Chicago Public Schools

View xForm - Research Review Board (RRB) Submission

New RRB Submission

Data Entry
- Submitted 10/02/2023 2:36 PM ET by Nikolajuk, Katie MSW, MBE

Amendment Summary

RRB Number	2022-1769
Study Title	TALLY: Total ALL-important pregnant and parenting Youth count
Event Type	Modification/Continuing Review defined 10/02/2023
Schools Participating	*No answer provided.*

Description of Research Activities to Date

The project collected survey data from 95 CPS staff survey respondents. Data was then analyzed and used to create a "TALLY Community Report" (attached). The study team (Lurie and CPS collaborators) additionally submitted an abstract to the Society of Epidemiologic Research (SER) Conference. The abstract was accepted, and our team presented a poster at the SER conference in June 2023.

Preliminary Results to Date

A total of 95 participants completed the survey representing 92 unique schools (57% of the district). Most survey participants were school Social Workers (39%) followed by School Counselors (32%). Most participants (94%) reported 0-5 pregnant students enrolled during the 2021-2022 school year. 4% of participants answered that 6-10 pregnant students were enrolled, 2% answered 11-20 pregnant students enrolled, and no one responded that their school had more than 20 pregnant students enrolled. When asked how these numbers compared to previous years, the majority (67%) responded that this was equal to previous years, 21% responded fewer than previous years, and 12% responded more than previous years. When asked about the number of parenting students enrolled during the 2021-2022 school year, the majority (83%) responded 0-5, 10% responded 6-10, 6% responded 11-20, and 1% responded more than 20.

Compared to the number of parenting students in previous years, the majority (68%) responded equal to previous years, 17% responded fewer than previous years, and 15% responded more than previous years. 39% reported that their school does not have a process for counting PPY students, 23% of participants answered that their school does have a system for tracking PPY students, and 38% were unsure about whether or not their school had a data collection process for counting enrolled PPY students. When asked about data collection methods for tracking PPY enrollment, the top responses were: 57% self-disclosure from students, 28% medical documentation, and 27% through applications for homebound instruction. When asked about challenges collecting data on PPY enrollment, the overwhelming majority (67%) responded that student records do not contain any information about PPY status. Additional challenges reported included confidentiality concerns with school records (26%), confidentiality concerns with medical records (20%), limited staff capacity (17%) and other such students requesting assistance with childcare and a student self-disclosure form completing during orientation (22%). When asked about how staff would ideally collect data on PPY enrollment responses included student disclosure (81%), medical documentation (59%), through applications for homebound instruction (34%), student accommodations (24%), student academic records (20%), support with lactation spaces (16%) and other (6%).

Type of Request

Continuing Review	*Please select continuing review if no changes have been made to your study protocol. If you plan on proposing a modification AND a continuing review, please select modification, as an approved modification will extend your approval period.*

Optional Attachments - please attach any reports/publications that have been created thus far here.

TALLY Community Report.docx Misc/Other

Pertinent CPS Documentation

Submitter

Nikolajuk, Katie MSW, MBE

Email: knikolajuk@luriechildrens.org **Mobile:** (616) 485-5749

Overview of Pertinent CPS Documentation

The RRB is composed of members representing various Central Office academic departments as well as the Law Department. The RRB meets quarterly to evaluate new proposals to conduct research. The RRB calendar and deadlines for submissions can be found on the CPS Research Website here. Decisions resulting from the research review process will be communicated to the applicant of the request as well as appropriate CPS staff in accordance with the estimated timelines outlined in the respective RRB calendar.
External researchers may not begin any research activities or obtain data for research purposes without first following the procedures outlined in this policy and securing the necessary approvals.

We expect all researchers to be familiar with the guidelines and policies guiding research within the district. Please verify that you have read and acknowledged the following:

External Research Study and Data Policy
✔ I have read and understood the External Research Study and Data Policy

CPS RRB Guidelines
✔ I have read and understood the CPS RRB Guidelines

CPS Equity Framework
✔ I have read and understood the CPS Equity Framework

CPS Vision
✔ I have read and understood the CPS Vision

CPS Volunteer Policy
✔ I have read and understood the CPS Volunteer Policy, including background check requirements

Study Personnel Details

Study Title

TALLY: Total ALL-important pregnant and parenting Youth count

Does your organization participate in a Research Practice Partnership (RPP) with Chicago Public Schools?

No

Primary Study Organization/University

Lurie Children's Hospital of Chicago

Current Study Contacts

Name	Role
Britten, Justine	In-School Research Staff
Hojjati, Ronus	Project Team Member
Johnson, Amy K PhD, MSW	Principal Investigator
Nikolajuk, Katie MSW, MBE	Coordinator

Is the Principal Investigator a Student?

No

Is the researcher a CPS Staff Member?

No

Funding and Intervention Information

Is this project contracted by the CPS Board of Education?

No

Is a funding source associated with the proposed research?

Yes

Who is the primary funding source?
Magoon Institute for Healthy Communities

What is the amount of funding awarded?
$10,000.00

Please list primary contact information of funder.
healthycommunities@luriechildrens.org
225 E Chicago Ave, Chicago, IL 60611

Select the option that applies to your study

My study will be occurring District-wide

Will this research require any in-person interaction or intervention activities?

No

Will this research require any virtual interaction or intervention activities (Google Meets, Zoom, etc.)?

No

Please note that Zoom is not approved for use with CPS Students. Any virtual activities will need to be conducted via Google Meets and safe@cps.edu must be invited to Google Meet. Please adjust virtual methods accordingly. For more information on permitted interactions with students and staff, please visit https://www.cps.edu/about/policies/acceptable-use-policy/external-volunteers/.

Please check all of the following that apply to your research protocol:

Questionnaire

Please outline your protocol for survey activities, describing when, where, duration, frequency, and with whom.

There is one online study visit to complete all research procedures. CPS staff will be invited to participate in a one-time online survey through RedCap, a secure web-based data collection platform. Participants will be screened for eligibility and if eligible will provide informed consent prior to completing the survey. The study visit will last approximately 15 minutes.

Please describe how data will be captured and stored securely
Consent and survey data will be collected via Northwestern's instance of REDCap, a highly secure web application for building and managing online surveys and databases. Data will be collected directly into REDCap using a weblink. Participants have the opportunity to enter an email address in order to receive a stipend for participation. This email will not be linked to study data. None of the remaining 18 identifiers will be collected for this study

Study data will be stored in password protected computers in locked offices to which only members of the study team have access. Only IRB approved study team members will have access to study data.

Please attach all study materials corresponding to interview procedures (i.e., consent forms, protocol, recruitment and incentive plans)

TALLY Email Script 9.2.22_CLEAN.docx	Misc/Other
TALLY Protocol 9.2.22.pdf	Misc/Other
TALLY Recruitment 9.2.22.png	Misc/Other
TALLY Recruitment 9.2.22_part 2.png	Misc/Other
TALLY Survey 9.2.22_CLEAN.docx	Misc/Other
TALLY_information sheet 9.2.22_CLEAN.doc	Misc/Other

Detail the method of Survey Administration (e.g. paper, online, etc.)
Consent and survey data will be collected via Northwestern's instance of REDCap, a highly secure web application for building and managing online surveys and databases. Data will be collected directly into REDCap using a weblink. Participants have the opportunity to enter an email address in order to receive a stipend for participation. This email will not be linked to study data. None of the remaining 18 identifiers will be collected for this study.

Will this research require the use or access of existing CPS data?

No

Will this research require the use or access of existing non-CPS data?

No

Study Details

Please select all of the following that will be participating in the study?

Teachers

Has this project been reviewed by an Institutional Review Board (IRB)?

Yes, and it was approved

IRB of Record Name
Lurie Children's Hospital

IRB Protocol Number
IRB 2022-5223

Please attach all of your IRB documentation here (include approval/exemptions letters, IRB study protocol, etc.).

TALLY Lurie IRB Mod Approval.pdf IRB Letters

IRB of Record Primary Contact Email Address
irb@luriechildrens.org

Please select your primary area of research from the following:

Health

Secondary Study Subject(s)

Health
School Structure/Functions

Study Overview

Executive Summary or Abstract

Please provide a high-level overview of your study, including a summary of the motivation, design, and implications of the project.

Our proposed project "TALLY: Total ALL-important pregnant and parenting Youth count" builds off an established community-academic partnership between the Potocsnak Family Division of Adolescent and Young Adult Medicine and Chicago Public Schools (CPS) Office of Student Health and Wellness (OSHW) (ARCC awardee 2018; Heathy Communities awardee 2020). Our expertise in leading this effort builds off existing success of Adolescent and Young Adult Medicine's research and community initiative teams. Our research efforts include an Alliance for Research in Chicagoland Communities funded "Identifying Best Practices to Support Pregnant and Parenting Young People in CPS" study in collaboration with Chicago Public Schools. This study aimed to increase CPS capacity by describing and identifying the needs of PPY students to develop and implement novel programmatic strategies using an intervention mapping framework. Our team conducted formative research including a literature review and logic model of current PPY challenges, a logic model of change was created to guide program design, and we conducted qualitative interviews with 51 participants (26 PPY; 25 staff). Additionally, we conducted focus groups with 7 participants (3 PPY; 4 staff) to preview potential programmatic strategies leveraged from the qualitative interviews.

Additionally, Adolescent Medicine's Community Programs team utilized previous Healthy Communities funding to develop a self-paced webinar for CPS staff to receive training in best practices in supporting PPY. As part of a process evaluation, our team conducted focus groups with 9 participants (2 PPY; 7 staff) to ask about training content reactions, modifications, and utility which further demonstrated the need for individualized academic support for PPY.

Through this work, our team discovered the need to collect quantitative data to provide CPS with an accurate number of pregnant and parenting students attending Chicago Public Schools.Our goal for the proposed project is to accelerate piloting programmatic strategies to support PPY attending CPS through development and implementation of a quantitative survey for CPS school counselors, social workers, and case managers. Our design plans to enroll N=200 CPS staff to to participate in a one-time online survey through RedCap, a secure web-based data collection platform. Upon completing data collection, descriptive statistics will be used to describe the characteristics of staff (school, job title) as well as experience working with and tracking progress and needs of pregnant and parenting students. The survey will provide CPS with data to gauge an accurate count of the number of pregnant and parenting students enrolled at CPS. Having this data will allow CPS to develop strategies on how to support PPY.

Research Questions and Hypothesis

Please list all research questions and hypotheses associated with this project.

This study will explore the methodology used to track the number of PPY attending CPS, and aim to provide an accurate count of PPY currently attending CPS, and assess concerns in tracking PPY students.

Purpose and Literature Review

Please provide an overview of the existing research and literature on this subject. What is the contextual history of this subject area and how does this research build upon the body of extant knowledge?

The teen birth rate in Chicago remains higher than the national average (24.2per 1000) and according to the 2019 Youth Risk Behavior Survey, in 2019, 4.8%(N=5,049)of Chicago Public School (CPS) high school students and 1.5%(N=3,030)of middle school students reported having been pregnant or gotten someone pregnant in the past 12 month1,2,3 Furthermore, teen birth rates are disproportionately higher in the Belmont Cragin and Austin neighborhoods (33.6 and 40.7 per 1000, respectively) as are teen birth rates in several community areas with a Very Low Child Opportunity Index. While citywide initiatives have placed emphasis on teen pregnancy prevention strategies through long-acting reversible contraceptives and sexual health education, limited attention has been given to identification, development, and implementation of best practices to support CPS students who are currently pregnant and/or parenting (PPY). Existing supports within CPS are varied throughout the district and are uncoordinated with minimal streamlined processes in providing comprehensive academic supports to pregnant and parenting students. Limited support and lack of tailored interventions contribute to the challenges that PPY are already facing, including but not limited to stigma, low academic achievement, school drop-out, pre-term births, low childbirth weight, and postpartum depression4. Addressing this gap provides opportunity for improved health outcomes for both pregnant and parenting students as well as their children.

References:

1. Centers for Disease Control and Prevention. (2019). Youth Risk Behavior Survey Questionnaire. Available at: www.cdc.gov/yrbs.

2.Hamilton BE, Mathews TJ. Continued declines in teen births in the United States, 2015. NCHS data brief, no 259. Hyattsville, MD: National Center for Health Statistics. 2016.

3.Hamilton BE, Rossen LM, Branum AM. Teen birth rates for urban and rural areas in the United States, 2007–2015. NCHS data brief, no 264. Hyattsville, MD: National Center for Health Statistics. 2016.

4.Bledsoe, S. E., Rizo, C. F., Wike, T. L., Killian-Farrell, C., Wessel, J., Bellows, A. M. O., & Doernberg, A. (2017). Pregnant adolescent women's perceptions of depression and psychiatric services in the United States. Women and Birth, 30(5), e248-e257

Research Activities and Student/Staff Involvement

Please provide an overview of all primary and secondary research activities associated with this study. Please use this space to describe, as thoroughly as possible, all that will be asked of your research subjects (e.g. surveys, focus groups, observations, etc.)

There is one online study visit to complete all research procedures. CPS staff will be invited to participate in a one-time online survey through RedCap, a secure web-based data collection platform. Participants will be screened for eligibility and if eligible will provide informed consent prior to completing the survey. The study visit will last approximately 15 minutes.

Research Methodology and Analytical Technique

Please provide an overview of your research methodology and specific analytical techniques that will be utilized as part of this study.

Descriptive statistics will be used to describe the characteristics of staff (school, job title) as well as experience working with and tracking progress and needs of pregnant and parenting students.

