

Expanded Preoperative Survey during Perioperative Care to Identify Substance Use in Teenagers and Adolescents

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NATIONWIDE CHILDREN'S HOSPITAL  
SHORT PROTOCOL (Waiver of Consent or Verbal Consent)

PROTOCOL TITLE: Survey to Identify Substance Use in Teenagers and Adolescents

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Expanded Preoperative Survey during Perioperative Care to Identify Substance Use in Teenagers and Adolescents

**PRINCIPAL INVESTIGATOR:**

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**VERSION NUMBER/DATE:**

Ver. 2/March 16, 2022

**Revision History**

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/16/2022	Changing written consent to verbal in 5.4 & 12.3, clarifying what will be collected in 9.4 & 9.5, removing dates & MRN from 15.1, changing to HIPPA authorization waiver in 15.2, clarification in 15.4 & 15.5.	Yes

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## 1.0 Study Summary

<b>Study Title</b>	Expanded Preoperative Survey during Perioperative Care to Identify Substance Use in Teenagers and Adolescents
<b>Study Design</b>	Patient survey
<b>Primary Objective</b>	To determine the incidence of illicit substance use and abuse prior to anesthetic care
<b>Secondary Objective(s)</b>	To determine the illicit substances used and their frequency in patients presenting for anesthetic care
<b>Study Population</b>	Patients 12-21 years of age presenting for anesthetic care
<b>Sample Size</b>	1000
<b>Study Duration</b>	3 years

## 2.0 Methods

- 2.1 Substance use disorders (SUD) and related psychopathology are persistent public health problems with over 20.3 million adults and 1.3 million children in the U.S. estimated to have a SUD. Worldwide, there are over 3.4 billion illicit drug users, accounting for more than 10% of all deaths each year. Drug overdose, mostly linked to opioids, is the leading cause of unintentional injury deaths in the United States. An estimated 2 million Americans  $\geq$  12 years of age 12 have had an opioid use disorder involving prescription opioids, and approximately 600,000 have had an opioid use disorder involving heroin. The number of overdose deaths from illicit opioids tripled from 2011 to 2015 in the United States and sadly has crossed 100,000 victims just this year. The consequences of substance use costs the United States more than \$600 billion every year.
- 2.2 Illicit substance use is often initiated during adolescence with reports suggesting that more than 80% of drug users began using during adolescence. Unfortunately, only about 11% of individuals  $\geq$  12 of age and only 6% of adolescents who need treatment for substance abuse receive it. Additionally, more than half of the adolescents receiving treatment will relapse within one year of treatment, suggesting more accessible and effective programs are needed to prevent and treat substance use in adolescents. The initial step in decreasing the impact of substance abuse is identification of those who are using followed by effective programs to deal with these problems.
- 2.3 In addition to acute and chronic issues associated with substance abuse, these medications and substances can impact the perioperative care of patients and interact with anesthetic agents. Preoperative

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screening for these issues is now undertaken by an on-line preoperative questionnaire sent to the parents to complete prior to anesthetic care. Given the nature of such concerns and these issues, it is likely that there is under-reporting of these problems for various reasons.

- 2.4 This is a prospective survey study of patients 12-21 years undergoing anesthetic care. The primary objective is to determine the incidence of illicit substance use and abuse prior to anesthetic care. The secondary objective is to determine the illicit substances used and their frequency in patients presenting for anesthetic care.
- 2.5 The participants will be asked to complete a survey in REDCap using an iPad during the visit. We will record any positive answers from the drug and tobacco use questions routinely asked of the parents during the on-line pre-admission testing process. These include yes/no answers regarding drug, alcohol, and tobacco use.
- 2.6 The information collected will include only demographic data including age, weight, gender, ethnicity/race, and zip code. Survey data will be coded and will not include patient information. Completion of the survey will take approximately 15-20 minutes. Explanation of the study, its confidentiality, and the purpose will take approximately 5-10 minutes.

**3.0 Data Banking**

- 3.1 All data collected during this study will be stored in a secure location, and only the collaborators directly involved with this research project will have access to this information. In addition, all electronic files will be stored on a secure, password-protected network.
- 3.2 Data will be stored for 6 years after the study is completed.
- 3.3 Data will not be stored for future use.

