PROTOCOL TITLE:

Evaluation of Contraception Care @ Behavioral Health Pavilion

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Version 2 / 10/8/2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/6/2021	Change in pilot study population	n
2	10/8/2021	- Updated ICF information - Updated communication methods - Revised EHR study variables – Appendix D	y

1.0 Study Summary

Study Title	Evaluation of Contraception Care @ Behavioral Health Pavilion
Study Design	Longitudinal Survey Study
Primary Objective	1. Examine interest in receiving contraception counseling among female adolescents hospitalized with mental health disorders. 2. Examine contraception initiation among female adolescents hospitalized with mental health disorders
Secondary Objective(s)	Examine associations between short- and medium-term outcomes and predictor variables among female adolescents with mental health disorders
Research Intervention(s)/ Investigational Agent(s)	The protocol here entitled "Evaluation of Contraception Care @ Behavioral Health Pavilion" describes how the investigators plan to examine interest in receiving contraception counseling and contraception initiation.
IND/IDE #	N/A
Study Population	Female adolescents 14 years and older hospitalized for mental health disorders at Nationwide Children's Hospital.
Sample Size	N = 450
Study Duration for individual participants	5 months
Study Specific Abbreviations/ Definitions	LARCs: long-acting reversible contraceptives LGBTQ: lesbian, gay, bisexual, transgender, queer EHR: electronic health record QI: quality improvement NCH: Nationwide Children's Hospital

2.0 Objectives

2.1 The purpose of this study is to examine interest in receiving contraception counseling and contraception initiation female adolescents hospitalized with mental health disorders.

The primary objectives of this study are to 1) Examine interest in receiving contraception counseling among female adolescents hospitalized with mental health disorders, and 2) Examine contraception initiation among female adolescents hospitalized with mental health disorders.

Multiple secondary objectives will be investigated during the study. They include:

- To assess the proportion of female adolescents hospitalized with mental health disorders that receive contraception counseling or are prescribed/initiate any contraceptive during hospital admission or immediately post discharge.

- To determine predictors of receipt of contraception counseling and contraception initiation among female adolescents hospitalized with mental health disorders
- Assess satisfaction with and person-centeredness of contraception care among participants who received contraceptive counseling

2.2 State the hypotheses to be tested: N/A

2.3 Of note, this study is externally funded by Merck Inc. The PI has a conflict management plan in place approved by the compliance department.

3.0 Background

3.1 Approximately one in five American youth have experienced severe impairment due to mental health disorders, with anxiety and mood disorders being most common among female adolescents.[1] Mental health disorders are associated with a range of sexual risk behaviors and unintended pregnancy.[2,3] Youth with mental health disorders have higher rates of condom and contraception non-use (especially short acting),[2,4–6] earlier sexual debut,[2] and higher fertility rates.[7]

Avoiding an unwanted or unintended pregnancy is particularly important for women with underlying mental health disorders. Experiencing a pregnancy exacerbates underlying mental health disorders in women with mental health disorder.[8] And children born out of an unintended pregnancy or in context of mother with active mental health disorder face additional risks to their wellbeing. Long-acting reversible contraceptives (LARCs), i.e., contraceptive implants and intrauterine devices, have attributes that may be particularly attractive to adolescents with mental health disorders. They are highly effective and do not require ongoing maintenance. However, adolescents with mental health disorders face multiple barriers to accessing contraception care. Novel solutions are needed to improve access to contraception care, including LARC, for adolescents with mental disorders.

The inpatient pediatric hospitalization setting is a missed opportunity for improving adolescent sexual and reproductive health.[9,10] Nearly 10% of pediatric hospitalizations are for a primary mental health diagnosis, and mood disorders are the most common primary mental health diagnosis among these hospitalizations.[11,12] Sexual and reproductive healthcare is rarely provided to hospitalized adolescents.

3.2 As part of the Hospital Pediatrics: Contraceptive Access Collaborative QI project at Nationwide Children's Hospital, a chart audit completed in December 2019 found that no adolescents hospitalized for mental health disorders on the Hospital Pediatrics service had documentation that they were screened for sexual activity.