Benefits and Commitment to Equity

Benefit to CPS

Which (if any) CPS vision goals does your research support?
90% of freshmen will be on track to graduate high school.
90% of students will graduate high school within five years.

Click here to access more information on the CPS Vision Goals.

Please describe how your project supports each of the Vision Goals selected above.
Limited attention has been given to identification, development, and implementation of best practices to support CPS students who are currently pregnant and/or parenting (PPY). Existing supports within CPS are varied throughout the district and are uncoordinated with minimal streamlined processes in providing comprehensive academic supports to pregnant and parenting students. Limited support and lack of tailored interventions contribute to the challenges that PPY are already facing, including but not limited to stigma, low academic achievement, school drop-out, pre-term births, low childbirth weight, and postpartum depression. Through the proposed study, having a more accurate count of the number of pregnant and parenting students attending CPS will allow for more tailored academic and social emotional supports to ensure PPY are able to continue their education while pregnant and/or parenting, increasing their ability to remain on track to graduate high school, graduate from high school, and plan for their post-secondary goals.

Which (if any) of the CPS core values does your research support?
Community Partnership
Equity

Please describe how your project supports each of the core values selected above.
Our project team developed our study survey in collaboration with CPS partners in order to continue building our community-academic partnership and to ensure the survey content matched the data needs of CPS. This study also supports equity as collecting data on the number of pregnant and parenting students attending CPS will ensure these students have access to educational and social/emotional supports so that they can continue to succeed as both CPS students and pregnant and parenting young people.

How does this project support the district broadly?
Collecting quantitative data on the number of pregnant and parenting students attending CPS will allow for the development of supports and strategies for pregnant and parenting students to academically, and socially and emotionally succeed as both students and parents.

Commitment to Equity

In what ways does this project reflect/challenge/progress the district's commitment to equity?
This project progresses the district's commitment to equity as we want to highlight a group of students (PPY) who may be often overlooked in designing interventions to support their academic growth. This project also partners with CPS to ensure that voices of a variety of staff are incorporated into the study design.

Reflect on the district's equity framework as well as the following: As a researcher, what is my privilege / bias when it comes to this question? Am I assuming that Black and brown students will inherently perform poorly? Have I consulted those whose communities I want to research? Is the research designed with the holistic humanity of the people I am researching in mind? Do I perceive the communities I want to research as allies, or as research subjects? Am I interrogating / challenging policies and systems that may be contributing to inequities? Will this project create an undue burden on the communities I am seeking to research?

How are your research activities accessible to individuals with disabilities?
Since our survey is conducted online, participants are able to access and participate in the survey at a time and location of their choosing.

Are your research activities translated into languages other than English as appropriate for the community?
Our research activities will not be translated into languages other than English as the study as the study team does not have staff who can support creating the survey in a language other than English

Please use the table below to list all District CPS Supporters and the role they will have in your study. Use the details box to describe your supporters' title and role in the district. List your primary supporter first.

Please click "save" after each line.

CPS Supporter Email Address	CPS Supporter Details

Link to New Contact Form
User had the option to start a different form here.

How will you share your research findings with the population(s) you are studying?
Our Adolescent Medicine team has maintained a sustained collaborative partner with CPS which will continue beyond this project. CPS and Lurie staff are dedicated to identifying ways to integrating positive project outcomes into future CPS partnerships. The project team is committed to the open and timely dissemination of project outcomes. The team has an extensive portfolio of publications that includes peer-reviewed manuscripts as well as

local and national conference presentations. Most recently, our team presented outcomes of our ARCC funded project to 27 CPS stakeholders through a 90-minute presentation to review findings as well as collaboratively discuss actionable steps in strategy implementation. We will leverage these types of dissemination opportunities to recruit national partners in effort to continue developing improved supports for pregnant and parenting students.

Research Activities

Start Date of Recruitment

05/16/2022

End Date of Recruitment
12/31/2022

Please provide the date that you will begin primary data collection

05/16/2022

Please provide the end date of primary data collection
12/31/2022

Please provide the date that you will begin analysis

01/02/2023

Please provide the end date of analysis
02/01/2023

Please provide the approximate date that you will finalize your research report.

02/28/2023

Description of Deliverable/Final Product (i.e., academic/journal article, white paper, memo, report)

Our final product will include a formal report of study findings, and a stakeholder event to share data with community members.

Will any portion of this research, including recruitment or consent, take place during or in any way interfere with standard activities?

No

With very few exceptions, research procedures cannot be carried out during or in any way interfere with standard activities, including instruction time or professional development sessions.

Will this study involve study subject randomization or a control group?

No

Will your research employ study-subject deception or non-disclosure?

No

Will this research involve Product Testing?

No

Will this research involve collection of biological samples or biometric data?

No

Does this research involve other research procedures not described previously?

No

Is this research tied to a standard or novel curriculum, teaching or other program, staff professional development training or program, or other non-research activity or activities?

No

Does this study involve the use of educational technology (including survey tools, video conference platforms, and third party websites. See note for add'l details)?

No

Please be aware that under The Student Online Personal Protection Act, SOPPA (105 ILCS 85/), any platform students interact with must be compliant with current data security and student privacy regulations. Please note that this definition includes online survey tools such as Qualtrics. Please use the following website to check if your proposed platform is complaint with SOPPA: https://cps.app.learnplatform.com/new/public/tools

Study Population

Will you be submitting a secondary Data Request?

No

Study Subject Inclusion Criteria

To be eligible to participate:
1.Staff must be 18 years of age or older
2.Employed by CPS
4. Able to understand written and spoken English

If the research involves more than one study subject population (e.g. students, parents, teachers, staff), please individually detail the inclusion criteria for each.

Study Subject Exclusion Criteria

1. Not 18 years of age or older
2. Not employed by CPS
3. Unable to understand written and spoken English

If the research involves more than one study subject population, please individually detail the inclusion criteria for each

Please select all special populations that may be targeted for your study

Other Vulnerable Populations

Describe the potential direct and/or indirect benefits for all detailed research procedures and populations

Participants will not experience direct benefits. However, they may feel good about sharing their experience working within CPS and with PPY. Potential benefits to society include generation of knowledge about tracking the number of pregnant and parenting students attending CPS and how to better ensure their academic and health needs are being met.

Describe the anticipated potential risks, however minimal, associated with the detailed research procedures and subject populations

The proposed study poses minimal risks to participants. Participants will be asked to answer questions they may find uncomfortable discussing topics around tracking the number pregnant and parenting students, however, we feel the risk of this discomfort is minimal.

How will the identified risks for all research procedures and subject populations be minimized and/or mitigated to the greatest extent possible?

Participants will have the right to refuse to answer any questions that they are uncomfortable answering. Additionally, participants will be able to end participation in the survey at any point. Study data will be stored in password protected computers in locked offices to which only members of the study team have access. Only IRB approved study team members will have access to study data.

What procedures will you use in the event that research questions/processes produce observable stress/distress in subjects?

Participants will have the right to refuse to answer any questions that they are uncomfortable answering. Additionally, participants will be able to end participation in the survey at any point.

Will you compensate study subjects?

Yes

Detail the proposed compensation (monetary and/or non-monetary) for each research procedure and population

Staff participants will receive a $10 Tango e-gift card at the completion of the survey. Tango is a secure platform that allows participants to select a gift card to a store of their choosing.

Student incentives must be appropriate, equitable, and reasonable in amount. All staff incentives are limited to $50 or less in a given year. Any amount in excess will require the secondary employment form to be completed by staff participants, or otherwise have the amount allocated to the school.

Describe when and where study subjects will be compensated and detail the mechanisms that will be in place to ensure study subject privacy when distributing compensation.

Participants have the opportunity to enter an email address in order to receive a stipend for participation. This email will not be linked to study data. Upon completion of the survey, participants will be emailed a code to the Tango platform that will allow them to choose the store of their $10 gift card stipend.

Describe the compensation schedule for participants that withdraw from the research or that are withdrawn from the research by the study team.

Participants who withdraw from the research will be unable to be compensated for their time. This is explained in the consent sheet.

Study Recruitment

Outline every aspect of the recruitment process for teacher participants.

Online recruitment ads will consist of emails, advertisements on social media sites, including Facebook.com, Twitter.com, and Instagram.com. The recruitment messages/posts will contain a link to the study survey, hosted via REDCap. Clicking on the link will take users to the webpage containing project information and the eligibility screener followed by the study survey.

Additionally, potential participants will be contacted by email or phone by trained study staff regarding research participation using a standardized recruitment script. Interested participants will then be sent an email to the eligibility screener and subsequent survey.

Please attach all recruitment materials not attached elsewhere (Optional).

No answer provided.

Please attach all consent/assent forms associated with this study not already attached elsewhere (Optional).

No answer provided.

Identify study team members who will recruit subjects.

All team members (Amy Johnson, Justine Britten, Ronus, Hojjati, and Katie Nikolajuk) will recruit subjects

Will this research involve screening procedures

Yes

Please provide a description of your screening procedure.
Participants who click the survey link through online advertisement or communicate with trained study staff will be taken to an online screening survey (attached). After completing the screening tool, eligible participants will proceed to the survey, and ineligible participants will be thanked for their time and interest in the study.

Attach all instruments, including, but not limited to, questionnaires, surveys, assessments, etc, that will be used for screening procedures.

TALLY Screener 9.2.22_CLEAN (1).docx Surveys

Compliance

FERPA

For more information on FERPA, click here.

Is any aspect of this research subject to FERPA?
No

ISSRA

For more information on ISSRA, click here.

Is any aspect of this research subject to ISSRA?
No

PPRA

For more information on PPRA, click here.

Is any aspect of this research subject to PPRA?
No

Permission, Confidentiality, and Security

Attach a draft of the permission letter that will be sent to school Principals

No answer provided.

Please note that Principals have final authority over what happens in their schools.

How will you protect the privacy of prospective research subjects? Please detail how study subject privacy will be protected during recruitment, screening, consent, and all research procedures. Provide an accounting for all applicable research procedures and study populations.

Participants will complete the surveys remotely via REDCap. It is up to their discretion as to the environment in which they complete the research activities. We will advise all participants to complete the consent and survey in private.

Describe the data confidentiality or security provisions that will be in place for all research data.

Study data will be stored in password protected computers in locked offices to which only members of the study team have access. Only IRB approved study team members will have access to study data.

How will you store participant data?

Without any identifiers or codes

These details must be included in all applicable consent forms

Explain how data will be de-identified. What information will be contained on the record such that re-identification is impossible?
Data will be de-identified by removing participant email addresses from RedCap upon sending out the study stipend. Study data will not be stored with participants' identifiers and identifiers will not be maintained (i.e. all collected identifiers will be deleted and not linked with a code) so that re-identification is impossible.

Will you keep participants' contact information on file after the data have been collected?

No

Will you share individual-level data with other researchers or practitioners beyond the designated key research personnel?

No

What will you do with the data once the research has been completed (choose all that apply)?

Retain data for three years or longer post-completion, then destroy it

Please note that the district discourages storing study data for longer than three years after study completion.

Please describe the purpose for which you will be storing data after the conclusion of the study. Also, explain the planned duration (i.e. how long) you will retain data
Study data will be stored for up to 3 years and will be used for future projects and grant opportunities in order to continue to partner with CPS on supporting pregnant and parenting students.

Attachments

Please attach all miscellaneous attachments

No answer provided.

If you are resubmitting your protocol following initial review, please attach your response letter here.

Are there any additional finalized contracts or agreements associated with this research that have not been attached elsewhere as part of this application (e.g. CPS Data Authorization Agreements)?

No

Are there any pending (i.e. not yet signed by both parties) contracts or agreements associated with this research that have not been attached elsewhere as part of this application?

No

Acknowledgements

Acknowledgements

Please acknowledge the following:

✔ All parts of this submission are accurate, complete, consistent, and clear.

✔ I have accurately and completely described all intended human subjects research procedures and the populations with whom they will be carried out.

✔ I have attached all study materials, including, but not limited to, all materials that will be given to, sent to, read to, or otherwise used with all prospective study subject populations.

✔ This submission adhere to all CPS policies and guidance as outlined in the link below

https://www.cps.edu/about/district-data/conduct-primary-research/

✔ I have accurately identified all personnel who will be involved in this study.

✔ I acknowledge that any/all changes required by the CPS RRB in the course of its review of this submission will be reported to my IRB of record during the entire lifetime of this study.

✔ I attest that I will work with my IRB of record to address any concerns raised in the review of this submission.

✔ I attest that all of the research procedures detailed in this submission have been carried out with prospective IRB review and approval.

✔ I agree to comply with all background check and volunteer procedures required of my study, per the official CPS Volunteer Policy (link provided below):

https://policy.cps.edu/download.aspx?ID=272

Submission Date

09/26/2022

All RRB new submissions, modifications, continuing reviews require a $50 processing fee. Please click on the following link to access our payment system. You will need to reference your assigned RRB number listed below:

CPS RRB/Data Request ePay System

Once you navigate to the Illinois E-Pay Site, please click on the blue text "RRB / Data Request Payment Option " to display the appropriate payment options. Once selected, your total will be displayed. Do not attempt to type in your total manually.

RRB #
2022-1769

Payment Confirmation Number
20000017

Load CR/Mod into IRBManager
- Submitted 10/02/2023 2:37 PM ET by System, The

CR/Mod Processing
- Submitted 11/01/2023 10:31 AM ET by Corson, Adam

CR/Mod Processing

Ready for Review

Approve

Approval Date

11/01/2023

Approval Period (in number of months)
12

Existing Background Check Level
Level I

Existing Background Check Justification
Interactions with Staff

Does background check level need to be updated?
No

Notes for Letter
No answer provided.

