COVID-19 Surveillance and Exposure in School Communities

Phase: N/A – prospective, observational, cohort study

Funding Sponsor:

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

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STATEMENT OF COMPLIANCE

This study will be conducted in compliance with the protocol, International Council for Harmonisation (ICH) E6 (R2) guideline for Good Clinical Practice (GCP), and the applicable regulatory requirements from the United States Code of Federal Regulations (CFR), including 45 CFR 46 (Human Subjects Protection); 21 CFR 50 (Informed Consent), 21 CFR Part 54 (Financial Disclosure), and 21 CFR 56 (Institutional Review Board [IRB]); as well as international regulatory requirements, if applicable.

All individuals who are responsible for the conduct, management, or oversight of this study have completed Human Subjects Protection and ICH GCP Training.

STUDY PRINCIPAL INVESTIGATOR

The signature below documents the review and approval of this protocol and the attachments (e.g., Manual of Procedures (MOP), package inserts), and provides the necessary assurances that this clinical study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements and to the principles outlined in applicable United States (U.S.) and international regulations and ICH guidelines.

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Principal Investigator Name (Print or Type)

_____ _____

Study PI Signature Date

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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CoC	Certificate of Confidentiality
COVID-19	Coronavirus Disease 2019
DCC	Data Coordinating Center
DCRI	Duke Clinical Research Institute
DUHS	Duke University Health Systems
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FERPA	Family Education Rights and Privacy Act
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council for Harmonisation
IRB	Institutional Review Board
LAR	Legally Authorized Representative
MOP	Manual of Procedures
NC	North Carolina
NCDHHS	North Carolina Department of Health and Human Services
NIH	National Institutes of Health
PHI	Protected Health Information
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus -2
U.S.	United States

PROTOCOL HISTORY OF CHANGES

Version	Date	Summary of Changes
v1.0	24 MAR 2021	N/A Original protocol

PROTOCOL SYNOPSIS

Protocol Title:	COVID-19 Surveillance and Exposure in School Communities
NCT #	Pending
Phase:	N/A, a prospective, observational study
Study Product(s)or Intervention:	None
Objectives:	Co-Primary: 1. Evaluate secondary transmission and/or prevalence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Kindergarten through 12th grade schools. 2. Describe return to school outcomes in Kindergarten through 12th grade schools.
Study Design:	Participating school communities are providing SARS-CoV-2 tests to students and staff at their schools per school, local, and national guidelines. This study will combine data received from the schools with data collected directly from participants to guide analysis of the co-primary objectives. Participants will be grouped into two different cohorts, depending on each school's SARS-CoV-2 test administration practices. Surveillance Cohort: Schools participating in this cohort will be performing surveillance testing weekly on approximately 10-20% of students and 100% of staff. Exposure Cohort: Schools participating in this cohort will be performing exposure testing on students and staff who have been identified as having close contact with school members diagnosed with SARS-CoV-2 infection.
Study Population:	School communities
Inclusion / Exclusion Criteria	Data from all participating school communities will be included in this study, no inclusion/exclusion criteria will be assessed.
Number of Participants:	Up to 1,000,000
Number of Sites:	Single coordinating site, direct-to-participant
Duration of Study:	2 years

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Background Information

1.1.1 COVID-19 and Kindergaten-12th grade school closures

Widespread Kindergarten through 12th grade school closures are the most important COVID-19-related threats to child health. Since February 2020, children have accounted for one-tenth of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) cases; up to 2.2% and 0.04% of pediatric cases have resulted in hospitalization or death, respectively, and as many as 50% of cases are asymptomatic.[1,2] However, children have been far from spared of the downstream effects of this pandemic. In March 2020, most Kindergarten through 12th grade schools preemptively closed to in-person education in an attempt to limit viral spread. Most publically-funded Kindergarten through 12th grade schools across the nation, responsible for educating >55 million of the nation's children, remained closed in the early 2020, citing concerns about viral transmission and risks to students and staff. Because public schools play such a vital role in the educational, social, and emotional development of young children as well as the delivery of vital services such as food and healthcare, it is not surprising that early data show food insecurity has doubled; 65% of children 9-13 years are less physically active; 1/6th of children have worsened behavioral health; suicidality may be increasing, and physical abuse is more severe.[3-7]