3.3 Adolescents are interested in learning about sexual and reproductive health and receiving sexual and reproductive healthcare in the hospital setting regardless of age, gender, and prior sexual experiences.[13,14] Two studies of pediatric hospitalists found that the majority of those physicians felt that sexual and reproductive services are appropriate for hospitalized adolescents, with high support for referrals and starting contraception in the hospital.[15,16] Numerous barriers to inpatient provision of contraceptives/sexual reproductive healthcare were endorsed, including: concerns about follow up after discharge, lack of knowledge about confidentiality, lack of knowledge about contraception, interference with the treatment plan, time constraints, and pregnancy risk in LGBTQ youth. Riese et al.[14] conducted a trial of an interactive patient-facing electronic sexual health module and found that it was acceptable to adolescents and their parents, and that most participants requested a sexual health service after completing the module. (The most requested service was viewing a contraception video made by this PI.)

4.0 Study Endpoints

4.1 The primary endpoints are interest in contraception and contraception initiation. Secondary endpoints are location of contraception counseling and initiation, and contraceptive method choice.

5.0 Study Intervention/Investigational Agent

5.1 The protocol here entitled "Evaluation of Contraception Care @ Behavioral Health Pavilion" describes how the investigators will examine interest in receipt of contraception counseling and initiation among female adolescents hospitalized with mental health disorders.

6.0 Procedures Involved*

6.1 This is an observational study. The study components include participant surveys, EHR data extracts related to sexual and reproductive health, and statistical process control charts for quality improvement analyses. Three surveys will be administered to participants, the first at the time of enrollment, the second immediately after discharge, and the third four months after discharge.

6.2 Potential participants will be approached during their admission at NCH and invited to participate in the study. If they are interested in participation, they will complete an electronic informed consent via redcap, all study participants will receive a copy of their consent via e-mail. If the participant is 14 years old the coordinator will be required to obtain verbal consent from the parent or guardian via Information Sheet. After the consent process is completed, they will fill out the first study survey while they are admitted to the hospital (see Appendix A). The

subsequent two surveys will be sent electronically via their preferred communication method , which will be determined at enrollment. After the last survey is completed the subject will have completed their portion of the study. This is a study with adolescents as the study population and there will be little parental involvement, there are concerns regarding study retention. We will be providing texts as a communication option for the participants as we believe this will be most successful. If a participant chooses this as their preferred contact method. In order to text participants, we will be utilizing Twilio, an NCH approved application.

Study staff will review responses on the following questions on the baseline survey: if the participant indicates they would like to a) learn more about, b) initiate or change contraception methods, and c) desire for privacy for contraception care. Study staff will notify the patient's clinical team if any of these are positive.

On the day of discharge, or the first business day after discharge if participant is discharged during the weekend or a holiday, study staff will send the second survey (see Appendix B) to the participants who indicated interest in contraception counseling and initiation via their preferred communication method. The patient will have 1 month to complete the survey. They will receive weekly reminders if the surveys is incomplete, and after 1 month the participant will be considered lost to follow up for the first follow-up survey. The third survey (see Appendix C) will be sent to the participants who indicated interest in contraception counseling and initiation 4 months after the patient is discharged from the hospital. Again, the participant will be provided the survey link via their preferred contact method and given 1 month to complete the survey and study staff will provide weekly reminders until completion. Completion of the third survey indicates the patient has completed their portion of the study. After 1 month, if the third survey is incomplete, the patient will be considered lost to follow up.

Additionally, routine data pulls from the electronic health record (EHR) will be generated to gather supplementary data not collected from the subject surveys (see Appendix D).

To ensure optimal readability, prior to the start of the enrollment period for the study we will be sending the surveys through the health literacy department. We will also pilot the surveys to 10-15 adolescent patients, ages 14 years and older, we would like to do this in order to get feedback on survey design, so that we can make necessary changes before enrollment starts. These patients may be approached in the Adolescent Medicine Clinic or may be children of NCH employees or other colleagues.

6.3 We do not anticipate any risks associated with enrollment in the study. All PHI and sensitive information recorded for research will only be available to study staff. Additionally, we will be requesting waived parental consent for participants 15 and older to mitigate any potential conflict between parent and participant due to the sensitive nature of this

study. Please see appendices A, B, and C and D for survey and data collection forms.

6.4 Once a participant enrolls in the study, they will then be prompted to complete the baseline survey (Appendix A).

Follow-up surveys will be completed by the participants that indicated interest in contraception counseling or initiation immediately following their discharge and an additional survey will be sent 4 months after discharge (Appendices B & C).