RRB Meeting Date for Notification

11/17/2023

Current School Sites

No answer provided.

School Sites Chosen Within Data Entry

School Contacts for Sites Chosen
No answer provided.

Are the Supplementary Sites the same?
True

Administrative Reviewer

Corson, Adam

Email: ACorson1@cps.edu **Phone:**

Determination Letter Finalization
- Submitted 11/01/2023 11:14 AM ET by Corson, Adam

Review Generated Letter and Confirm Before Sending

RRB #

2022-1769

Study Title
TALLY: Total ALL-important pregnant and parenting Youth count

Principal Investigator
Johnson, Amy K PhD, MSW
Email: akjohnson@luriechildrens.org **Business:** (312) 227-7733

Determination Letter

In some cases you may see other determination letters attached by the submitter. However, only the generated determination letter will be sent in the decision email.

Name	Type	Date
RRB#2022-1769- Amy K Johnson, PhD, MSW 2023-11-01.docx	Determination Letter	11/01/2023

This determination letter will be automatically attached to an email being sent to the principal investigator.

Please use the link below, click on the Attachments link on the left side of the page if you need to upload an edited version of the above letter.
Modification/Continuing Review defined 10/02/2023

Output Background Check Level

N/A

Additional Attachments to Decision Email

No answer provided.

Notes for Determination Email

No answer provided.

Study Site Contact Background Check Expirations

Name	Role	Background Check Expiration
Britten, Justine	In-School Research Staff	Missing
Hojjati, Ronus	Project Team Member	Missing
Johnson, Amy K PhD, MSW	Principal Investigator	Missing
Nikolajuk, Katie MSW, MBE	Coordinator	Missing

Please use the text box above to indicate the background check level required or any other pertinent information.
Level I

Background Check Level Justification
Interactions with Staff

Other Notes in Letter
N/A

Please enter the date by which the coordinator should submit the Data Use Agreement. Automatic notifications will be sent out based upon this date.

12/01/2023

Ann & Robert H. Lurie Children's Hospital of Chicago and Chicago Public Schools

ACTIVITY INPUT TO DATE:

TOTAL ALL-IMPORTANT PREGNANT AND PARENTING YOUTH COUNT (TALLY) STUDY

A COLLABORATION BETWEEN LURIE'S DEPARTMENT OF ADOLESCENT AND YOUNG ADULT MEDICINE AND CPS'S OFFICE OF STUDENT HEALTH AND WELLNESS

JANUARY TO DECEMBER 2022

Table of Contents

1. EXECUTIVE SUMMARY

Between January-December 2022 Lurie's Division of Adolescent and Young Adult Medicine in collaboration with Chicago Public School's Office of Student Health and Wellness developed and conducted a quantitative survey with CPS staff to determine the number of pregnant and parenting young people (PPY) who were enrolled in school during the 2021-2022 school year.

The purpose of this project is to provide CPS and other key stakeholders with accurate data on the number of PPY attending CPS, and to increase CPS capacity for developing a method to sustainably collect this data. Having accurate data on the number of PPY attending CPS provides an opportunity to establish the need to develop programs and services that support students academically, as well as socially and emotionally in continuing to attend school while balancing pregnancy and/or parenting.

2. BACKGROUND AND PURPOSE

According to the Center for Disease Control and Prevention, the teen birth rate in Illinois is at an all-time low with 13.6 births per 1,000 females aged 15-19.[1] However, in the city of Chicago, the overall teenage birth rate is more than double the state rate at 27.5 births per 1,000 females aged 15-19 years old based on the most recent data available.[2] Across the country, racial disparities exist in teen birth rates with a rate of 23.5 births per 1000 females for those who identify as Black, or Hispanic compared to 10.4 births among females who identify as White.[3] Cygan et al., 2020 used Youth Risk and Behavior Survey (YRBS) data to learn that these disparities also exist in Chicago Public School (CPS) students, where 5.8% of African American students reported a pregnancy experience compared to only 3.7% of white students.[4]

Although these statistics can provide a theoretical estimate, there is significantly less data for an accurate count of pregnant and parenting young people (PPY) enrolled in school. Since the actual number has not yet been quantified, it remains an overlooked public health problem. This is pertinent given that 36% of CPS students are African American and 46.6% are Hispanic, and rates of teen pregnancy and infant mortality are increased among these groups relative to White populations.[3,5]

CPS does not currently report on the number of PPY enrolled during each school year, limiting the ability to provide coordinated programming and support since the impact or plan for services cannot be quantified. Meanwhile, quantitative data and coordinated programming exists for other groups of students who also need extra support, including students who are bilingual with limited English proficiency (21% of CPS students during the 2021-2022 school year), students enrolled in special education or an Individualized Education Plan (14.8% during 21-22) and students who come from economically disadvantaged backgrounds (69.8% during 21-22).[5] This problem is not exclusive to CPS, as there is limited information in the literature nationally on gathering data about the number of PPY in school on a jurisdictional level. Instead, teen birth rate is used to provide an indirect approximation of the number of PPY attending school. Understanding the scope of support needed through an accurate count of PPY in the school district is imperative to advancing health equity for this population.

It is also important to quantify the number of PPY and assess trends across different neighborhoods in Chicago. The Sexual and Reproductive Health Burden Index (SRHBI) is a measure used to assess sexual health risks, using outcome variables including teen births, low birth weight and infant mortality. This tool used Chicago Department of Public Health data to assign a score across different neighborhoods to predict community-level variables that increased burden.[6] Significant predictors of higher SRBI scores included percentage of Black residents in a neighborhood, percentages of same-sex couple

households, community violence, economic hardship, and population density.[7] Additionally, data examining levels of community violence in the South and West sides of Chicago noted that adolescents and young women who experience increased levels of community violence are more likely to have had sex without contraception and are at higher risk for teen pregnancy.

Pregnant and parenting young people aspire to achieve the same goals and ambitions as their non-PPY peers including graduation and post-secondary planning. To understand needed supports and services to achieve these goals, Lurie Children's Hospital of Chicago and the Office of Student Health and Wellness (OSHW) within CPS developed a community-academic and established a census of all high schools within CPS to quantify the total number of PPY enrolled in school. The goals of this study were to achieve the following: 1. Obtain an accurate count of the number of PPY attending CPS, and 2. Determine the feasibility of developing a standardized data collection process on PPY enrollment.

3. METHODS AND APPROACH

3.1. SURVEY DESIGN

Prior to survey development, the team at Lurie conducted a literature review on survey strategies to gather quantitative information from school staff. The review examined previously used survey designs from the National Survey of School Counselors and Supporting Safe and Healthy Schools for LGBTQ Students: A National Survey of School Counselors, Social Workers, and Psychologists which informed our survey design and data collection strategy.[8,9] Then, in collaboration with partners at CPS, our team developed a survey to quantify the number of PPY attending CPS during the 2021-2022 school year by gathering data from school counselors, social workers, case managers, and other staff. Survey questions ask about the participant's role within CPS, number of pregnant students attending school, number of parenting students attending school, existing methods for tracking PPY students, challenges in tracking PPY, and how data would ideally be captured.

3.2. RECRUITMENT

To collect survey data, our team utilized a variety of recruitment strategies including online recruitment consisting of emails, advertisements on social media sites, and multiple professional Listservs. Additionally, potential participants were contacted by phone by trained study staff regarding participation using a standardized recruitment script. Interested participants were sent an email to the eligibility screener and subsequent survey. Participants were eligible to complete the survey if they were 18 years of age and older, employed by CPS (including charter and contract schools) and able to understand written and spoken English.

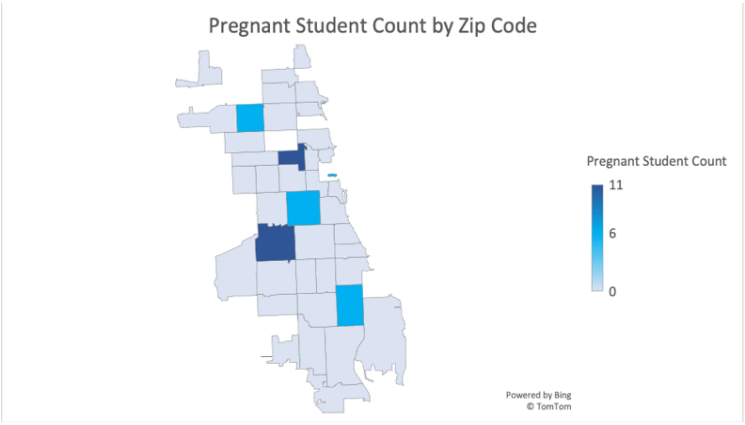
4. ANALYSIS AND FINDINGS

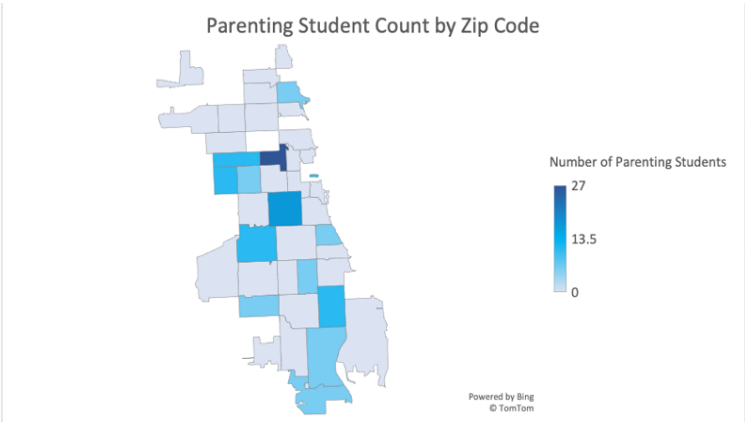
4.1. SUMMARY OF RESULTS

A total of 95 participants completed the survey representing 92 unique schools (57% of the district). Most survey participants were school Social Workers (39%) followed by School Counselors (32%). Most participants (94%) reported 0-5 pregnant students enrolled during the 2021-2022 school year. 4% of participants answered that 6-10 pregnant students were enrolled, 2% answered 11-20 pregnant students enrolled, and no one responded that their school had more than 20 pregnant students enrolled. When asked how these numbers compared to previous years, the majority (67%) responded that this was equal to previous years, 21% responded fewer than previous years, and 12% responded more than previous years. When asked about the number of parenting students enrolled during the 2021-2022 school year, the majority (83%) responded 0-5, 10% responded 6-10, 6% responded 11-20,

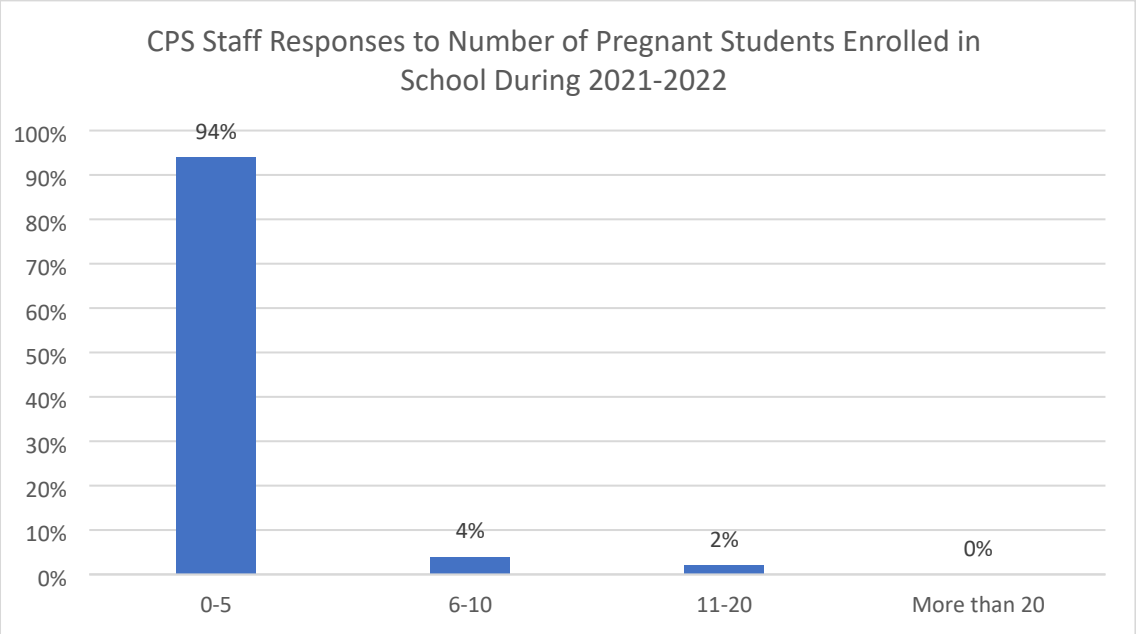
and 1% responded more than 20. Compared to the number of parenting students in previous years, the majority (68%) responded equal to previous years, 17% responded fewer than previous years, and 15% responded more than previous years. 39% reported that their school does not have a process for counting PPY students, 23% of participants answered that their school does have a system for tracking PPY students, and 38% were unsure about whether or not their school had a data collection process for counting enrolled PPY students. When asked about data collection methods for tracking PPY enrollment, the top responses were: 57% self-disclosure from students, 28% medical documentation, and 27% through applications for homebound instruction. When asked about challenges collecting data on PPY enrollment, the overwhelming majority (67%) responded that student records do not contain any information about PPY status. Additional challenges reported included confidentiality concerns with school records (26%), confidentiality concerns with medical records (20%), limited staff capacity (17%) and other such students requesting assistance with childcare and a student self-disclosure form completing during orientation (22%). When asked about how staff would ideally collect data on PPY enrollment responses included student disclosure (81%), medical documentation (59%), through applications for homebound instruction (34%), student accommodations (24%), student academic records (20%), support with lactation spaces (16%) and other (6%).