**4.0 Inclusion and Exclusion Criteria**

- 4.1 *Inclusion:* Patients 12-21 years of age presenting for surgery or procedure requiring anesthesia.
- 4.2 *Exclusion:* Patients who are not able cognitively to complete the computerized survey due to physical or intellectual impairment or communication issues related to non-English speaking patients.

**5.0 Vulnerable Populations**

- 5.1 This research involves children but does not involve greater than minimal risk under 21 CFR §50.51/45 CFR §46.404.
- 5.2 All data collected during this study will be stored in a secure location, and only the collaborators directly involved with this research project will have

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access to this information. In addition, all electronic files will be stored on a secure, password-protected network.

- 5.3 The subjects will not be exposed to greater than minimal risk.
- 5.4 Parents/legal guardians will be asked to give verbal consent and children will provide assent.

**6.0 Number of Subjects (Records)**

- 6.1 1000.

**7.0 Recruitment Methods**

- 7.1 Patients will be identified using the operating room schedule. The study coordinator, PI, or sub-investigators will screen and identify appropriate participants. Screening participants will occur according to the protocol defined inclusion and exclusion criteria under the auspices of a partial waiver in accordance with the HIPAA privacy rule.
- 7.2 Potential subjects will be approached in the pre-op area on the day of surgery by a member of the research team. The study will be explained to the patient and parents/guardians and they will be provided a copy of the consent form to review.

**8.0 Withdrawal of Subjects**

- 8.1 Patients may withdraw from the study at any time.
- 8.2 There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

**9.0 Data Management and Confidentiality**

- 9.1 All data collected during this study will be stored in secure password protected computer files to which only trained members of the research team and collaborators directly involved with this research project will have access.
- 9.2 The data will be stored for the duration of the study and retained for 6 years after the study is completed per NCH as this meets both HIPAA and OHRP regulations.
- 9.3 No data will be transmitted to or from external institutions.
- 9.4 Subjects will be assigned a study identification number and no identifiers will be entered into REDCap. Names and MRNs will not be recorded.
- 9.5 The subject's survey answers will not be looked at until the time of analysis at the end of the study.

**10.0 Provisions to Protect the Privacy Interests of Subjects**

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- 10.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.
- 10.2 Only the absolute minimum information necessary for this study will be collected from the patient's records. Access to the patients' charts will be limited to only the research team who have completed all the necessary training.
- 10.3 We will only be publishing de-identified research information.

**11.0 Economic Burden to Subjects**

- 11.1 There will be no costs to subjects and subjects will not receive any compensation.

**12.0 Consent Process**

- 12.1 The consent process will begin in the preoperative surgery unit on the day of surgery, by PI, Sub-Investigators, Study Coordinators, and/or trained research staff.
- 12.2 The study will be thoroughly explained to the patient and their family. There will be ample time allotted for questions and answers. An explanation of voluntary participation will take place, and the family will be asked if they are interested in participating in the study. The patient will then be enrolled in the study with the understanding that they can elect to stop the study and be withdrawn from the study at any time.
- 12.3 Potential subjects will be provided a written information sheet and verbal consent will be obtained.

**13.0 Setting**

- 13.1 Potential subjects will be identified from the surgery schedule in Epic and recruited from the pre-op area of the surgery unit. Surveys will be completed via REDCap on iPads in the pre-op area.

**14.0 Resources Available**

- 14.1 The research team is comprised of a PhD research scientist, a research nurse, a research coordinator, and two research associates. All team members will meet with the PI, co-investigators, and the research team for a study start up meeting for training about the protocol, research procedures, and their duties and functions.

**15.0 Protected Health Information Recording**

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

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- 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.)
- Protocol meets the criteria for waiver of authorization. (Attach the [HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST](#) form.)
- 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.)

\*Find the HIPAA forms in the [IRB Website Library, Templates](#).

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

**3.0 How long will identifying information on each participant be maintained?**  
Identifying information on each participant will be retained for 6 years after the research is complete which meets both HIPAA and OHRP regulations.

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- 4.0 Describe any plans to code identifiable information collected about each participant.** Subjects will be assigned a study identification number and no identifiers will be entered into REDCap. Names and MRNs will not be recorded.
- 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.)** Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study

### **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

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None

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

It is necessary to review the above health information to enable us to describe our patient population, ensure they meet the study inclusion specifications and evaluate our study outcomes.

**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**