Additionally, EHR data will be collected (Appendix D) for information the participant may not be able to answer (insurance status, previous test results, unit census, etc.)

EHR data will be pulled to create variables for analysis and statistical process control charts to examine predictors of and receipt of contraception-related care among female adolescents 14 and older hospitalized for mental health disorders

7.0 Data and Specimen Banking*

7.1 The data will be kept for 3 years after completion of the study in order to complete data analysis. Through this time period the data will be kept on a password protected spreadsheet in a secure shared drive, only study staff will have access. At this time all data will be de-identified to ensure subject privacy.

7.2 List the data to be stored or associated with each specimen: N/A

7.3 No data containing PHI will be released. However, de-identified study data will need to be reported back to the study sponsor.

8.0 Sharing of Results with Subjects*

8.1 At the completion of data analysis, we plan to send each participant a short letter outlining study findings and how their participation in the study has helped the hospital. We would like to do this to show the importance of research at Nationwide Children's Hospital.

9.0 Study Timelines

- From enrollment to the last follow-up survey subjects' participation will span 5 months.
- It is estimated to take about 18 months to enroll 450 subjects.

10.0 Inclusion and Exclusion Criteria*

10.1 The study coordinator will screen for eligible patients each morning by checking the census in the EHR of specified behavioral health units. The coordinator will enter the charts of patients that appear to eligible for the study to determine whether they meet inclusion criteria.

10.2 Inclusion criteria: female adolescents, 14 years and older, admission to the following units – Psychiatric Units (BHP7B and 8A), Youth Crisis Stabilization Unit, Psychiatric Crisis Department Extended Observation Care Unit and patients with mental health disorders admitted to Hospital Pediatrics 3 service awaiting a psychiatric bed/disposition.

Exclusion criteria: wards of state, unable to consent due to mental health disorder, serious medical conditions, non-English speaking, intellectual disability, and known pregnancy.

10.3 Indicate specifically whether you will include or exclude each of the following special populations:

- Individuals who have not yet reached the age of legal consent will be required to complete study consent. We will be submitting the form to waive parental consent for participants 15 and older as the study questions are sensitive and may impede ability to enroll participants with requirements for parental consent. We will require verbal, parental consent for potential participants who are 14 years of age. We will provide the parent or guardian with a study Information Sheet.
- Pregnant women will be excluded from eligibility in the study. However, if a participant becomes pregnant during the study she will not be required to withdraw, as the only study procedures are questionnaires.

11.0 Vulnerable Populations

11.1 This study intends to enroll children, a special population, and will accordingly adhere to additional protections specified under 45 CFR Part 46 Subpart D – Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46.401-409). The study presents no more than minimal risk, we are requesting a waiver of parental consent for participants 15 years and older. For participants that are 14 years old, verbal parental consent will be obtained. In order to facilitate the participation of youth who may not have disclosed diagnosis and treatment of an STD or contraceptive decisions, to remain consistent with standard of clinical care, and to prevent undo conflict or unsafe situations with guardians regarding the nature of these topics, we request a waiver

of parental consent. However, we will be requiring informed consent to completed by participants as we believe adolescents 14 years of age and older obtain the knowledge and maturity to consent to this study, especially due to the minimal risk associated.

12.0 Local Number of Subjects

12.1 It is expected that 450 participants will be recruited for the study.

12.2 It is expected that 1,000 adolescents will be eligible for the study from 2021-2023. We estimate that 45% will agree to participate.

13.0 Recruitment Methods

13.1 Subjects will be recruited 2021 – 2023. The research coordinator will screen specific inpatient units or services at Nationwide Children's Hospital as identified by the PI, specifically psychiatric units or units where patients with a mental health diagnosis are generally admitted. Each day the coordinator will screen the hospital census for these units to determine admitted patients that meet inclusion criteria. If there is a question, the research coordinate will confer with the patient's psychiatric healthcare provider and/or PI. The coordinator will then approach the patient to determine if they are interested in participation. If they express interest, the research coordinator will confirm inclusion/exclusion criteria and then consent the subject.

13.2 Patients will be identified through the hospital census, of specified units, for admitted patients. A HIPAA waiver will be completed in order to access minimal information to identify potential participants.

13.3 The research coordinator will screen each day from the hospital census of specified units. They will then complete a brief chart review to ensure the patient does meet criteria for the study.