Survey data was then analyzed by geography (Figure 1) and demonstrated both a higher number of parenting students compared to pregnant students as well as an increased number of PPY in specific zip codes. The highest numbers of both pregnant and parenting students were in Brighton Park (60632), Chatham (60619), and Pilsen (60608) on the South side, West Town (60622) on the West side, and The Loop (60602) located in Downtown Chicago. Meanwhile, Portage Park (60641) on the North side demonstrated a higher number of pregnant students only while neighborhoods with higher numbers of only parenting students included Ashburn (60652), Englewood (60621), Grand Boulevard (60653), Riverdale (60827), and Roseland (60628) on the South side, and Austin (60644), Humboldt Park (60624), and West Garfield Park (60624) in the West. Comparing the survey results against geographic location is crucial because literature notes that the highest teen birth rates are in the South and West sides of Chicago which can inform allocation of future resources and services.

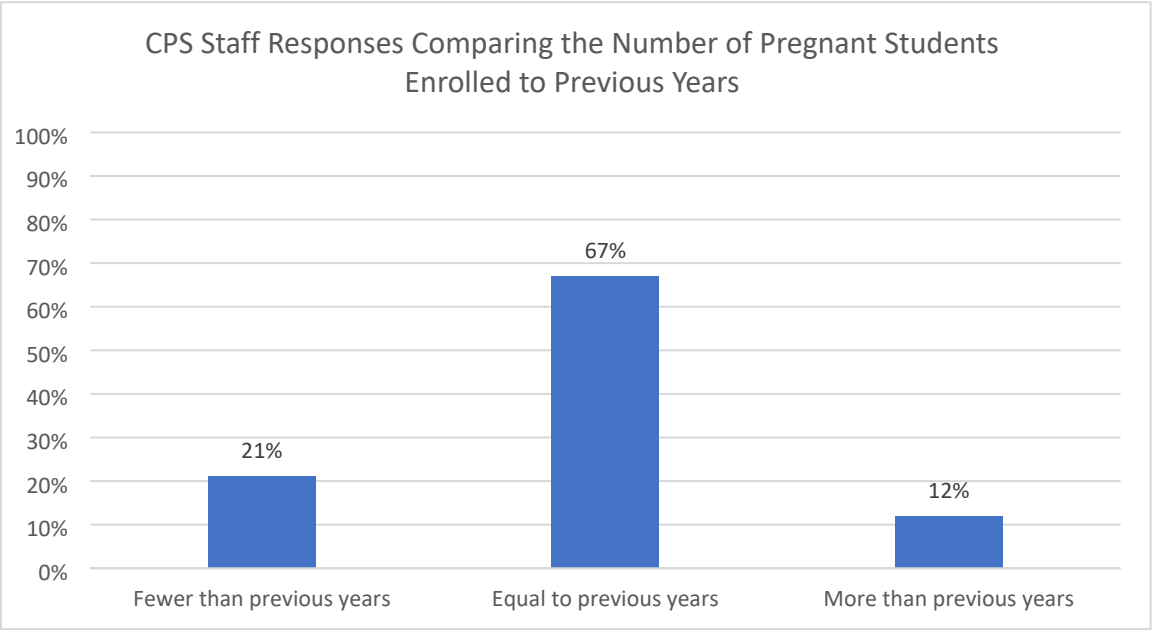




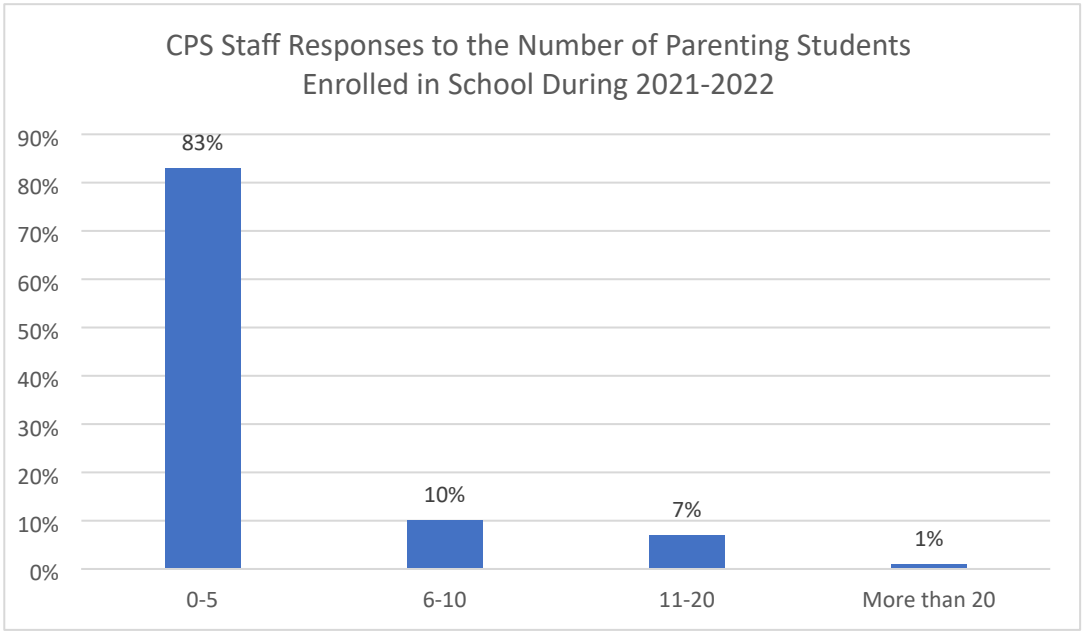
4.2. QUESTION 1: "APPROXIMATELY HOW MANY PREGNANT STUDENTS ATTENDED YOUR SCHOOL DURING THE 2021-2022 SCHOOL YEAR?"



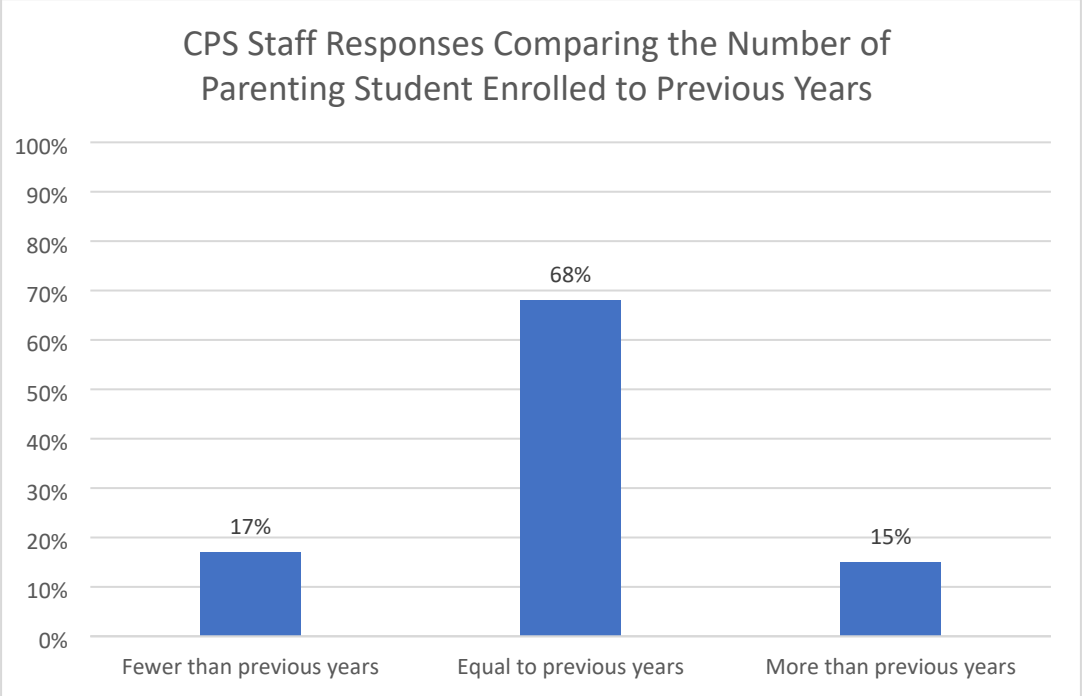
4.3. QUESTION 2: "HOW DOES THE NUMBER OF PREGNANT STUDENTS WHO ATTENDED YOUR SCHOOL DURING THE 2021-2022 SCHOOL YEAR COMPARE TO PREVIOUS YEARS?"



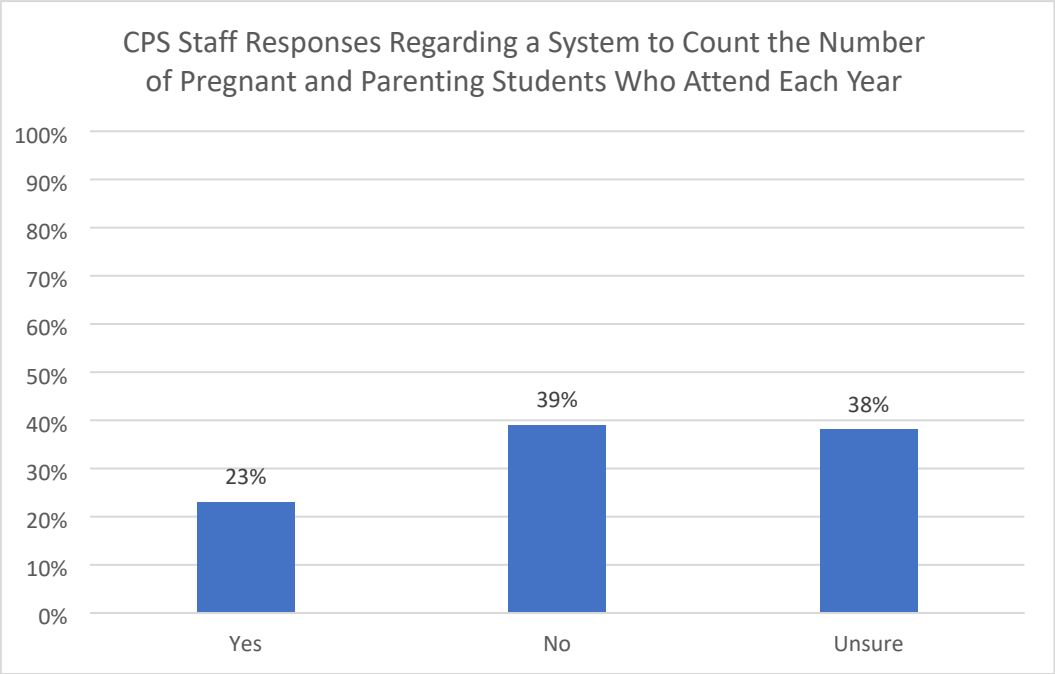
4.4. QUESTION 3: "APPROXIMATELY HOW MANY PARENTING STUDENTS ATTENDED YOUR SCHOOL DURING THE 2021-2022 SCHOOL YEAR?



4.5. QUESTION 4: "HOW DOES THE NUMBER OF PREGNANT STUDENTS WHO ATTENDED YOUR SCHOOL DURING THE 2021-2022 SCHOOL YEAR COMPARE TO PREVIOUS YEARS?"



4.6. QUESTION 5: "DOES YOUR SCHOOL HAVE A SYSTEM TO COUNT THE NUMBER OF PREGNANT AND PARENTING STUDENTS WHO ATTEND EACH YEAR?



4.7. QUESTION 6: "SELECT ALL THAT APPLY. IF YOUR SCHOOL DOES COUNT THE NUMBER OF PREGNANT AND PARENTING STUDENTS WHO ATTEND EACH YEAR, HOW DOES YOUR SCHOOL COLLECT THIS NUMBER?

Response Option	Percentage of Responses
Through student academic records	4%
Through student attendance records	10%
Through applications for homebound instruction	27%
Through self-disclosure from student	57%
Student accommodations (elevator pass, excusal from gym, bathroom pass, etc.)	17%
Medical documentation	28%
Support with lactation space	5%
Other	14%
Our school does not count the number of PPY who attend each year	30%

4.8. QUESTION 7: "SELECT ALL THAT APPLY. WHAT ARE THE CHALLENGES YOU'VE EXPERIENCED IN TRACKING THE NUMBER OF PPY ATTENDING SCHOOL?"

Survey Response	Percentage of Responses
Confidentiality concerns with school records	26%
Confidentiality concerns with medical records	20%
Limited staff capacity	17%
Student records do not contain any information about their PPY status	67%
Other	22%

4.9. QUESTION 8: "IN YOUR OPINION, HOW WOULD THE NUMBER OF PPY ATTENDING YOUR SCHOOL IDEALLY BE CAPTURED?"

Response Option	Percentage of Responses
Through student academic records	20%
Through student attendance records	16%
Through applications for homebound instruction	34%
Through self-disclosure from student	81%
Student accommodations (elevator pass, excusal from gym, bathroom pass, etc.)	24%
Medical documentation	59%
Support with lactation space	16%
Other	6%

5. RECOMMENDATIONS AND ACTIONS

5.1. LIMIT RELIANCE ON STUDENT DISCLOSURE

Survey results demonstrated that staff rely heavily on student disclosure regarding their PPY status. 57% of respondents stated that self-disclosure is part of the school's data collection process and 81% answered that data on PPY status would be ideally captured through student self-disclosure. Given that pregnant and parenting students face a higher level of stigmatization compared to their non PPY peers, and the potential worry about being unable to attend their home institution in lieu of an alternative or online school, students may be hesitant to reveal their status to school staff. Additionally, relying on students to provide data on their PPY status increases the chances for human error and limits the ability to collect accurate data. This limits the ability to establish a need for PPY programming and supports because the impact cannot be quantified. One potential solution to this system is to consider a less subjective method of collecting PPY status, such as applications for homebound instruction, or educational accommodations.