For many underserved children, school building closures have been especially profound. Black and Latino families have disproportionately experienced increases in poverty at a time when access to free and reduced lunches at schools has been limited.[8] In addition, remote learning has revealed deep inequities in digital access, precluding many children from participating in the only available form of education. As a result, there has been a decline in reading test scores among Black and Latino students, compared to improvements among white and/or wealthy students.[9] In some districts, the proportion of Black and Latino students with chronic absenteeism has doubled, and up to 70% have failing grades. The potential consequences of these findings are deep and far-reaching; children with food insecurity are twice as likely to be in fair or poor health, more likely to be hospitalized, and more likely as adults to have poor job readiness. Chronic absenteeism in early primary school decreases the likelihood of reading at grade level by the third grade and increases the risk of drop out by 4 times compared to proficient readers.[10] Adults with less than a high school education are 2.4 times as likely as high school graduates to rate their health as poor and live 10 years fewer than those with graduate education. Considering these profound impacts, access to in-person education is imperative.

In North Carolina (NC), schools have been able to show low secondary transmission of SARS-CoV-2 within school buildings.[11] Given these findings, schools are beginning to open their doors; these results have influenced national guidance from Centers for Disease Control (CDC) to focus on prioritization of schools as well as NC state legislation around school reopening. However, even when school doors open, many schools are failing to return their Black and Latino students due to mistrust of schools' systems; and students who choose to return may continue to have limited and disproportionate access to schools due to varied in-person education practices.

Surveillance and exposure SARS-CoV-2 testing within school communities have been proposed as potential methods to help get children back to school and safely keep them there; however, little available evidence exists to support substantial investment in testing, including test kits, personnel for swabbing, and tracking systems, among others, in the Kindergarten through 12th grade setting.

1.2 Scientific Rationale

This study will evaluate the impact of school-provided SARS-CoV-2 testing (either surveillance or testing following exposure) to students and staff on transmission rates and return to school. This information will be critical for determining future policies surrounding SARS-CoV-2 testing in the Kindergarten through 12th grade school environment. Staff and students who participate in this study will provide consent for collection of data on demographic factors using a unique direct-to-participant, direct-to-family, and direct-to-community approach. This approach is necessary because schools are a critical link to underserved children and their families and are invested in the return of children to a safe school environment. Additionally, as hospital resources continue to be strained due to the pandemic, a direct-to-participant study design is beneficial to eliminate site burden while encouraging community involvement. The existing partnerships with schools established through the ABC Science Collaborative, a partnership between Duke and UNC faculty and Kindergarten through 12th grade schools in NC, which was formed in the summer of 2020 will be leveraged. Through partnering with schools, longitudinal data on rates of return to school and secondary transmission within schools will be collected.

This study will be conducted across multiple age groups of school-age children and staff, multiple different educational settings, and multiple different educational cultures to increase the potential generalizability of study results.

1.3 Potential Benefits

There is no anticipated direct benefit to participants in this study; however, participants may benefit from SARS-CoV-2 testing and early identification of COVID-19. Additionally, they may benefit from the broader impact that data collection has on advancing the scientific understanding of COVID-19 and associated outcomes, which may benefit others in the future.

1.4 Known Potential Risks

This is a minimal risk study, with the only identifiable risk being the potential loss of confidentiality.

Potential Risk of Loss of Confidentiality:

There is a potential risk of loss of confidentiality. Every effort will be made to protect the participant’s protected health information (PHI) as well as other identifying information, but this cannot be guaranteed.