13.4 Upon enrollment the subject will be provided with a ClinCard for study compensation. Those who pilot the surveys will receive a one-time compensation of $20. For those enrolled in the full study, at the time of completion of the enrollment survey $50 will be added to the card. At the time of completion of the two subsequent follow-up surveys $25 will be added for each survey. Subjects can earn up to $100 for their participation. The study is externally funded by Merck.

14.0 Withdrawal of Subjects*

14.1 Participation in the study is always voluntary, so subjects can decide to withdraw at any time by notifying the research coordinator. There are no instances that would require the study team to withdraw a subject as there are no risks to participating in the study.

14.2 Describe any procedures for orderly termination: N/A

14.3 If a subject decides they would like to withdraw they will receive no further contact from study staff, this includes follow-up surveys as well as the memo at study completion. Any data collected prior to the withdraw will be kept and de-identified to protect the subject, unless they request all of their information be removed from the study.

15.0 Risks to Subjects*

15.1 There is minimal risk associated with this study. There is a risk of the subject's parent or guardian learning of the subject's participation study. Additionally, the study surveys do ask some sensitive information; to mitigate any discomfort they may be associated with these questions we will be requesting to waive parental consent, so that the subject is more comfortable participating in the study.

16.0 Potential Benefits to Subjects*

16.1 It is important for researchers and clinicians to better understand the sexual and reproductive healthcare needs of adolescents with mental health disorders, an area that has received little research and clinical interest. Adolescents, themselves, will benefit as care protocols are informed with scientific evidence derived from researching them directly.

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

For our first objective, the dependent variables are interest in receiving contraception counseling during a hospital stay and interest in starting a contraceptive during a hospital stay.

- We will examine interest in receiving contraception counseling during hospitalization among female adolescents hospitalized with mental health disorders by assessing the proportion of participants who answer yes to the following survey question "Interest in learning more about contraception during your hospital stay".
- We will examine interest in initiating contraception during hospitalization among female adolescents hospitalized with mental disorders by assessing the proportion of participants who answer yes to the following question "Interest in starting a contraceptive during your hospital stay".
- We will perform univariate descriptive analyses on all variables.
- We will perform bivariate analysis to explore the relationship between variables "Interest in learning more about contraception during your hospital stay" and "Interest in starting a contraceptive during your hospital stay" using 2 X 2 contingency tables.

- We will explore associations with dependent variables and predictor variables by performing bivariate analyses of "Interest in learning more about contraception during your hospital stay" and "Interest in starting a contraceptive during your hospital stay" with predictor variables from surveys and EHR variables using Chi square for categorical variables and Students T-test for continuous variables.
- We will regress significant predictor variables ($p < 0.1$) on dependent variables to determine predictors of "interest in receiving contraception counseling during your hospital stay" and "interest in starting a contraceptive during your hospital stay".

For our second objective the dependent variables are contraceptive prescription/initiation during hospitalization and contraceptive prescription/initiation following discharge.

- We will create derived variables:
    - Initiation any contraceptive (in hospital, in BC4Teens clinic, none)
    - Initiation preferred contraceptive (in hospital, in BC4Teens clinic, none)
    - Time interval (days) between enrollment and contraception prescription/initiation
    - Initiation of contraceptive not preferred contraceptive (in hospital, in BC4Teens)
- We will perform univariate descriptive analyses on all variables.
- We will examine contraception initiation all among participants by assessing the proportion of participants who initiate any contraceptive in the a) hospital setting, b) in BC4Teens clinic, and c) either hospital or BC4Teens clinic.
- We will examine contraception initiation all among participants by assessing the proportion of participants interested in contraception care who initiate any contraceptive in the a) hospital setting, b) in BC4Teens clinic, and c) either hospital or BC4Teens clinic.
- We will examine how time between enrollment and Initiation any contraceptive varies by location of contraception prescribing/initiation using Student's T test.
- We will also perform the 3 analyses above on the variable "initiate preferred contraceptive"
- We will examine the type of contraceptive method prescribed/initiated in the a) hospital setting, b) in the BC4Teens clinic setting, and c) either hospital of BC4Teens clinic
- We will examine variation in type of contraceptive method prescribed/initiated between the hospital setting and the BC4Teens clinic setting using Chi square.
- We will explore associations with dependent variables and predictor variables by performing bivariate analyses of "initiation

any contraceptive" and predictor variables from surveys and EHR variables using Chi square for categorical variables and Students T-test for continuous variables.

