Parental perceptions on prescription opioid use for pain control in children undergoing orthopedic surgery

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May 12, 2022

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

PROTOCOL TITLE: Parental perceptions on prescription opioid use

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Parental perceptions on prescription opioid use for pain control in children undergoing orthopedic surgery

PRINCIPAL INVESTIGATOR:
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VERSION NUMBER/DATE:
Ver. 2/May 12, 2022

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?
1	5/12/2022	Changing the PI to Dr. Tobias and clarifying section 9.3.	Yes

PROTOCOL TITLE: Parental perceptions on prescription opioid use

1.0 Study Summary

Study Title	Parental perceptions on prescription opioid use for pain control in children undergoing orthopedic surgery
Study Design	Anonymous survey
Primary Objective	The primary objective of the study is parental perceptions on prescription opioid use for pain control in children undergoing orthopedic surgery
Secondary Objective(s)	The secondary objective is to assess social and environmental factors in opioid perception among parents
Study Population	Parents of children undergoing orthopedic surgery at NCH
Sample Size	125
Study Duration	3 years

2.0 Methods

2.1 Potential subjects will be identified by reviewing the daily OR schedule in Epic. Parents will be approached in the pre-op area on the day of surgery, the study will be explained to them, and a written information sheet will be provided.

2.2 After receiving verbal consent, the parents will be given a research iPad and asked to complete the survey on REDCap (see attached survey).

2.3 All continuous variables will be summarized using mean +/- standard deviation and categorical variables using counts and percentages. The chi-square test will be used to test whether parental perceptions on opioids use for pain control differed by gender, educational, or employment status.

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:* Parents of patients between 1-18 years of age scheduled for orthopedic surgery at Nationwide Children's Hospital.

4.2 *Exclusion:* Parents with children less than 1 or greater than 18 years of age; scheduled for surgery other than orthopedic; non-English speaking parents.

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

6.0 Number of Subjects (Records)

6.1 125

7.0 Recruitment Methods

7.1 Subjects will be recruited from the surgery unit pre-op area. They will be identified by reviewing OR schedules in Epic.

8.0 Withdrawal of Subjects

8.1 N/A

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. The OU medical student working on the project will only have access to the data using NCH computers.

9.4 The surveys will be anonymous.

10.0 Provisions to Protect the Privacy Interests of Subjects

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 Patient charts will only be accessed for screening purposes. No patient information will be recorded.

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 We are requesting a waiver of documentation of informed consent.

12.2 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.

12.3 The study will be thoroughly explained to the parents. 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 parents 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.

12.4 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 two PhD research scientists, 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.

☐ 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?
No identifying information will be collected.

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

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
- ☐ 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 ensure that potential subjects meet the study inclusion specifications.

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