2 OBJECTIVES AND OUTCOME MEASURES

	Objective	Outcome Measures
Co-primary #1:	Evaluate secondary transmission and/or prevalence of SARS-CoV-2 in Kindergarten through 12th grade schools.	• Proportion of students/staff with positive SARS-CoV-2 test identified by surveillance testing (Surveillance Cohort). • Proportion of students/staff with positive SARS-CoV-2 test following within-school exposure (Exposure Cohort).
Co-primary #2:	Describe return to school outcomes in Kindergarten through 12th grade schools.	• Proportion of students who return to in-person education in Fall 2021, Spring 2022, and Fall 2022 from participating schools conducting surveillance testing compared to districts without testing (Surveillance Cohort). • Mean time to return-to-school after SARS-CoV-2 exposure in the month after initiation of the school-provided testing program compared to the month prior to initiation of the school-provided testing program (Exposure Cohort).

3 STUDY DESIGN

3.1 Overall Design

Study design: This is a prospective, observational study with co-primary objectives of evaluating secondary transmission of SARS-CoV-2 in school communities and describing return to school outcomes. All of the schools providing data for this study will use rapid SARS-CoV-2 testing kits that are Food and Drug Administration (FDA)-authorized under an emergency use authorization (EUA) for non-prescription use for both symptomatic and asymptomatic evaluation in children and adults. Testing will occur per Centers for Disease Control (CDC) and North Carolina Department of Health and Human Services (NCDHHS) guidelines and school practices.

Schools participating in the Surveillance Cohort will administer weekly testing to approximately 10-20% of the students and 100% of the staff. Schools will identify which students will be tested, likely in a rotating manner. Schools participating in the Exposure Cohort will provide testing kits to all students and staff who are in close contact, as defined by NCDHHS guidelines, of school community members diagnosed with SARS-CoV-2 infection, upon identification as a contact of index case. In order to determine whether quarantine can be discontinued, schools will then repeat testing at 5-7 days after exposure or in accordance with CDC and NCDHHS guidance. All testing information will be collected by the school and provided to the Duke Clinical Research

Institute (DCRI) as aggregate, de-identified data for data analysis purposes. Data regarding school attendance will also be provided by the schools in aggregate. Individual participant data will be collected directly from participants who consent to participate in this study.

3.2 Study Definition of Enrollment

Study enrollment is defined as the participant has provided informed consent (or assent) and completed study evaluations (see Section 5.1). For this study, participants will only be enrolled to complete one set of study evaluations and will then be considered off-study. Participants will be asked to re-enroll for each set of study evaluations obtained, which will occur approximately once a semester.

3.3 Study Definition of Completion

The study will be complete after data has been collected for approximately 2 years.

4 STUDY POPULATION

4.1 Selection of the Study Population

There will be no inclusion/exclusion criteria assessed as part of this study. All students and staff who are members of participating school communities will be given the opportunity to consent to this study. Both children and adult school community members will be included in this study.

4.2 Participant Discontinuation/Withdrawal

A participant or his/her parent (or legal guardian) may voluntarily withdraw consent to participate in the study at any time. Participants are not obligated to state the reason for withdrawal. No additional study data should be collected after consent has been withdrawn, however, all data collected prior to consent withdrawal will be maintained in the database. Because this study is re-consenting at each point of data collection, withdrawal from further data collection is not applicable. Participants will be given the opportunity to re-consent at each round of data collection, they may choose to NOT re-consent at the next round of data collection and no further data will be collected (see Section 3.2).

5 STUDY PROCEDURES

5.1 Summary of Evaluations

Participants or their parent/legal guardian will provide informed consent (or assent). Applicable informed consent from the participant or parent/legal guardian (and assent if applicable) for all participants will be documented. Participants or their parent/legal guardian will be asked to complete a questionnaire via an online survey at the time of consent, no additional procedures or assessments will be collected from the participants as part of this study. The questionnaire will include the following:

- Demographic variables including race, age, sex, and English proficiency
- School-related questions
- Food insecurity, internet access

- COVID-related data elements

5.2 Evaluation Details

5.2.1 Food Insecurity

The 2-item food insecurity screen developed by Hager et al is a validated tool that identifies household risks of food insecurity.[12]

5.2.2 COVID-related Data Elements

Participants will be asked to provide the following data by self-report or parent/guardian-report:

- Virtual school satisfaction
- 2020-2021 educational experience satisfaction
- 2021-2022 academic preparedness satisfaction
- Feelings surrounding vaccination

6 ASSESSMENT OF SAFETY

No safety will be recorded as part of this study.