- We will regress significant predictor variables ($p < 0.1$) on dependent variables to determine predictors of initiation any contraceptive.
- To better understand personal and system-level differences in initiation of contraception during hospitalization and in BC4Teens clinic, we will examine differences in demographics, survey variables of interest, and EHR variables of interest between participants who initiate "any contraceptive during hospitalization" and initiate "any contraceptive in BC4Teens clinic" using Chi square.
- To better understand personal and system-level differences in initiation of preferred contraceptive and not-preferred contraceptive we will examine differences in demographics, survey variables of interest, and EHR variables of interest between participants who initiate "preferred contraceptive" and initiate "not preferred contraceptive" using Chi square.
- Statistical process control methods will be used to evaluate trends in contraceptive contraception counseling for hospitalized female adolescents with mental health disorders.
- Statistical process control methods will be used to evaluate trends in contraceptive initiation for hospitalized female adolescents with mental health disorders.
- Statistical process control methods will be used to evaluate trends in initiation of contraceptive implant for hospitalized female adolescents with mental health disorders.

17.2 The enrollment survey as well as follow-up surveys will be collected in RedCap. The database is a secure data management platform that only study staff will have access to. When the data is exported it will all be de-identified. Additionally, there will be quarterly data pulls to gather additional patient information. The data will be stored on a password-protected spreadsheet that only study staff have access to. At the completion of data collection the spreadsheet will be de-identified for purposes of analysis. At this time, the only PHI will be stored on an enrollment log to serve as a master list of all participants, this will also be password protected with access only provided to the study staff.

17.3 Describe any procedures that will be used for quality control of collected data.

- When enrollment begins the EHR data will be gathered more frequently to ensure that the process is obtaining accurate information. During this time the coordinator will

also do manual chart reviews to ensure the data reports are providing the same information. As the study progresses the data extraction will occur less frequently; however, the study coordinator will be required to chart review 5 patients to ensure the data is still intact.

17.4 Describe how data will be handled study-wide:

- During data collection surveys will be stored within RedCap, a secure data management platform. The data pull variables will be kept in a password protected excel spreadsheet. Once the data collected period is over the RedCap data will be merged onto the password protected spreadsheet. At this time the data will be de-identified and a separate participant master list containing PHI will be kept separately. Only study staff will have access to the PHI.
- Data will be stored for three years after the data collection period is complete, this will allow for data analysis to take place.
- Only study staff included on the IRB will have access to the data. When the data is analyzed and given to the biostatistician it will be completely de-identified.
- OSU staff associated with the study will receive study reports. The data will be transmitted via secure transfer through approved electronical modalities. NCH study staff will be responsible for ensuring all data is de-identified prior to sending as well as ensuring secure transfer is successful.
- The sponsor, Merck, has requested quarterly reports as a part of this study. Data transfer will occur electronically through Merck's grant management website. Any study subject level data will be coded with a number and no PHI will be included.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 As research is completely voluntary the study coordinator will fully review the informed consent with the participant, at any time they can decide they do not want to participate and forgo their enrollment. If a patient consents to participate they will be made aware that they may skip any question on the study surveys that they do not feel comfortable answering. At the end of study collection period we will de-identify their responses and keep a separate master list of participants.

18.2 Subjects will be informed that they may skip any portion of the study that they do not feel comfortable with. They will also be informed that they may withdraw from the study at any time with no consequence to their standard of care treatment. The survey questions may be viewed as sensitive and patients may be uncomfortable disclosing information such as sexuality, birth control knowledge or sexual activity with their parent or guardian. The population for the study is ages 14 and up and we believe that subjects have the cognitive maturity to decide whether or not to participate in the study. Accordingly, we will be requesting to waive parental consent for this study.

18.3 All sources of information will be outlined in the consent form, so that the potential survey subject is aware and can make an informed decision. Most of the data will be self-reported from the study surveys. Other demographic and health data will need to be gathered from the patient's EHR to ensure quality data, this data includes information the patient may be unable to report at the time of baseline survey, such as insurance status, administrative hospital census data, results of sexually transmitted infection testing, and hospital encounter diagnoses.

19.0 Economic Burden to Subjects

19.1 Patients will not accrue any additional costs from participating in this study, as the only procedures are three surveys.

