

Title: Promoting Recovery in Children Who Sustain a Mild Traumatic Brain Injury:
mTBI Evaluation and Management (TEaM)

NCT#: NCT04576715

Date: 08/15/2024

Emory University and Children's Healthcare of Atlanta
Oral Consent and HIPAA Authorization Script and Information Sheet
For Research Study Screening

Study Title: TBI Evaluation and Management (TEaM)
Principal Investigator: David Wright, MD, Emory University, Department of Emergency Medicine
Funding Source: Centers for Disease Control and Prevention

Introduction and Study Overview

Thank you for your interest in the TBI Evaluation and Management study. To see whether you may be a candidate for this study, we need to ask you for some information about yourself. But first, let me tell you about this screening interview and what we will do with your information.

1. This screening interview will take about 10 minutes.
2. You can also stop the screening interview at any time. This is completely voluntary.
3. We can send you an information sheet about this screening, along with the screening questions, if you would like. We will also give you a form you can send in later if you change your mind and want us to remove your child's information from our records.
4. We will ask you about your child's mild traumatic brain injury (concussion) and will record this information in a database containing information from others who have also shown interest in the study.
5. This information will only be used for the research study you are interested in.
6. The only risk to your child in this phone screening is a potential loss of privacy. However, your child's privacy is very important to us and we will be very careful with the information.
7. Your child's health information that identifies him/her is "protected health information" or "PHI." We will use your child's PHI to screen you for our research study
8. The PHI we will use includes your child's doctor's name, date of visit for potential concussion, medical diagnosis, prognosis, and clinical evaluation notes.
9. To protect your child's PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (called HIPAA or "the Privacy Rule" for short).
10. The following persons or groups may use and/or disclose your child's PHI for this study:
 - The Principal Investigator and the research staff
 - Centers for Disease Control and Prevention, who funds this Research, and people or companies they use to carry out the study
 - Emory and Children's Healthcare of Atlanta offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing
 - Any government agencies who regulate the research including the Office of Human Subjects Research Protections.
11. We will disclose your child's PHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders.
12. You may revoke your authorization at any time by calling the principal investigator, Dr. David Wright, or by using the form that we will send to you.
13. If identifiers (like your child's name, address, and telephone number) are removed from your child's PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.
14. If we share your child's PHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your PHI to others without your authorization. Let me know if you have questions about this.

- 15. Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.
- 16. We can send you a copy of this information, if you would like.

Contact Information

If, at any time, you have questions about this screening process, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the Project Team, Nick Stanley, or the Emory Institutional Review Board.

Nick Stanley [redacted]
Emory Institutional Review Board at [redacted] or toll-free at [redacted]

If you are a patient receiving care at Children’s Healthcare of Atlanta of Atlanta and have a question about your rights, please contact Sarah Marie Huban, Director of Clinical Research at 404-785-7477.

You can also stop the screening interview at any time. This is completely voluntary.

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to participate in the screening process, and authorize the use and disclosure of your protected health information as I described?

Participant agrees to participate: Yes No

If Yes:

Name of Participant

Name of Legally-Authorized Representative
(if non-treatment study, must be parent/legal guardian of minor, or have Power of Attorney for Research)

Relationship of Legally-Authorized Representative to Participant

Signature of Person Conducting Informed Consent Discussion Date Time

Name of Person Conducting Informed Consent Discussion