7 Study Termination

This study may be terminated at any time by the funding agency or the study principal investigators. Reasons for termination may include but are not limited to, if in their judgment, there are no further benefits to be achieved from the study. If the study is terminated, notifications will be made to the IRB of record and study participants, in accordance with all applicable regulations governing the study and site/investigator.

8 STATISTICAL CONSIDERATIONS

8.1 Study Endpoints

8.1.1 Primary Endpoints

Co-Primary Objective #1: Evaluate secondary transmission and/or prevalence of SARS-CoV-2 in Kindergarten through 12th grade schools.

Co-Primary Endpoint #1:

- Surveillance Cohort: Proportion of students/staff with positive SARS-CoV-2 test identified by surveillance testing.
- Exposure Cohort: Proportion of students/staff with positive SARS-CoV-2 test following within-school exposure.

Co-Primary Objective: Describe return to school outcomes in Kindergarten through 12th grade schools.

Co-Primary Endpoint #2:

- Surveillance Cohort: Proportion of students who return to in-person education in Fall 2021, Spring 2022, and Fall 2022 from participating schools conducting surveillance testing compared to districts without testing.
- Exposure Cohort: Mean time to return-to-school after SARS-CoV-2 exposure in the month after initiation of the school-provided testing program compared to the month prior to initiation of the school-provided testing program.

8.2 Analysis Population

All participants enrolled to the study, regardless of their percent completion of the study evaluations, will be included in the analysis population.

Students and staff who do not consent to this study will not report individual data, however, de-identified aggregate data will be used for relevant analysis.

8.3 Analysis Plan

Summary statistics of the schools and the students/staff in the two cohorts will be presented using data collected during study enrollment. Means/medians with standard deviations (and interquartile ranges) will be tabulated.

8.3.1 Primary Analysis

For the first co-primary endpoints for both the surveillance cohort (proportion of students/staff with positive SARS-CoV-2 test identified by surveillance testing), and exposure cohort (proportion of students/staff with positive SARS-CoV-2 test following within-school exposure), the proportions overall will be reported and the trend by week will be presented in graphical form in each cohort. To account for the within-school correlation of outcomes, 95% confidence intervals will be estimated for the proportion using a generalized estimating equations approach with an exchangeable correlation structure.[13]

For the co-primary endpoint #2 for the surveillance cohort (proportion of students who return to in-person education in Fall 2021, Spring 2022, and Fall 2022 from participating schools conducting surveillance testing compared to districts without testing), to account for within-school correlation, a risk between the two groups of schools using a generalized estimating equation approach with an identity link and exchangeable correlation structure will be estimated. The risk difference will be estimated for each semester during the study period, as well as overall.

For the co-primary endpoint #2 for the exposure cohort (mean time to return-to-school after SARS-CoV-2 exposure in the month after initiation of the school-provided testing program compared to the month prior to initiation of the school-provided testing program), the average time to return to school will be estimated using a generalized estimating equation approach to account for within-school correlation of outcomes. Students will be censored by end of data or study withdrawal. Censoring will be

addressed by incorporating inverse-probability censoring weights into the regression model, with censoring risk estimated with a Kaplan-Meier estimator.[14]

8.3.2 Subgroup Analysis

For the co-primary endpoint #2 for the surveillance cohort (proportion of students who return to in-person education in Fall 2021, Spring 2022, and Fall 2022 from participating schools conducting surveillance testing compared to districts without testing), a subgroup analysis will be conducted among Black and Latino students. This will involve repeating the analysis for the endpoint restricted to Black and Latino students, separately.

8.4 Sample Size Considerations

No formal sample size calculation was completed for this study. This study will enroll up to 1,000,000 participants.

9 Future Use of Study Records

The research data collected in this study, and provided to the sponsor, will be kept indefinitely.

Information about this study, including study results, will be published without further permission from the participant as detailed in the informed consent (and assent) form. Participants will not be identified in any publications or presentations made about the study.