20.0 Consent Process

20.1 Indicate whether you will you be obtaining consent, and if so describe:

- The consent process will take place at the patient's bedside during their admission.
- After reviewing the consent with the subject, the research coordinator will ask if they have any questions. There will not be an official waiting period; however, if they would like time to think about participation that will be granted.
- When a participant indicates they would like to learn more about the study, informed consent will be reviewed with the subject by the research coordinator. Potential participants will be educated on the purpose of the study as well as any risks or benefits associated with their participation. The informed consent will contain all study processes as well as the measures that will be taken to ensure any data collected will be kept confidential. They will also be made aware that they can discontinue their participation at any time as research is completely voluntary.
- This study is important because little is known about the sexual and reproductive healthcare needs of female adolescents with mental health disorders. The principle of justice supports the

inclusion of these minor adolescent females, who are often excluded from sexual health research, in this project. We request to waive parental consent for this study, as the study presents no more than minimal risk. We are concerned that requiring parental consent will decrease participation in this project because parents may object to the sensitive nature of the survey content, and it has been demonstrated that fewer adolescents enroll in research about sexual health topics when parental consent is required[19] We are also concerned that requiring parental consent would potentially oversample youth with positive parent-child communication about sexuality, which would negatively impact our study. We believe that our target population can reason as adults and to perceive the possibility of the negative consequences of their actions. Moreover, the criteria for competence have moved from biological age towards individual children's experiences and understanding[20,21]. Moreover, minor adolescents in the State of Ohio and at Nationwide Children's are permitted to consent to many sexual healthcare services, including contraception care at age 15 and older within Nationwide Children's Hospital. In summary, we believe they are capable of and should be able to consent to participate in research that will inform this care.

- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
  - The study coordinator will be tasked with completing the informed consent with each participant to ensure continuity. They will be thoroughly trained on the informed consent process. Additionally, if the protocol and consent are modified, they will be required to complete additional training prior to consenting additional patients.
  - In total we estimate the consent process will take 20-30 minutes, this includes time for participant questions.
  - All risks and benefits will be discussed in full with each participant.
  - The research coordinator will ensure that they review each section in full with the participant. They will also periodically pause to ensure the participant does not have additional questions. Prior to signing of the consent, the participant will be reminded that research is completely voluntary and that they may withdraw at any time during the study with no consequence to their standard of care. Each participant will be provided with a copy of their consent via e-mail after signing so that they may review the study at any time, this will also contain contact information for the study staff if questions arise.

Subjects who are not yet adults (infants, children, teenagers)

- For this study a chart review will be completed in order to determine if a patient is eligible to participate. The included population are those 14 years and older. This will also be verified at the bedside.
- We are requesting to waive parental consent for this study and allow participants to consent for themselves if they are 15 years or older. Participants who are 14 will require verbal consent from parent or guardian, via information sheet, prior to their enrollment in the study. Participants will be the only party completing study surveys, the parents will not.
- No one other than the participant will have the ability to provide informed consent for this study. Exclusion parameters such as inability to consent due to mental health diagnosis or acute illness are in place to protect the subjects.

21.0 Process to Document Consent in Writing

21.1 We would like to waive parental consent but obtain informed consent from the participants directly. The patient population is 14 years of age and up and we believe that the population can consent for themselves due to the nature of the study, survey only.

22.0 Setting

22.1 Describe the sites or locations where your research team will conduct the research.

- The research coordinator will be responsible for identifying and recruiting new subjects. They will screen the census each morning to determine patients that meet criteria. All recruitment activities will take place at NCH units as specified in the inclusion criteria.
- The enrollment questionnaire will be completed by the subject during their admission at NCH. The follow-up surveys will be sent to participants electronically after admission for them to complete on their own time; they will have one month to complete the follow-up surveys.