5.2. EVALUATE STORAGE AND CONFIDENTIALITY OF STUDENT DATA

Results demonstrated that the biggest challenges collecting data on PPY status included the fact school records do not contain this information (67%), confidentiality concerns with school records (26%) and medical records (20%). Creating a feasible and sustainability method of data collection on PPY status requires both a centralized location to store this data so that it is coordinated across the district. It also requires a protocol to maximize student confidentiality.

5.3. CENTRALIZE DATA COLLECTION STAFF

During data collection, study staff noted mixed results across school districts in establishing the staff person who was most likely to have the most accurate knowledge on PPY enrolment. In some schools it was the social worker, others the guidance counselor, and then some schools referred staff to the assistant principal. Establishing a point person for collecting PPY data would increase accuracy in collecting district-level data since staff collecting district wide data would be able to ask each school's specific point person.

5.4. CONDUCT FOCUSED NEEDS ASSESSMENT IN SCHOOLS WITH HIGHER REPORTED NUMBERS OF PPY ENROLLMENT

Results demonstrated that schools located in neighborhoods on the South and West sides of Chicago had higher numbers of PPY enrolled in school compared to other neighborhoods. Conducting a needs assessment with schools located in these zip codes would provide CPS the opportunity to further establish specific needs for PPY students and create an equitable learning environment by allocating resources and services to specific schools. Additionally, it would allow CPS to quantify the impacts of potential programs and services.

6. CONCLUSIONS AND REFLECTIONS

Collecting accurate quantifiable data on PPY enrollment is challenging for several reasons. Students might not reveal their PPY status, especially if they are a non-birthing parent and show no symptoms of pregnancy, they might be unenrolled from school, or, they might have become pregnant or started parenting while remote learning during the COVID-19 pandemic and school staff were not meeting face to face with students and therefore may not have noticed a student experiencing symptoms of pregnancy. Additionally, in CPS, students do not have to attend high school based on the neighborhood they reside in and instead can elect to attend school in a different neighborhood. Unless there is an accurate count on PPY enrollment, it is difficult to ascertain the impact of further public health challenges associated with teen pregnancy and parenting at the population level. One, PPY status data is not collected individually from students. Instead, staff rely on student self-disclosure of their PPY status. Second, PPY status is not collected in student records. This means there is not a central location for staff to access information about a student's PPY status. Lastly, it is difficult to collect student data on PPY status due to its sensitive nature, and student fear of stigmatization or being "pushed out" of their school of choice for an alternative school.

It is critical to think about PPY enrollment from an epidemiological standpoint due to the evidence that indicates pregnant and parenting teens (including men, women, and transgender men and women) are more likely to encounter further public health issues including community violence, delayed engagement in first trimester prenatal care, preterm birth, sexual assault, cervical cancer, prostate cancer, smoking during pregnancy, and sexually transmitted infections including HIV (Rosentel et al 2022). Further, PPY are less likely to finish high school, leading to increased poverty and lower educational attainment, which plays a role in overall population health outcomes (CDC 2019). Therefore, collecting data on the true number of PPY enrollment in school is crucial to assessing the incidence and prevalence of these additional public health outcomes.

7. REFERENCES

1. Centers for Disease Control and Prevention. (2020). Teen Birth Rate by State. Available at: https://www.cdc.gov/nchs/pressroom/sosmap/teen-births/teenbirths.htm

2. Chicago Department of Public Health. Health data and reports. Available at: https://www.cityofchicago.org/city/en/depts/cdph/provdrs/health_data_and_reports.html.

3. Office of Adolescent and Sexual Health. (2019). Adolescent Health. Available at: https://opa.hhs.gov/adolescent-health?adolescent-development/reproductive-health-and-teen-pregnancy/teen-pregnancy-and-childbearing/trends/index.html

4. Cygan, H. R., McNaughton, D., Reising, V., Fogg, L., Marshall, B., & Simon, J. (2020). Teen pregnancy in Chicago: Who is at risk?. *Public Health Nursing*, *37*(3), 353-362.

5. Chicago Public Schools (2021). Demographics. Available at: https://www.cps.edu/about/district-data/demographics/

6. Rosentel, K., VandeVusse, A., & Schuh, T. (2021). The Sexual and Reproductive Health Burden Index: development, validity, and community-level analyses of a composite spatial measure. *Journal of urban health*, *98*, 481-495

7. Laursen L, Hebert L, Newton S, Norcott C, Gilliam M. Community Violence Exposure and Adolescent Pregnancy in Chicago. J Interpers Violence. 2022 Jan;37(1-2):NP742-NP756. doi: 10.1177/0886260520917509. Epub 2020 May 12. PMID: 32394782.

8. Bridgeland, J., & Bruce, M. (2011). 2011 National survey of school counselors: Counseling at a crossroads. *College Board Advocacy & Policy Center*.

9. Kuff, R. M., Greytak, E. A., & Kosciw, J. G. (2019). Supporting Safe and Healthy Schools for Lesbian, Gay, Bisexual, Transgender, and Queer Students: A National Survey of School Counselors, Social Workers, and Psychologists. *Gay, Lesbian and Straight Education Network (GLSEN)*.

TALLY Email Script

Dr. Amy Johnson is inviting Chicago Public Schools staff to participate in a survey We are conducting this study to study to learn more about the number of parenting young people who attend Chicago Public Schools. The study will involve one, 15 minute online-survey. Participants will receive a $10 gift card for their participation. Eligible participants will be at least 18 years old, currently be employed by Chicago Public Schools and be able to understand written and spoken English. Please see click the link below to see if you are eligible, or contact Katie at knikolajuk@luriechildren**s.**org if you have more questions.

Submission Type: Modification Date: 9-2-2022

IRB #: IRB 2022-5223
Title: TALLY: Total ALL-important pregnant and parenting Youth count
Creation Date: 9-2-2022
Status: Unsubmitted
Principal Investigator: Amy Johnson

M1 Modification Information

*required

A What type of submission is this?

✓ Modification

*required

A Has the Lurie Children's IRB accepted the review of an external IRB for this study?

Yes

✓ No

Report of modification(s) implemented for immediate patient safety without prior IRB approval

Five day follow-up report after emergency use of a test article (drug, biologic or device)

M2 Modification Details

*required

Modification Description and Justification

Please refer to IRB Policies & Procedures Manual Section 9.2D.iv for details regarding Modification submissions.

Mark all items below being changed/updated/added/removed with this modification and thoroughly complete all follow-up questions.

A

Please remove tracked changes versions of documents that are not being revised with this modification from the application.

If this study is subject to Institutional Biosafety Committee review and the changes require submission to the IBC, please ensure to submit the required study documents and Amendment form to IBC@luriechildrens.org. For more information visit the IBC Website.

A.1 Study Title

A.2 Funding source(s)

A.3 Northwestern University or its affiliates involvement/engagement

A.4 Principal Investigator (PI)

A.5 Study personnel

✓ A.6 Study design and/or procedures and/or updated study protocol

*required

A.6a Does this modification include the submission of an updated study protocol?

✓ Yes

*required

A.6a-1 Provide the Version Date/Number of the updated study protocol.

TALLY Protocol 9.2.22

Ensure that the updated study protocol is provided in *Section* 9.

No

*required

Provide the details of the change(s) in study design and/or procedures.

A.6b

The new proposed protocol will remove the criterion of eligible participants being a Social Worker, Case Manager, or School Counselor.

*required

Provide justification for the change(s) in study design and/or procedures.

A.6c

As our team has been collecting data, we've gotten feedback from several participants that there are staff better equipped to complete the survey, but do not fit into the current inclusion criteria based on their role at a CPS school. Removing this criterion will allow the staff person most qualified to complete the survey regardless of role.

Please ensure that this change is made in *Section 3* and applicable study documents (consent forms, recruitment materials, etc).

A.7 Number of study participants

A.8 Study population or inclusion/exclusion criteria

✓ A.9 Waivers of Consent and/or HIPAA Authorization

*required

Provide details for the change in consent and/or HIPAA waiver(s).

A.9a

Revised survey information sheets to reflect updated inclusion criteria.

*required

Provide justification for the change in consent and/or HIPAA waiver(s).

A.9b

Modified the information sheet as they explain only counselors, social workers, and case managers are eligible to participate in the survey. Since we are expanding eligibility, this language is no longer needed.

Please ensure that this is updated in *Section 7* (or research plan and HIPAA Waiver Request Form if applicable).

A.10 Addition of foreign language translation of consent/assent or other documents

✓ A.11 Recruitment materials, verbal scripts, survey instruments, web-based instruments, questionnaires, etc.

*required

A.11a Provide details of the change in recruitment materials and/or other study documents.

Recruitment materials have been revised to remove criteria about eligible participants serving in a Counselor, Case Manager, or Social Worker role.

*required

A.11b Provide justification of the change in recruitment materials and/or other study documents.

These materials have been revised in order to expand the scope of eligible survey participants.

Please ensure that these new documents are provided in *Sections 3, 4 and/or 9*.

A.12 New information about the investigational agent (i.e., updated Investigational Brochure)

A.13 Updated safety information or change in study status (i.e., DSMB/C or monitor report, or opening or closing of study enrollment)

A.14 Planned protocol deviation

A.15 Expanded recruitment/enrollment to include persons from an European Economic Area (EEA) or sponsor notification of GDPR requirement

A.16 Addition of electronic or technology platform to conduct recruitment, consenting, or research procedures.

A.17 Other

*required

B **Modifications Requiring Re-Consent of Active or Past Participants**
Please see IRB Policies & Procedures Manual Section 11.1K for guidance regarding the requirement for re-consent of previously enrolled subjects.

Have any participants been enrolled in this study at Lurie Children's?

✓ Yes

*required

B.1 Does this modification include new information (changes to risks/benefits, study procedures, etc) about which current or past participants should be notified?

Yes

✓ No

*required

B.2 Does this modification require the re-consent of current or past participants?

Yes

✓ No

No

N/A - study does not enroll active participants.

1 General Information

Study Identification

Guidance for specific questions is included to the right of the question in the Helper Text (Question Mark Icon).

A

- Links to applicable sections of the IRB Policies & Procedures Manual are included throughout this application for reference.
- For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB, please refer to the Cayuse IRB Submission Process guide.

---

*required

What type of submission is this?

A.1

For details regarding the types of submission, please refer to IRB Policies & Procedures Manual Section 9.

Research Study Involving Human Subjects - **Expedited Review**
✓ (Study involves procedures that are no more than minimal risk.)

Research Study Involving Human Subjects - **Full Board Review**
(Study involves procedure(s) greater than minimal risk or a minor increase over minimal risk; or the study includes an investigational device that is non-exempt and requires a Risk Determination.)

Research Study Involving Human Subjects - **Exempt Determination Request**

Research Study Involving Human Subjects - **External IRB Review**
(i.e. request for Lurie Children's IRB to rely on an External IRB)

Treatment Use of Investigational Drug or Device
(i.e. Expanded Access, Humanitarian Use Device (HUD), Compassionate Use - Device)

Emergency Use of an Investigational Drug or Device

Use of Protected Health Information (PHI) Preparatory to Research

Case Report / Case Series

Quality Improvement / Quality Assurance Project

Use of Decedents' Protected Health Information (PHI)

Non-Human Subjects Research Determination

Study Personnel

B

For guidance regarding PI Responsibilities and who to list in Study Personnel, refer to IRB Policies & Procedures Section 5.

*required

Select the Principal Investigator (PI).

B.1 Any study conducted by a PI who is not a Lurie Children's employee must have at least one Lurie Children's faculty member within the division/department where the research will be conducted serve as a Sub-Investigator.

Name: Amy Johnson
Organization: Adolescent Medicine
Address:
Phone: 773-303-6060
Email: AKJohnson@luriechildrens.org

*required

Select all Primary Study Contact(s).

B.2 Name: Kaitlyn Nikolajuk
Organization: Adolescent Medicine

Address: , Chicago, IL 60611-2605
Phone:
Email: knikolajuk@luriechildrens.org

B.3 Select all Sub-Investigators.

Select all other study staff.

B.4 If you are working with REDCap at Northwestern, please list "REDCap User" in this role so that REDCap staff may access to approval status and letters.

Name: REDCap User
Organization: Non-Medicine
Address: , Chicago, IL 60611-2605
Phone:
Email: redcap@northwestern.edu

Name: Ronus Hojjati
Organization: Child Abuse Pediatrics
Address: , Chicago, IL 60611-2991
Phone:
Email: rhojjati@luriechildrens.org

B.5 Select non-Lurie Children's personnel engaged in the study conduct at Lurie Children's site(s).

---

*required

B.6 To whom has the PI delegated responsibility to obtain informed consent?

