth) will be destroyed immediately once the variables are created.

    c. The investigator, by their submission of this application to the IRB gives assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule (HIPAA).
    Explanation: The investigator's signature on this submission gives this assurance. Yes

    d. The research could not practically be conducted without the waiver or alteration
    Explain: As noted in section A, approximately 19,000 patients are seen at the 4 practices involved in the cluster randomized controlled trial. Since the study is being implemented at the practice level, all patients in the 2 primary care practices randomized to receive the intervention will potentially have exposure to the intervention (e.g. flyers in clinic or vaccine clinics in the community) and patients in all 4 practices will have data collected in the EHR. It would be impractical to consent all 19,000 patients.

    e. The research could not be practically conducted without access to and use of PHI.
    Explain: Data about intention to vaccinate and registration for COVID-19 vaccination, as well as demographic and health history information, are collected in the EHR as part of routine clinical care. These represent the primary outcomes and covariates of interest. To assess some of these variables, it is necessary to access child PHI from the EHR. However, as noted in part Cb, we will destroy all identifiers as soon as the data is processed.

Note: A hand written signature is not required, the IRBNet electronic signature is valid and is compliant with FDA regulations. Electronically signing and submitting an application to the IRB through IRBNet indicates that

the Investigator, and/or valid delegate, has read the application, and attests to the completeness and accuracy of the entire submission.

Nemours Office of Human Subjects Protection
Nemours/Alfred I. duPont Hospital for Children
1600 Rockland Road
Wilmington, DE 19803
Fax: 302-651-4683
Office: 302-298-7613
MEMORANDUM

DATE:	June 7, 2021
TO:	Thao-Ly Phan, MD, MPH
FROM:	Nemours IRB 2
STUDY TITLE:	1772085-1 Improving Pediatric COVID-19 Vaccine Awareness, Access, and Accountability in Underrepresented Communities
IRB #:	1772085
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
REVIEW DATE:	June 7, 2021
NEXT REPORT DUE:	June 7, 2022

Thank you for your submission of New Project materials for this research study. Your submission received expedited review under expedited review categories 6 and 7 based on the applicable federal regulation under the revised Common Rule and meets all DHHS criteria for approval. The above-referenced research study is approved.

The IRB has determined that:

- This is Research not involving greater than minimal risk per 45CFR46.404 and 21CFR50.51.
- Informed Consent or Parental Permission is required prior to initiation of any research procedures using only the most current IRB approved form(s) posted as a Board Document in IRBNet. All approved study documents can be accessed through "Designer" by clicking "Review Details" in IRBNet. Please note that consent documents will not have an expiration date, however if the documents are amended they must be submitted to the IRB for review and approval. It is the responsibility of the research team to ensure the most current IRB approved forms are used.
- The permission of one parent is sufficient. A person who is not a parent may not give permission without prior IRB review and approval.
- Assent of minors is required prior to initiation of any research procedures, using only the most current assent form(s) posted as a Board Document in IRBNet.
- The research does not meet the criteria for including a copy of the PPF/ICF and research data in the Nemours' medical record, but may be included at the investigator's discretion.
- The IRB requires that a copy of the participant brochure: "Becoming A Research Volunteer" will be given to every individual enrolled in a research study. The PDF file for this document has been attached to this study as a Board Document.
- To continue, the research requires administrative IRB review on an annual basis. On or before the date one year from this review (June 7, 2022), it is required to submit an Annual Status Report (see 'Next Report Due'). If the study is complete, a Closure Report is required.
- **You, as the Principal Investigator, are responsible for the timely submission of the Annual Status Report form. Please post this date on your research calendar. Failure to do so may constitute noncompliance and result in the administrative closure of the study. The IRB**

recommends that the annual status reports are submitted 2 weeks before the due date to ensure sufficient time for IRB review.

Reviewed/approved documents in this submission:

- Application Form - Application - Waiver of Consent and or HIPAA Authorization 1772085.docx (UPDATED: 06/7/2021)
- Application Form - Application - Initial Review of Human Subjects Research 1772085.docx (UPDATED: 06/6/2021)
- Child Assent - Adolescent Assent Crowdsourcing 1772085.docx (UPDATED: 06/6/2021)
- Child Assent - Child Assent Crowdsourcing 1772085.docx (UPDATED: 06/6/2021)
- Consent Form - ICF_crowdsourcing 1772085.docx (UPDATED: 06/6/2021)
- Cover Sheet - Cover Letter COVID Vaccine Study.docx (UPDATED: 06/6/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure Attestation 1772085 Kazak.docx (UPDATED: 06/6/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure AttestationImproving Pediatric COVID-19 Vaccine Awareness Access and Accountability in Underrepresented Communities_enlow.docx (UPDATED: 06/4/2021)
- Investigator Agreement - RTM Agreement_CT_6.4.2021.docx (UPDATED: 06/4/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure AttestationImproving Pediatric COVID-19 Vaccine Awareness Access and Accountability in Underrepresented Communities Phan.docx (UPDATED: 06/4/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure AttestationImproving Pediatric COVID-19 Vaccine Awareness, Access, and Accountability in Underrepresented Communities.docx (UPDATED: 06/4/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure AttestationImproving Pediatric COVID-19 Vaccine Awareness Access and Accountability in Underrepresented Communities JMiller.docx (UPDATED: 06/4/2021)
- Investigator Agreement - Research Team Member Agreement Disclosure AttestationImproving Pediatric COVID-19 Vaccine Awareness Access and Accountability in Underrepresented Communities_LPelaez.docx (UPDATED: 06/4/2021)
- Parental Permission Form - PPF_crowdsourcing 1772085.docx (UPDATED: 06/6/2021)
- Parental Permission Form - PPF_ICF_crowdsourcing 1772085.docx (UPDATED: 06/6/2021)
- Protocol - COVID Vaccine Proposal - Research Strategy.pdf (UPDATED: 06/4/2021)
- Questionnaire/Survey - Acceptability of Intervention Measure.pdf (UPDATED: 06/6/2021)

Investigator Agreement: As the PI, you have agreed to assure that this research is conducted in compliance with Nemours policy and all applicable federal regulations and ICH standards, which also includes the following:

- All research must be conducted in accordance with this approved submission. Any revision to approved materials must be approved by the IRB prior to initiation.
- Remember that informed consent/parental permission is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.
- All serious and unexpected adverse events and unanticipated problems affecting participants must be reported promptly to the IRB according to NOHSP policy.
- All non-compliance issues or complaints regarding this study must be reported to the Director, NOHSP.

- All research records must be retained for a minimum of three years.
- A Closure Report must be submitted to the IRB when this protocol is completed.

If you have any questions, please contact Tammy Aguilar at Nemours Children's Specialty Care, 807 Children's Way, Jacksonville, FL 32207 at (904) 697-3415 or Tammy.Aguilar@nemours.org. Please include your study title and reference number in all correspondence with this office.