23.0 Resources Available

23.1 Describe the resources available to conduct the research: For example, as appropriate:

- We conservatively estimate that the demand for inpatient hospitalization will be equally present in 2021 and 2022 as it was in 2019.We estimate that at least 1000 adolescents eligible

for our study will be admitted to Nationwide Children's Hospital following units – Psychiatric Unit, Youth Crisis Stabilization Unit, Psychiatric Crisis Department Extended Observation Care Unit and Hospital Pediatrics service. We estimate that 45% will agree to participate in our study. A demonstration that at least 25% of this sample is interested in contraception care during hospitalization will be notable

- A span of 2 years will be dedicated to study recruitment. The time devoted during that span may vary based upon eligible patients per day as well as follow-up survey schedules.
- All research processes will be carried out on the unit at the time of enrollment. The only exception is verbal consent from the parent or guardian of those who are 14. In those cases, consent may be obtained verbally via telephone after receipt of the study information sheet. The follow-up surveys will be sent electronically, and subjects will complete them on their own time.
- We do not anticipate any medical or psychological distress as a result of this study; however, at the time of enrollment subjects will be admitted so they will have access to all medical and psychological services that NCH provides.
- All study staff are required to complete all research training (CITI and NCH specific human subjects training) prior to being added to the IRB. Additionally, staff will be required to undergo study specific education before involvement in study procedures. All education will be tracked on a training log. If there are any changes made to the IRB all staff will also be required to review the changes. The dates of training will be available in the study Training Log.

24.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

- ☒ Name
- ☒ Complete Address
- ☒ Telephone or Fax Number
- ☐ Social Security Number (do not check if only used for ClinCard)
- ☒ Dates (treatment dates, birth date, date of death)
- ☒ Email address , IP address or url
- ☒ Medical Record Number or other account number
- ☐ Health Plan Beneficiary Identification Number
- ☐ Full face photographic images and/or any comparable images (x-rays)
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)

☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☒ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.) – All participants will complete an ICF and those under 15 will require parent/guardian to review the information sheet
☒ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.) – **for screening purposes only**
☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)
☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)
☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

3.0 How long will identifying information on each participant be maintained?

3.1 Identifiable information will be kept for 6 years for purposes of data analysis. However, this information will be coded and stored separately.

4.0 Describe any plans to code identifiable information collected about each participant.

4.1 At the time of enrollment all patients will be given a subject ID number, after the data collection period is over the PHI will be removed from the study data and stored separately in a password protected document.

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

☒ Research records will be stored in a locked cabinet in a secure location
☒ Research records will be stored in a password-protected computer file
☒ The list linking the assigned code number to the individual subject will be maintained separately from the other research data
☒ Only certified research personnel will be given access to identifiable subject information

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to

their information. (This is not the same provision to maintain the confidentiality of data.)

6.1 The subjects will only have one in-person encounter with study staff, at the time of enrollment. All other contact will be via their preferred contact method (phone call, text or e-mail). Participants will only be contacted at the study time points directly after discharge and 4 months after. Study staff will reach out a total of 4 times until the surveys have been completed. After the 4th contact attempt the participant will be considered lost to follow-up. EHR data pulls will be completed for newly enrolled patients to gather additional information (Appendix D). Aside from these encounters subjects as well as their information will not be accessed.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

☒ Demographics (age, gender, educational level)
☒ Diagnosis
☒ Laboratory reports
☐ Radiology reports
☐ Discharge summaries
☒ Procedures/Treatments received
☒ Dates related to course of treatment (admission, surgery, discharge)
☐ Billing information
☒ Names of drugs and/or devices used as part of treatment
☒ Location of treatment
☒ Name of treatment provider
☐ Surgical reports
☒ Other information related to course of treatment
☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.

2.1 Important research study endpoints and outcomes, as well as predictor variables, will only be available as patient-level health information available in the EHR, this includes information such as hospital unit census data, insurance status, disposition of outpatient encounters, medical diagnoses, and prescription or initiation/discontinuation of contraception.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☒ Yes ☐ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No