All Primary Study Contact(s) listed in B.2

All Sub-Investigators listed in B.3

All other study staff listed in B.4

All non-Lurie Children's personnel listed in B.5

Limited to the following personnel:

✓ Not applicable (waiver of informed consent being requested or informed consent not required)

2 Study Setting(s)

A Study Setting(s)

*required

A.1 Select all locations below where this study will be conducted.

- [x] Ann & Robert H. Lurie Children's Hospital of Chicago and/or one of its outpatient centers.
- [ ] Northwestern University or a Northwestern University Affiliate site (Prentice Women's Hospital, Northwestern Medicine, Shirley Ryan Ability Lab, Central DuPage Hospital, etc.)
- [x] School

*required

A.1b Specify the school or school district.

- [x] Chicago Public Schools (CPS)

Please note that all research at CPS require review and approval by the Research Review Board prior to implementation of research activities.

- [ ] Other
- [ ] Community Setting(s)
- [ ] Pediatric Practice Research Group (PPRG); including those within/utilizing Community Connect.
- [ ] Primary Care Physician Offices
- [ ] Other

*required

Is Lurie Children's serving as the IRB of record for any other study sites (e.g., Northwestern University, Prentice, Shirley Ryan, or other external sites)?

A.2

For more information on Lurie Children's serving as the IRB of record for Northwestern University, please visit the ORIC Website.

Yes, Lurie Children's will serve as the IRB of record for another site.

No, Lurie Children's is relying on an external IRB of record for this study.

No, each institution will conduct a separate IRB review.

✓ N/A, there are no other study sites

*required

B Research Support Services

*required

Select all support services that are being used for this study:

B.1

For more information regarding letters of support and other resources provided for Investigators and research personnel conducting clinical studies at Lurie Children's, please see the Clinical Studies Resources page.

Research Pharmacy -
The study involves preparation/storage or dispensing of medications or biologics.

Clinical Research Unit (CRU) -
The study requires CRU space and/or CRU personnel to support study visits.

Medical Imaging Research Committee -
The study requires deviation from the Medical Imaging standard of care imaging protocol and/or research imaging that is not being billed to patient insurance.

Research Laboratory (Department of Pathology and Laboratory Medicine) -
The study requires specimen, tissue, or slide processing, testing, storage, and/or shipping.

Cardiopulmonary Lab -
The study involves cardiopulmonary testing.

Infection Prevention and Control -
The study 1) utilizes equipment/instrumentation (provided or purchased) that will be used on more than one patient including items that requires sterilization/disinfection before first time use, and/or 2) involves the administration of a microorganism or a product that contains one or more microorganisms (i.e., bacteria, fungi, or virus; even if attenuated/non-replicable) to a participant.

Nursing Research Council -
The PI/Co-PI is a nurse or the subjects being studied are nurses.

Lurie Cancer Center Scientific Review Committee -
An oncology protocol that has not been reviewed by the NCI peer-review agency.

Emergency Medicine -
Studies that will directly recruit study participants from the Emergency Department (ED), or utilize ED services or staff for research purposes require written support from the Division.

Other internal or external divisions/departments/groups (Pediatric Intensive Care Unit, Ophthalmology, Anesthesia, etc).

✓ N/A; No support services used.

*required

Safety Reviews

C

If any additional safety committee reviews are required for this protocol, the review and approval by these safety committees will be required before the IRB will issue a final approval. For more information, refer to IRB Policies and Procedures Manual Section 9.

*required

Radiation Safety Review:

C.1 Does this study include ionizing radiation imaging exams (i.e., x-rays, DEXA, fluoroscopy, CT, nuclear medicine, and PET/CT scans)?

Questions regarding Radiation Safety and if review is required should be directed to the Radiation Safety Officer *(link to email)*.

Yes

✓ No

Institutional Biosafety Review:

Does this study involve the transfer into one or more human participants of recombinant or synthetic nucleic acid molecules; cells, organisms, and viruses containing such molecules; (including Human gene transfer; Vaccine trials that involve the administration of recombinant or synthetic nucleic acid molecules)?

In the context of the ***NIH Guidelines***, recombinant and synthetic nucleic acids are defined as:

C.2

I. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
II. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
III. *molecules that result from the replication of those described in (i) or (ii) above.*

Questions regarding Institutional Biosafety Committee and if review is required should be directed to IBC@luriechildrens.org.

Yes

✓ No

3 Study Design

A Study Design

*required

Is this study a clinical trial?

A.1 A clinical trial is defined by the NIH as: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- Yes
- ✓ No

*required

A.2 Is there more than one study group (i.e., treatment vs. control) to be enrolled into this study?

- Yes
- ✓ No

B Study Background and Objectives

*required

Provide the background and justification for conducting this study.

Include appropriate references, if these are not included in a separate document in Section 9.

B.1

The teen birth rate in Chicago remains higher than the national average (24.2per 1000) and according to the 2019 Youth Risk Behavior Survey, in 2019, 4.8%(N=5,049)of Chicago Public School (CPS) high school students and 1.5%(N=3,030)of middle school students reported having been pregnant or gotten someone pregnant in the past 12 month[1,2,3] Furthermore, teen birth rates are disproportionately higher in the Belmont Cragin and Austin neighborhoods (33.6 and 40.7 per 1000, respectively) as are teen birth rates in several community areas with a Very Low Child Opportunity Index. While citywide initiatives have placed emphasis on teen pregnancy prevention strategies through long-acting reversible contraceptives and sexual health education, limited attention has been given to identification, development, and implementation of best practices to support CPS students who are currently pregnant and/or parenting (PPY). Existing supports within CPS are varied throughout the district and are uncoordinated with minimal streamlined processes in providing comprehensive academic supports to pregnant and parenting students. Limited support and lack of tailored interventions contribute to the challenges that PPY are already facing, including but not limited to stigma, low academic achievement, school drop-out, pre-term births, low childbirth weight, and postpartum depression[4]. Addressing this gap provides opportunity for improved health outcomes for both pregnant and parenting students as well as their children. Building off findings from a previous study and Healthy Communities funded project, we propose to explore methodology used to track the number of pregnant and or parenting students attending CPS as well as count the number of PPY attending CPS, and types of support provided to PPY using a newly developed survey.

References:

1. Centers for Disease Control and Prevention. (2019). Youth Risk Behavior Survey Questionnaire. Available at: www.cdc.gov/yrbs.

2.Hamilton BE, Mathews TJ. Continued declines in teen births in the United States, 2015. NCHS data brief, no 259. Hyattsville, MD: National Center for Health Statistics. 2016.

3.Hamilton BE, Rossen LM, Branum AM. Teen birth rates for urban and rural areas in the United States, 2007–2015. NCHS data brief, no 264. Hyattsville, MD: National Center for Health Statistics. 2016.

4.Bledsoe, S. E., Rizo, C. F., Wike, T. L., Killian-Farrell, C., Wessel, J., Bellows, A. M. O., & Doernberg, A. (2017). Pregnant adolescent women's perceptions of depression and psychiatric services in the United States. Women and Birth, 30(5), e248-e257

*required

State the main hypothesis and/or objective(s).

B.2

This study will explore the methodology used to track the number of PPY attending CPS, aim to provide an accurate count of PPY currently attending CPS, and assess concerns in tracking

PPY students.

*required

State the main study outcome measures/endpoints.

B.3

Explore how staff at CPS high schools track the number of PPY attending CPS and quantify the number of PPY attending CPS.

*required

List the inclusion criteria.

B.4

To be eligible to participate:
1.Staff must be 18 years of age or older
2.Employed by CPS
4. Able to understand written and spoken English

*required

List the exclusion criteria.

Include the justification for any exclusions related to age, biological sex, race, ethnicity, language, or social status.

B.5

1. Not 18 years of age or older
2. Not employed by CPS
3. Unable to understand written and spoken English

Participants will be excluded if the are under the age of 18 as we are looking for adult survey participants, not employed by CPS as we are specifically looking to assess tracking PPY students attending CPS schools. Participants will also be excluded if they are non-English speaking. Non-English-speaking participants are excluded from the study as the study team does not have staff who can support creating the survey in a language other than English.

C Population

*required

C.1 Check all targeted age ranges of participants to be enrolled in this study.

Children (*0-17 years*)

✓ Adults *(18 years and older)*

Parents of children treated at Lurie Children's

*required

Select all other targeted special populations in this study.

C.2

For guidance regarding Vulnerable Participants, refer to IRB Policies & Procedures Manual Section 12.

Pregnant individuals, Fetuses

Nonviable Neonates and Neonates of uncertain viability

Research involving the placenta, the dead fetus or fetal material after delivery

Prisoners/Detainees

Minors who can consent for themselves.

- This includes minors, ages 12-17, that can consent to diagnosis, treatment or care for pregnancy, birth control, alcohol or substance abuse, HIV or other STI testing/treatment, and/or mental health services.

Lurie Children's and/or Northwestern Employees/ Medical Students

Cognitively Impaired Adults

Children within DCFS custody (Illinois Department of Children and Family Services)

✓ N/A

*required

C.3 Does this study target any health disparity population(s)?

Yes, a health disparity population is a targeted population of this research.

Yes, a health disparity population is not a specific target of the research but the recruitment and study contact methods will be enrolled to assure inclusion of a health disparity population.

✓ No, a health disparity population is neither a specific target nor is the study written to assure inclusion of health disparity populations.

*required

How many participants are expected to be enrolled at Lurie Children's?

C.4

Provide the number of participants needed to complete the study. For studies without direct participant contact, "N/A" is an acceptable answer.

N=200 participants will complete the survey.

*required

C.5 Is this a multi-center study with enrollment at other sites?

Yes

✓ No

D Research Procedures

*required

List and describe all procedures/interventions to be done and/or data to be collected as part of this study. Ensure all optional study procedures (e.g., banking, genetic testing, etc.) are also included below.

D.1 If a visit schedule/table is not provided in D.2, ensure that this narrative includes the expected location and length of each visit.

There is one online study visit to complete all research procedures. CPS staff will be invited to participate in a one-time online survey through RedCap, a secure web-based data collection platform. Participants will be screened for eligibility and if eligible will provide informed consent prior to completing the survey. The study visit will last approximately 15 minutes.

D.2 If a visit schedule/table is being used to outline these procedures/interventions, upload it here.

This table should include the expected location and length of each visit.

*required

D.3 Aside from chart review, are any of the procedures listed in *Item D.1* being done for research purposes only or being done more frequently than for usual clinical care?

- Yes
- ✓ No

*required

D.5 Does this study include genetic testing?

- Yes
- ✓ No

E Statistical Analysis

*required

Describe the statistical plan for the study, including appropriate references to the protocol.

E.1

Descriptive statistics will be used to describe the characteristics of staff (school, job title) as well as experience working with and tracking progress and needs of pregnant and parenting students.

F Survey, Questionnaire, or Interview

*required

F.1 Does the study utilize surveys, questionnaires, or interviews/focus groups?

✓ Yes

*required

Attach all copies of surveys, questionnaires, or scripts for interviews/focus groups.

F.1a

TALLY Survey 9.2.22_CLEAN.docx

TALLY Survey 9.2.22_TRACKED.docx

No

4 Drugs, Biologics, and Devices

A Inclusion of Investigational Drugs, Biologics, and Devices

For guidance on Investigational Use of Drugs/Biologics, refer to IRB Policies & Procedures Manual Section 8.

*required

A.1 Select all that will be included:

- [ ] Investigational Drug(s) or Biologic(s)
- [ ] Investigational Device(s)
- [x] N/A

5 Risks, Benefits, and Safety

A Study Risks

*required

A.1 Are there risks associated with study participation aside from those related to confidentiality / privacy as outlined in *Section 6?*

✓ Yes

*required

List and describe the physical / psychological / emotional risks and discomforts of the study interventions and procedures.

A.1a

The proposed study poses minimal risks to participants. Participants will be asked to answer questions they may find uncomfortable discussing topics around tracking the number pregnant and parenting students, however, we feel the risk of this discomfort is minimal.

*required

Summarize the procedures for minimizing risks that are related to study interventions and procedures.

A.1b

Participants will have the right to refuse to answer any questions that they are uncomfortable answering. Additionally, participants will be able to end participation in the survey at any point.

*required

Confirm that each of the following elements will be utilized as a part of the patient safety monitoring plan at Lurie Children's study site(s).

A.1c

- The PI will monitor all safety events and treat side effects as applicable. Monitoring will be maintained until all events/side effects resolve.
- The sponsor, if applicable, will be notified of all safety events as required per protocol and policies.
- The IRB will be notified of all Unanticipated Problems, Serious Adverse Events, Incidents, and Major Protocol deviations as

required per the IRB Policies and Procedures Manual Section 13. An Incident Assessment tool is also available to assist with these evaluations.

✓ Yes

*required

A.1d

Confirm that the following steps will be taken if clinically significant incidental findings occur during the course of study related interventions or procedures (e.g. genetic testing, imaging, blood tests, testing for infectious disease, etc.):

- The PI will assess and identify which incidental findings are of likely clinical significance.
- The PI will identify which results will be reported to participants. The PI will develop a plan for disseminating results that may include referral to another clinic, physician or provider, or information about alternative resources for obtaining care.

✓ Yes

No

*required

A.2

Describe the monitoring plan to periodically assess the data to ensure the safety of participants.

Study staff will examine how many participants choose to skip questions, which questions are frequently skipped, as well as how many participants choose to terminate the survey due to discomfort and modify the survey as needed.

*required

A.3 Is there a data safety monitoring board/committee (DSMB/C) for this study?