After the study is completed, information about the study, including study data, will be submitted to RADx-UP for storage in the RADx-UP database. Data submitted to the RADx-UP database will be de-identified. Consenting participants will be given the option via an opt in/out question on the ICF to share identifiable information (e.g. name, address, contact information, and date of birth) with RADx-UP for storage in a second RADx-UP database containing identifiable data. The DCRI is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. Identifiable data will be kept at the DCRI and the DCRI will not share these data with the NIH. Non-identifiable data will be transferred and stored in a secure database for COVID-19 research at the NIH.

With NIH approval, the data submitted may be used by other researchers for future research. The study data submitted will be de-identified, meaning it will not include any information that can identify the participant. The study team may also share the de-identified study data with other researchers. When the participant's de-identified study data are provided to other researchers for the purposes of future research, it will be done without obtaining additional permission.

10 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Data collected for this study will include data provided from schools and data entered by the participant and/or their parent/guardian directly into the Data Coordinating Center (DCC)-held database or into REDCap. All data received from schools will be de-identified, aggregate data and be provided in accordance with the Family Education Rights and Privacy Act (FERPA) regulations.

11 QUALITY CONTROL AND QUALITY ASSURANCE

The principal investigator will ensure that all study personnel are appropriately trained and applicable documentation is maintained. The DCC will implement quality control procedures beginning with the data entry system and generate data quality control checks that will be run on the database.

12 ETHICS/PROTECTION OF HUMAN PARTICIPANTS

12.1 Informed Consent Process

Informed consent and assent procedures are initiated prior to the individual agreeing to participate in the study and continuing throughout the individual's study participation. For this study, participants will be consented prior to each round of surveying, which may occur up to once a semester during the study period. Risks and possible benefits of participation in this study will be provided to the participants and their parents/guardians, as appropriate, prior to consenting via Redcap.

This study enrolls children. Per 21 CFR 50.3 (o) and 45CFR 46.402 (a) "children" is defined as persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations (or the research), under the applicable law of the jurisdiction in which the clinical investigation (or the research) will be conducted and so the legal age for consent may be different in different jurisdictions.

Consent forms with detailed descriptions of the study procedures, risks, and potential benefits will be approved by the IRB. Consent forms (and assent forms, if appropriate) will be provided to the participant or the participant's parent/guardian electronically to read and note any questions. The consent must be completed prior to performing any study-specific procedures.

If information about new potential risks related to participating in this study emerges or procedures are modified, the consent/assent forms will be updated to reflect those potential risks, and the participants currently active in the study will be re-consented with the updated consents. If the consent forms are changed for any other reason and the local IRB requires re-consenting of active participants, the participant will be asked to review and complete the new consent forms electronically.

Participants who become an adult (of legal age) while participating in the study and who are capable of providing consent will also be re-consented using the adult consent form prior to the next round of surveys in the study. Participants who become an adult while participating in the study who are incapable of providing consent may continue to participate if they have a legally authorized representative (LAR) who consents on their behalf. Given that participants will be consented prior to each round of surveys, the study team has not included an age of majority consent form. Rather, these participants will complete an adult consent form.

A copy of the executed informed consent/assent documents will be provided to the participant and/or the participant's parent/legal guardian (as appropriate) for their records.

The assent process for the study will occur as appropriate, as described, per protocol.

12.1.1 Pediatric Assent

The participant should be informed about the study to the extent compatible with the participant's understanding. As required by local regulatory authorities, the participant should assent to participate in the study. A separate IRB--approved assent form, describing (in simplified terms) the details of the study, study procedures, and risks, may be used. Assent forms do not substitute for the consent form signed by the participant's LAR.

Under 21 CFR 50.52, and 50.55, and 45 CFR Part 46.405, the IRB of record is responsible for determining that adequate provisions are made for soliciting the assent of children.

12.2 Assent Process

This study includes minor participants who may be enrolled in the study only with the consent of their parent/legal guardian. The minor participant should be informed about the study to the extent compatible with his/her neurodevelopmental abilities. Participants who are nonverbal or minimally verbal, have significant intellectual disability, are younger than seven years old, or have marked thought disorganization or positive psychotic symptoms are very unlikely to be considered developmentally able to provide assent. If the participant is developmentally able to understand the concepts of voluntary participation in research, the participant will be given a simplified, developmentally appropriate assent form to review and will be asked to sign and personally date the assent form.