References

1. Merikangas KR, He JP, Burstein M, et al. Lifetime prevalence of mental disorders in U.S. adolescents: Results from the national comorbidity survey replication-adolescent supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry*. 2010;49(10):980-989. doi:10.1016/j.jaac.2010.05.017
2. Ramrakha S, Caspi A, Dickson N, Moffitt TE, Paul C. Psychiatric disorders and risky sexual behaviour in young adulthood: Cross sectional study in birth cohort. *Br Med J*. 2000;321(7256):263-266. doi:10.1136/bmj.321.7256.263
3. Hall KS, Kusunoki Y, Gatny H, Barber J. The risk of unintended pregnancy among young women with mental health symptoms. *Soc Sci Med*. 2014;100:62-71. doi:10.1016/j.socscimed.2013.10.037
4. Brown A, Yung A, Cosgrave E, et al. Depressed mood as a risk factor for unprotected sex in young people. *Australas Psychiatry*. 2006;14(3):310-312. doi:10.1080/j.1440-1665.2006.02291.x
5. Ghobadzadeh M, Moore D. Association between Depressed Mood and Youth Condom/Contraceptive Nonuse: A Systematic Review of Literature. *Issues Ment Health Nurs*. 2018;39(2):102-116. doi:10.1080/01612840.2017.1364810
6. Stidham Hall K, Moreau C, Trussell J, Barber J. Young women's consistency of contraceptive use - Does depression or stress matter? *Contraception*. 2013;88(5):641-649. doi:10.1016/j.contraception.2013.06.003
7. Vigod SN, Dennis CL, Kurdyak PA, Cairney J, Guttmann A, Taylor VH. Fertility rate trends among adolescent girls with major mental illness: A population-based study. *Pediatrics*. 2014;133(3):e585-e591. doi:10.1542/peds.2013-1761
8. Bahk J, Yun SC, Kim Y mi, Khang YH. Impact of unintended pregnancy on maternal mental health: A causal analysis using follow up data of the Panel Study on Korean Children (PSKC). *BMC Pregnancy Childbirth*. 2015;15(1):85. doi:10.1186/s12884-015-0505-4
9. Coles MS, Lau M, Akers AY. If You Do Not Ask, They Will Not Tell: Evaluating Pregnancy Risk in Young Women in Pediatric Hospitals. *J Adolesc Heal*. 2016;58(3):251-252. doi:10.1016/j.jadohealth.2015.12.008
10. Masonbrink AR, Miller MK. Caring for Hospitalized Adolescents: Opportunities to Identify and Address Unmet Reproductive Health Needs. *J Adolesc Heal*. 2019;64(6):689-690. doi:10.1016/j.jadohealth.2019.03.014
11. Bardach NS, Coker TR, Zima BT, et al. Common and costly hospitalizations for pediatric mental health disorders. *Pediatrics*. 2014;133(4):602-609. doi:10.1542/peds.2013-3165
12. Leyenaar JK, Ralston SL, Shieh M-S, Pekow PS, Mangione-Smith R, Lindenauer PK. Epidemiology of Pediatric Hospitalizations at General Hospitals and Freestanding Children's Hospitals in the United States. doi:10.1002/jhm.2624
13. Guss CE, Wunsch CA, McCulloh R, Donaldson A, Alverson BK. Using the hospital as a venue for reproductive health interventions: a survey of hospitalized adolescents. *Hosp Pediatr*. 2015;5(2):67-73. doi:10.1542/hpeds.2014-0043

14. Riese A, Houck C, Abdullahi N, Davies AC, Baird J, Alverson B. An Electronic Sexual Health Module for Hospitalized Adolescent Girls. *Hosp Pediatr*. 2019;9(11):880-887. doi:10.1542/hpeds.2018-0276
15. Goldstein RL, Carlson JL, Halpern-Felsher B. Contraception for Adolescents and Young Adults in the Inpatient Setting: The Providers' Perspective. *Hosp Pediatr*. 2018;8(4):194-199. doi:10.1542/hpeds.2017-0167
16. Masonbrink AR, Stancil S, Reid KJ, et al. Adolescent Reproductive Health Care: Views and Practices of Pediatric Hospitalists. *Hosp Pediatr*. 2019;9(2):100-106. doi:10.1542/hpeds.2018-0051
17. Kroenke K, Spitzer RL, Williams JBW, Löwe B. An Ultra-Brief Screening Scale for Anxiety and Depression: The PHQ–4. *Psychosomatics*. 2009;50(6):613-621. doi:10.1016/s0033-3182(09)70864-3
18. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385-396. doi:10.2307/2136404
19. Reed JL, Huppert JS. Predictors of Adolescent Participation in Sexually Transmitted Infection Research: Brief Report. *J Adolesc Heal*. 2008;43(2):195-197. doi:10.1016/j.jadohealth.2008.01.020
20. Piko BF, Gibbons FX. Behavioral and psychosocial influences of risk perception among Hungarian adolescents. *Int J Public Health*. 2008;53(3):131-138. doi:10.1007/s00038-008-7054-9
21. Horn SS, Kosciw JG, Russell ST. Special issue introduction: New research on lesbian, gay, bisexual, and transgender youth: Studying lives in context. *J Youth Adolesc*. 2009;38(7):863-866. doi:10.1007/s10964-009-9420-1