Yes

✓ No

B Potential Benefits and Alternatives

*required

B.1 Are there any anticipated direct benefits to the individual study participants?

Yes

✓ No

*required

Describe any potential indirect benefits to future persons, science, and/or society.

B.2 Participants will not experience direct benefits. However, they may feel good about sharing their experience working within CPS and with PPY. Potential benefits to society include generation of knowledge about tracking the number of pregnant and parenting students attending CPS and how to better ensure their academic and health needs are being met.

*required

B.3 Does this study involve interventions?

Yes

✓ No

6 Confidentiality and Privacy

Protections for Participant Confidentiality

A

Confidentiality refers to the protection of a participant's identity, their protected health information, and the information/documents collected as a part of a research study.

*required

A.1 Will medical records be accessed as part of this study?

- Yes
- ✓ No

*required

A.2 How will the study data will be stored? Select all that apply.

- Study data will be stored with participant's identifiers.
- Study data will be stored separately from participants' identifiers and will be linked by a code.
- ✓ Study data will not be stored with participants' identifiers and identifiers will not be maintained (i.e. all collected identifiers will be deleted and not linked with a code).

*required

A.3 How will the study specimens will be stored? Select all that apply.

- Study specimens will be stored with the participants' identifiers.
- Study specimens will be stored separately from participant identifiers and will be linked by a code.
- Study specimens will not be stored with participants' identifiers and identifiers will not be maintained (i.e. all collected identifiers will be deleted and not linked with a code).
- ✓ N/A; no specimen collection is occurring in this study.

*required

Provide the security plan for the confidential storage of study data and / or specimens (e.g., password protections, locked cabinets, use of encryption, etc.).

A.4

Study data will be stored in password protected computers in locked offices to which only members of the study team have access. Only IRB approved study team members will have access to study data.

*required

A.5 Will study data and/or specimens be stored for future research purposes?

Yes

✓ No

*required

A.6 Is there a Certificate of Confidentiality for this study?

Yes

✓ No

*required

Protections for Participant Privacy

B

Privacy refers to the way potential participants are identified/contacted, the setting in which they'll be approached/seen, and who is present during participant interaction.

*required

B.1 Will there be direct participant contact or interaction?

✓ Yes

*required

B.1 Select the precaution(s) that will be used a to maintain participants' privacy.

✓ The consent process will be done privately.

✓ All study procedures will be conducted in a private room/space.

✓ Participant information and study conduct will only be discussed with individuals listed in the study personnel.

Other

No

*required

C Release of Participant Data/Specimens

Release refers to the transfer of Lurie Children's study participant data and/or specimens to authorized individuals/entities outside of the institution.

*required

C.1 Will participants' study data be released outside of Lurie Children's?

Yes

✓ No

*required

C.2 Will participants' specimens be released outside of Lurie Children's?

Yes

✓ No

*required

D Will any recruitment, consenting, or research procedures be conducted via an electronic or technology platform?

✓ Yes

*required

D.1 Select which platform(s) will be used and describe the procedures that will take place using the platform(s).

Lurie Children's Microsoft Teams

Lurie Children's Zoom

Avaya EC500 Dialer

✓ Northwestern University REDCap

If electronic consent will be obtained via REDCap and the study is FDA drug/device/biologic) please review the required training and informatic https://www.nucats.northwestern.edu/resources/data-science-and-infor

Qualtrics

Lurie Children's Telemedicine

Other

*required

D.2 Describe the procedures that will be conducted on the platform(s) selected above.

Participants will complete the surveys remotely via REDCap. It is up to their discretion as to the environment in which they complete the research activities. We will advise all participants to complete the consent and survey in private.

*required

D.3 Provide details on how study participant's confidentiality (personal information) will be protected while using the platform(s) selected above.

Consent and survey data will be collected via Northwestern's instance of REDCap, a highly secure web application for building and managing online surveys and databases. Data will be collected directly into REDCap using a weblink. Participants have the opportunity to enter an email address in order to receive a stipend for participation. This

email will not be linked to study data. None of the remaining 18 identifiers will be collected for this study.

*required

Provide details on how study participant's privacy (undisturbed or observed) will be protected while using the platform(s) selected above.

D.4

Participants will be encouraged to complete the survey in a private environment. Should the participant start the survey, and no longer have access to a private space, they will be able to pause the survey, and resume once they are able to complete the survey in a private space.

*required

D.5 Does the research activity to be conducted over the technology involve the collection, sharing or transmission of Protected Health Information (PHI)?

Yes

✓ No

*required

D.6 Will research encounters be recorded on the requested software?

Yes

✓ No

No

*required

General Data Protections Regulation (GDPR) for International Participants

E *The General Data Protection Regulation (GDPR) is a European Union law that protects the privacy and security of personal data of individuals (data subjects) are who are in the European Economic Area (EEA). The GDPR applies to individuals physically present in the EEA, which includes: EEA citizens, EEA residents, anyone visiting an EEA country while enrolled on a study.*

*required

E.1 Will persons in a European Economic Area (EEA) be recruited and/or enrolled for participation in this study?

Yes

✓ No

If during the course of this study, the investigator/study team becomes aware that a participant will be in an EEA country, extra consent provisions may apply. Please contact ORIC Staff for guidance.

---

7 Recruitment and Compensation

A Recruitment

For guidance regarding Participant Selection and Recruitment, refer to IRB Policies & Procedures Manual Section 10.

*required

A.1 Select all recruitment methods that will be used.

- ✓ Verbal (Direct participant contact)
- ✓ Referral from colleagues
- Direct recruitment by study staff in departments/divisions/clinics not represented by the study personnel listed in Section 1 General Information
- ✓ Email
- ✓ Flyers
- Letter from investigator
- Letter from personal physician
- Newspaper/Magazine Advertisements
- ✓ Telephone interview (recruitment script)
- Public Website(s)
- Medical Records
- Investigator's Records (study records, databases, or registries)
- ✓ Social Media (e.g., Facebook, Twitter, Instagram, Snapchat, etc)
- Other

*required

Describe how participants will be recruited in this study, using the methods as indicated above.

A.2 Online recruitment ads will consist of emails, advertisements on social media sites, including Facebook.com, Twitter.com, and Instagram.com. The recruitment messages/posts will contain a link to the study survey, hosted via REDCap. Clicking on the link will take users to the webpage containing project information and the eligibility screener followed by the study survey. Additionally, potential participants will be contacted by email or phone by trained study staff regarding research participation using a standardized recruitment script. Interested participants will then be sent an email to the eligibility screener and subsequent survey

*required

Attach all recruitment materials.

All public recruitment materials must include the following required language (completed with the study information):

"This study is Lurie Children's IRB #, TITLE, Principal Investigator Name. The content of this flier/brochure/e-mail/etc. has been approved by the Lurie Children's IRB."

A.3 TALLY Screener 9.2.22_CLEAN.docx

TALLY Screener 9.2.22_TRACKED.docx

TALLY Email Script 9.2.22_CLEAN.docx

TALLY Email Script 9.2.22_TRACKED.docx

TALLY Recruitment 9.2.22.png

TALLY Recruitment 9.2.22_part 2.png

*required

List all sites/applications/platforms that will be utilized.

For guidance regarding the use of Internet and Social Media, refer to IRB Policies & Procedures Manual Section 10.2.

A.4 Online recruitment ads will consist of emails, advertisements on social media sites, including Facebook.com, Twitter.com, and Instagram.com. The recruitment messages/posts will contain a link to the study screening survey, hosted via REDCap. Clicking on the link will take users to the webpage containing project information and the eligibility screener. Ads and recruitment messages will be posted until recruitment goals for the study are met.

*required

A.5 Confirm that if the site/platform is governed by an administrator (i.e. for private or semi-private sub-groups within the site/application), permission has been or will be obtained from the administrator and the groups policies and rules will be upheld.

✓ Yes

*required

A.6 What is the name and owner of the account from which the recruitment will be posted? Include appropriate justification if the recruitment will be posted by the investigator's personal account.

Recruitment will be posted from Lurie Children's Adolescent Medicine accounts, and/or Chicago Public Schools accounts.

*required

A.7 Confirm the frequency of each post is keeping the number of posts to the minimum necessary to achieve exposure.

✓ Yes

*required

A.8 Confirm that that persons who share or comment to posts will not be directly solicited/contacted for direct recruitment and that questions are responded to with a statement that indicates who that person can contact to have this question answered directly.

✓ Yes

*required

A.9 Confirm that investigators and members of the study team will not “tag” specific individuals in posts or replies/comments.

✓ Yes

*required

A.10 Confirm that if any PHI is posted in response to recruitment posts that this information will not be collected for part of the study data.

✓ Yes

*required

A.11 Provide the plan to monitor replies, sharing, and likes of recruitment posts and answering questions to posts.

A spreadsheet tracking shares, and likes will be updated on a monthly basis. Potential participants who have questions will be able to contact the researcher listed on the recruitment post.

*required

A.12 Will children be recruited via social media?

Yes

✓ No

B Payment/Compensation/Reimbursement to Participants and Families

For guidance on Compensation and Reimbursement, refer to IRB Policies & Procedures Manual Section 10.1.D.

*required

B.1 Will there be payment/compensation/reimbursement to participants and/or their families?

✓ Yes

No

*required

B.2 Select all types of payment(s) to participants and/or families.

Reimbursement for expenses.

✓ Compensation for time and effort.

*required

B.2b Specify the dollar amount method/form and timing of compensation for expenses to participants/families. f this will be provided in the form of a gift card, please provide the details of the gift card.

Participants will receive a $10 Tango gift card upon completion of the survey.

Gifts (such as presents or toys)

8 Informed Consent

Informed Consent and Waivers

A

For guidance regarding Informed Consent and Waivers, refer to IRB Policies & Procedures Manual Section 11.

*required

A.1 From the list below indicate how consent will be obtained for this study. Select all that apply.

- Written/signed permission for a minor by a Parent or Legal Guardian
- Written/signed consent by the adult or a Legally Authorized Representative (for adults incapable of consenting)
- Written/signed assent (patients 12-17)
- ✓ Waiver or Alteration of the informed consent process (including waivers of parental permission or adolescent assent, waiver of documentation, or alteration)

*required

A.2 Indicate the type(s) of waiver of informed consent requested for this study. If more than one type of waiver is being requested for different groups in the study, select all that will apply.

For guidance regarding waivers of informed consent, refer to IRB Policies & Procedures Manual Section 11.5.

- Waiver of Informed Consent
- Waiver of Parental Permission
- Waiver of Adolescent Assent
- ✓ Waiver of the Requirement of Obtaining a Signed Consent Form
- Alteration of the Informed Consent Process

*required

A.3 Indicate if you are obtaining HIPAA authorization from the participant or requesting a waiver of HIPAA authorization.

Obtaining HIPAA authorization in consent form

Full or partial waiver of HIPAA authorization

✓ HIPAA does not apply as no identifiers are being maintained with this study.

B Consent Process

For guidance regarding the Informed Consent process, refer to IRB Policies & Procedures Manual Section 11.

*required

B.1 Describe the expected method of obtaining consent from potential participants. Include the following:

- Where consent will take place
- Measures to ensure that potential participants understand the study procedures
- Describe the timing of the informed consent process prior to study procedures occurring. Include a discussion of the adequacy of the allotted time for potential participants/their families to make a decision.

Online consenting will be facilitated by web-based platform administered through RedCap. Rather than being required to sign the document, potential participants will indicate their consent by clicking. The potential participant must provide informed consent by clicking that they agree to participate in the study when the Informed Consent process occurs remotely online.

*required

B.2 Describe the measures that will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion.

Any study that pays a stipend may engender coercion. Eliminating the possibility of coercion by not awarding stipends would make it impossible to conduct many studies, and would shortchange subjects who provide time and energy, and may incur costs such as bus, train or car fares. The resolution to this problem is to ensure that stipends are not inappropriately

large, to probe potential subjects to make sure they have not been coerced, and to give persons who may have been coerced the opportunity not to enroll in the study in a manner that will protect them from retribution by the person coercing them. We believe we meet these conditions. The stipends we proposed are in use now in other studies at both Lurie Childrens and have been reviewed by our own and other IRBs for potential coerciveness.

*required

B.3 Does the PI anticipate obtaining consent from non-English speaking patients?

For guidance regarding obtaining consent from non-English speaking patients, refer to IRB Policies & Procedures Manual Section 11.3.

Yes

✓ No

B.3b Confirm that if non-English speaking participants are found to be eligible and offered consent, the IRB short form and an interpreter will be used to obtain consent.

✓ Yes

F Waiver of the Requirement of Obtaining a Signed Consent Form

For guidance regarding Waivers or Alterations of Consent, refer to IRB Policies & Procedures Manual Section 11.5.

*required

F.1 Select which criterion applies to this study.

(1) That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The participant must be offered an opportunity to sign a consent form and be told this document will link them with the research.

(2) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the

✓ research context.

Please ensure the information sheet(s) is attached in Section 9 *Supporting Documents*.

*required

Provide justification for how this study meets the criteria for this waiver.

F.2

We believe this study meets the criteria for minimal risk as defined by 21 CFR 50.3(k) or 56.102(i)). The probability and degree of harm or discomfort anticipated in the survey are not greater in and of themselves than those ordinarily encountered in daily life.

9 Supporting Documents

A Protocol and Consent Documents

Refer to the IRB Consent Forms & Resources Page for all informed consent templates and guidance for writing the documents.