Assent does not substitute for the permission form signed by the participant's parent/legal guardian.

12.3 Documentation of Permission, Assent, and Consent

Permission, assent, and consent must be documented using forms and processes determined by the Duke University Health System (DUHS) IRB.

Prior to enrollment of participants into this study, the protocol, the applicable informed consent/assent template, and any materials or advertisements presented to participants will be reviewed and approved by the DUHS IRB.

Should amendments to the protocol and consent/assent documents be required, the amendments will be written by the sponsor and approved by the DUHS IRB.

For non-English speakers, a fully translated consent may be used to obtain informed consent. The fully translated consent must be approved by the DUHS IRB and executed according to local requirements.

The informed consent process will be conducted and the form fully executed, before the participant undergoes any study-specific procedures.

12.4 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The principal investigator will ensure that the use and disclosure of PHI obtained during a research study complies with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The rule provides U.S. federal protection for the privacy of PHI by implementing standards to protect and guard against the misuse of individually identifiable health information of participants participating in clinical trials. Authorization is required from each research participant (i.e., specific permission granted by an individual to a covered entity for the use or disclosure of an individual's protected health information). A valid authorization must meet the implementation specifications under the HIPAA Privacy Rule. Authorization may be combined in the informed consent document (if approved by the IRB).

The study participant's contact information will be securely stored for use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the DCC. All study data systems used by the DCC research staff will be secured and password protected.

To further protect the privacy of study participants, this study is covered by a Certificate of Confidentiality (CoC) from the NIH. The CoC limits the ability of courts and other agencies from forcing the study team to share participant information or body fluids during a legal or legislative action without the participant's permission. The CoC does not restrict the parents from sharing information voluntarily.

13 DATA HANDLING AND RECORD KEEPING

The investigator is obligated to conduct this study in accordance with U.S. Federal Regulation 21 CFR 312.60-68 as specified by applicable state and federal laws, and the International Council for Harmonisation: Good Clinical Practice: Consolidation Guideline.

13.1 Data Handling

Data will be captured using multiple systems and approaches. All data collected in the context of this study will be stored and evaluated per applicable regulatory requirements and guidance for electronic records.

Data will be stored and evaluated in a manner that protects participant confidentiality in accordance with the legal stipulations applying to confidentiality of data.

13.2 Data Management Responsibilities

The DCC for this study will be responsible for data management, quality review, analysis, and reporting of the study data.

13.3 Data Capture Methods

Participant/parent/guardian-reported data will be entered directly into the Duke REDCap system.

13.4 Types of Data

Data for this study will include participant reported information including demographics, food insecurity, internet access, and COVID-related data elements (see Sections 5.2.2). Additional de-identified data will be provided by schools, including COVID-19 testing results, demographics, and school attendance; these data will be provided in aggregate or at the individual level.

13.5 Study Records Retention

All records will be retained for at least 5 years after study completion, per Duke Policy.

13.6 Protocol Deviations

A protocol deviation is any noncompliance/unplanned excursion from approved investigational plan (e.g., protocol, MOP), or ICH GCP guidelines. The noncompliance may be on the part of the participant, investigator, or staff. No protocol deviations will be reported for this study, but indirectly tracked via missing data in the database.

14 PUBLICATION POLICY

The study will adhere to authorship standards described in the International Committee of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Authorship credit should be based on:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Additional authorship requirements imposed by individual journals will also be met. Authorship credit will be assigned in an equitable fashion and will be commensurate with participation and effort on the individual manuscript. Committee members will appear as authors on manuscripts based solely on actual contributions to the writing of the manuscript.

All investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The NIH Public Access Policy ensures the public

has access to the published results of NIH-funded research. It requires investigators to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. Further, the policy stipulates that these papers must be accessible to the public on PubMed Central no later than 12 months after publication.

Refer to:

http://publicaccess.nih.gov/

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

15 LITERATURE REFERENCES

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