A.1 Attach the main study protocol

A.2 Attach the Lurie Children's parental permission forms to be used for this study

A.3 Attach the Lurie Children's adolescent assent forms to be used for this study

A.4 Attach the Lurie Children's adult consent forms to be used for this study

A.5 Attach the Study Information Sheets if a Waiver of the Requirement of Obtaining a Signed Consent Form was requested

TALLY_information sheet 9.2.22_CLEAN.doc

TALLY_information sheet 9.2.22_TRACKED.doc

B Additional Supporting Documents

B.1 Attach Package Inserts or Investigator's Brochures for drugs/biologics and device label and instructions for use.

B.2 Study diaries

B.3 Miscellaneous Sponsor/FDA Documentation

*required

B.4 Do any other documents require IRB review?

✓ Yes

*required

Attach any other documents requiring IRB review.

B.4 TALLY Screener 2.1.22.docx

RRB#2022-1769- Amy K Johnson, PhD, MSW 2022-04-29.docx

No

WE WANT TO HEAR FROM

HELP US LEARN MORE ABOUT THE NUM PREGNANT AND PARENTING STUDENTS A CPS!

You may be eligible if you are...

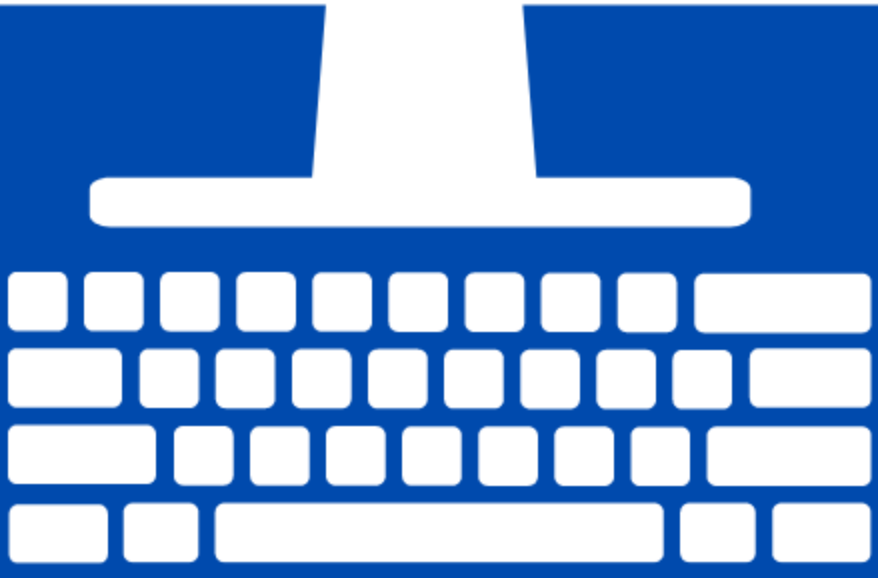
- 18 years of age or older
- Employed by CPS
- Understand written and spoken English

LEARN MORE →

To participate in this study, you would complete a brief online survey.

Participants receive a $10 gift card for their time.

If you're interested in participating in the survey, email knikolajuk@luriechildrens.org for more information.



Date:

Lurie Children's Hospital and Chicago Public Schools are collaborating on a survey study to gather data on how staff at CPS schools track the number of pregnant and parenting young people (PPY) attending school, and the support staff provide to these students. Survey results will remain anonymous. We will combine all survey data to report our findings to CPS to help develop new strategies to support PPY as well as refine current strategies. Please take 10-15 minutes to complete the following questions. Thank you for your time.

1. Which of the following best describes your role at CPS? Select all that apply.
□ School Counselor
□ School Social Worker
□ Case Manager
□ Other (please describe)

2. What is the name of the school where you spend most of your time?

3. Approximately how many **pregnant** students attended your school during the 2021-2022 school year?
   A. 0-5
   B. 6-10
   C. 11-20
   D. More than 20

4. How does the number of **pregnant** students who attended your school during the 2021-2022 school year compare to previous years?
   A. Fewer than previous years
   B. Equal to previous years
   C. More than previous years

5. Approximately how many **parenting** students attended your school during the 2021-2022 school year?

   A. 0-5
   B. 6-10
   C. 11-20
   D. More than 20

6. How does the number of **parenting** students who attended your school during the 2021-2022 school year compare to previous years?
   A. Fewer than previous years
   B. Equal to previous years
   C. More than previous years

7. Does your school have a system to count the number of pregnant and parenting students who attend each year?

A. Yes
B. No
C. Unsure

8. Select all that apply. If your school does count the number of pregnant and parenting students who attend each year, how does your school collect this number?

A. Through student academic records
B. Through student attendance records
C. Through applications for homebound instruction
D. Through self-disclosure from student
E. Student accommodations (elevator pass, excusal from gym, bathroom pass, etc.)
F. Medical documentation
G. Support with lactation space
H. Other (please describe)
I. Our school does not count the number of PPY who attend each year

9. Select all that apply. What are the challenges you've experienced in tracking the number of PPY attending school?

A. Confidentiality concerns with school records
B. Confidentiality concerns with medical records
C. Limited staff capacity
D. Student records do not contain any information about their PPY status
E. Other (please describe)

10. In your opinion, how would the number of PPY attending your school ideally be captured?

A. Through student academic records
B. Through student attendance records
C. Through applications for homebound instruction
D. Through self-disclosure from student
E. Student accommodations (elevator pass, excusal from gym, bathroom pass, etc.)
F. Medical documentation
G. Support with lactation space
H. Other (please describe)

Ann & Robert H. Lurie
Children's Hospital of Chicago

Study Title: TALLY: **T**otal **All**-important pregnant and parenting **Y**outh count
Study Doctor/Researcher: Amy K. Johnson, PhD, MSW
Sponsored by: Magoon Institute for Healthy Communities

You are being asked to take part in this study because you are 18 years of age or older, employed by Chicago Public Schools (CPS), and are able to understand written and spoken English. If you choose to be in the study, you will complete a survey. This survey will help us learn more about the number of pregnant and parenting students attending CPS. The survey will take about 15 minutes to complete. About 200 participants will be asked to take this survey.

Being in this study is optional and voluntary. You do not have to take this survey if you do not want to. The answers that you provide in the survey may still be used if you stop the survey and do not finish. You can skip questions that you do not want to answer or stop the survey at any time.

The survey will ask you for information that can identify you. The identifiable information that will be collected is your email address. The investigators need to collect this information because it will allow investigators to provide you with a stipend for your time. If you do not want to receive a stipend, you do not need to provide your email address. The answers you give for the survey will not be stored with your identifiable information but will be stored separately in a secured file. The answers to the survey will be coded with a unique ID number.

You must be at least 18 years old to take part in this research survey.

There are no direct benefits to you for taking this survey. The information learned from this survey will help the researchers learn more about the number of pregnant and parenting students attending Chicago Public Schools (CPS).

There is a risk of breach of confidentiality or privacy. The investigator is taking steps to reduce this risk by coding the survey answers with an ID number and storing the information on a password protected computer.

Insert if this will be an online survey: This survey will be done online using the service of RedCap. Information provided in this survey can only be kept as secure as any other online communication.

Participants who complete the survey will receive a $10 dollar e-gift card for their time. Gift cards will be emailed to participants at the completion of the survey. Participants who do not complete the survey or withdraw from the study will not be compensated.

This study survey will be placed the Principal Investigator's research file. The principal investigator, co-investigators, Lurie Children's doctors who are involved in the study and the staff who work on the study, such as study nurses and coordinators, will have access to the study results. The Lurie Children's Institutional Review Board, the committee that is in charge of protecting the rights of all adults and children who take part in research studies at Lurie Children's, and federal agencies may have access to this information. These are the only people to which we will give your information. We cannot guarantee that those listed above will not share it with others without your permission.

Your name will not be included in any written or verbal reports of study results.

If you agree to take part in this study, you are not giving up any of your legal rights. If you agree to take part in this research survey, you will not be able to look at or ask for a copy of your information collected only for this study, while you are taking part in the study.

If you have any questions about the research, you should contact the principal investigator, (Amy K Johnson)), or colleagues (Katie Nikolajuk) by contacting akjohnson@luriechildrens.org or knikolajuk@luriechildrens.org.

If you have questions about your rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

This study has been reviewed and approved by the Lurie Children's Institutional Review Board (IRB); IRB #2022-5223.

By clicking on the button below, you indicate your voluntary agreement to take part in this research study by completing this online survey.

Ann & Robert H. Lurie
Children's Hospital of Chicago®

Expedited Modification Approval Letter

Amy Johnson, MD
Adolescent Medicine

PROTOCOL TITLE: TALLY: Total ALL-important pregnant and parenting Youth count

IRB 2022-5223

IRB APPROVAL DATE: September 25, 2022

IRB EXPIRATION DATE: January 31, 2025

Please Note: Due to COVID-19 restrictions, please refer to the Lurie COVID-19 Resource Page for Healthcare Providers for more information before conducting research procedures.

Approved as Risk/Benefit Category:

45 CFR 46.404/21 CFR 50.51 Research not involving greater than minimal risk.

The Ann & Robert H. Lurie Children's Hospital of Chicago Institutional Review Board (Lurie Children's IRB) has reviewed and approved by expedited review the modification to the protocol referenced above. Refer to the PDF of the Cayuse IRB application for the details and documents reviewed with this modification. This modification includes the following as fully described in *Section M2 SubSection A*:

- Study design and/or procedures and/or updated study protocol [TALLY Protocol 9.2.22]
- Waivers of Consent and/or HIPAA Authorization
- Recruitment materials, verbal scripts, survey instruments, web-based instruments, questionnaires, etc.

YOUR OBLIGATIONS AS PRINCIPAL INVESTIGATOR:
As the Principal Investigator, you are ultimately responsible for the conduct of the use, the protection of the rights and welfare of human subjects and adherence to the Lurie Children's IRB and hospital policies and procedures (Lurie Children's IRB Policy and Procedure Manual), including, but not limited to Section 5: Investigator Responsibilities and the following:

1. Ensure that all individuals who will work on the approved protocol are qualified, listed as Research Personnel in the Cayuse IRB application, and have completed the human subject protections education requirement.
2. Submit the renewal progress report for review and approval in advance of the expiration date.
3. Do not implement changes in the approved protocol or consent form(s) without prior IRB approval (except to eliminate apparent immediate hazards to safeguard the well-being of human subjects).
4. Obtain the legally effective written informed consent from human subjects or their legally authorized representatives as is applicable, using only the currently approved Lurie Children's IRB stamped consent form(s).
5. Report any unanticipated problems or noncompliance per IRB policies.
6. Wait until the study contract/award (if applicable) is fully executed before beginning work on the study. Contact the Office of Sponsored Programs for information about the status of the clinical trial agreement or grant award.
7. Register your study: Applicable clinical trials (i.e., interventional studies of FDA-regulated drugs, biological products, or devices) must be registered on clinicaltrials.gov by the responsible party, typically the sponsor or a PI if designated by the sponsor (refer to FDAAA 801). In addition, the International Committee of Medical Journal Editors (ICMJE) recommends that all medical journal editors require registration of clinical trials in a public trials registry at, or before, the time of first patient enrollment as a condition of consideration for publication. Their definition of a clinical trial is much broader than federal requirements. Please refer to the ICMJE recommendations Section IIIK. Your study will be listed on the Clinical and Translational Research webpage for the hospital.
8. Notify any departments providing research support of modifications to the protocol that would impact services provided (e.g., pharmacy, medical imaging, laboratory services, etc.).

Sincerely,

Institutional Review Board
Ann & Robert H. Lurie Children's Hospital of Chicago

TALLY

IRB#:2022-5223
Version Date: 9/2/2022
Principal Investigator: Amy Johnson, PhD

Staff Screening Survey

We are seeking to learn more about the number pregnant and/or parenting young people who attend CPS. To determine your eligibility to participate in our study, we need to ask a few screening questions. You may skip any questions that you do not feel comfortable answering. cking on the button below, you indicate your voluntary agreement to determine your eligibility to compete the research survey,

What is your age?	Years:
Are you employed by Chicago Public Schools?	☐ Yes ☐ No
Are you able to speak and understand English?	☐Yes ☐ No
Script if participant is **eligible**: Thank you for completing this survey. You are eligible to participate in the study.	Script if participant **is not eligible**: Thank you for completing this screening survey. Unfortunately, you are not eligible to participate in the study. Thank you for your interest.

42 W. Madison | 2nd Floor | Chicago, IL 60602
Telephone: (773) 553-4444
Fax: (773) 553-2421

11/01/2023

Amy K Johnson, PhD, MSW
1440 North Dayton Street
Chicago, IL 60642

Dear Dr. Johnson,

Thank you for your interest in conducting research in The Chicago Public Schools. The Research Review Board has reviewed your Continuing Review proposal 10/02/2023 for research, titled: TALLY: Total ALL-important pregnant and parenting Youth count.

The Research Review Board has completed the review of your Continuing Review proposal and has approved your request to conduct this research. Although your study is approved, school principals have final authority over activities that are allowed to take place in the school. If data collection continues beyond a year from this approval, please complete the Modification & Continuing Review Process Form through IRBManager.

Please note the following--

Background Check Level Required: Level I

Other Notes: Interactions with Staff

Upon completion of the research study, a copy of the final report or summary of the results must be provided to the Research Review Board. The Board reserves the right to use the information in the research report or summary for planning, solicitation or grants, and staff development.

Please note that your study has been assigned Project ID #2022-1769. If you have any questions, please contact our office by email at research@cps.edu.

Sincerely,

Sarah Dickson
Co-Chair, Research Review Board