

WAIVERS OF CONSENT FOR RESEARCH WITH PROSPECTIVE DATA COLLECTION

Description

The University of Utah IRB ~~most often~~routinely grants waivers of consent for retrospective chart review and secondary data analysis studies. Investigators occasionally request waivers of consent for studies collecting data prospectively. This research often has a prospective, observational design, where the data is limited to standard of care data yet to be collected or data that will otherwise be collected for routine clinical care in a future time period. This guidance document is intended to assist board members in making the determination of whether granting a waiver of consent is appropriate for research with prospective data collection.

In order to grant a waiver of consent, investigators must provide sufficient justification that conducting the research with the requirement to obtain consent is not “practicable”. This term is sometimes incorrectly interpreted to mean that the waiver may be granted only when it is impossible to obtain consent. However, the term is only intended to refer to the feasibility of obtaining consent given the available means or resources of the investigator.

“Put another way, it would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent was required. The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent.” ([SACHRP](#))

While practicability should not be solely justified by considerations of possible inconvenience or burden to the researcher (e.g., convenience, time, costs, etc.), they can be part of the overall justification for the waiver.

Acceptable reasons for it to be impracticable to conduct research using a consent process include, but are not limited to:

- Participants are no longer followed, or are lost to follow-up (e.g., moved away, expired, no longer coming to clinic, etc.)
- There are too many participants to be included in the study to contact them all
- The scientific validity of the research would be compromised if consent was required (e.g. the research depends on inclusion of all possible participants, i.e. rare condition, limited participant pool, etc.)
- The sample size required is such that if the investigators only included those for which consent could be obtained, the conclusions could be skewed (e.g. epidemiology studies)
- Ethical concerns may occur if consent is required (e.g. the only link to participants is the consent, contacting participants could inflict harm on individuals or their families)

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When considering a waiver of consent for the use of standard of care data that exists up until the time the waiver is granted, as well as data that will be created in the future as a participant receives normal care by their providers:

1. Generally, if a participant is seen prospectively, consent should be obtained prior to study participation. It is reasonable for an individual to be given an opportunity to consent or refuse participation in a research study even when the research only involves collection of data prospectively as the participant receives standard of care procedures.
2. Even though an opportunity to obtain consent is provided to investigators in prospective research, there may be constraints making it impracticable for the research to be conducted if researchers do not have resources or infrastructure to allow for obtaining consent. In order to facilitate consent for standard-of-care observational studies, a cover letter explaining the study with a waiver of documentation of consent may be appropriate rather than granting a waiver of consent.

While the above guidelines should be followed, they are not binding. The board should consider and discuss whether granting a waiver is appropriate on a case-by-case basis. The board retains the authority approve a waiver of consent for research with prospective data if the IRB finds and documents that: (1) the research involves no more than minimal risk to the subjects; (2) ~~the research could not practicably be carried out without the waiver or alteration; the waiver or alteration will not adversely affect the rights and welfare of the subjects;~~ (3) ~~if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; the research could not practicably be carried out without the waiver or alteration;~~ and (4) ~~the waiver or alteration will not adversely affect the rights and welfare of the subjects;~~ and (5) whenever appropriate, the subjects will be provided with additional pertinent information after participation¹. See Appendix A for a practical example of prospective research with an approved waiver of consent.

References & Links

SACHRP Letter to HHS Secretary, January 31, 2008

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html>

FDA Guidance on IRB Waiver of Informed Consent

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk>

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Appendix A: Example of Waiver of Consent & Authorization for Research with Prospective Data Collection

The following example is an approvable proposal for a Waiver of Consent & Authorization for a prospective element of a study. In this example, standard of care data would be collected throughout

¹ [45 CFR 46.116\(f\)](#); [21 CFR 50.22](#)

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a trauma situation and during a follow-up period under a Waiver of Parental Permission & Authorization. In some cases, parents would be contacted for additional follow-up information. A parental permission document/process would take place after the waivers have been activated for a period of time and data has been collected. The parental permission document includes standard language about the right to withdraw.

The investigator needs to clearly outline the study procedures including a description of how the Waiver of Parental Permission and Authorization is used.

Study Procedures

We will conduct a prospective observational study of children 0-17 years-old who present to the ED for care following known or suspected exposure to blunt trauma regardless of whether or not injuries were sustained.

Presence of Cerebral Spinal Injury (CSI) will be determined by review of study site cervical spine imaging reports and if applicable spine surgeon consultation notes and phone follow-up. At 21 days after the ED visit for injury, the study site medical records will be reviewed for cervical spine imaging and spine surgeon consultation. To ensure that there are not missed CSI for those children not undergoing cervical spine imaging, we will review the medical record for follow-up encounters and if necessary, conduct phone follow-up 21-28 days post study enrollment. We will also collect data on patients that are eligible for the study but are missed.

We estimate that it will require a total observation of at least 22,000 children who are evaluated after blunt trauma to adequately assess our study aims.

The workflow for the prospective observational study is as follows:

1. A patient arrives in the emergency department (ED) by emergency medical services (EMS) or private vehicle.

(a) RC identifies patient: The RC is notified of the potential subject and reviews the patient chart to verify the patient has known or suspected blunt trauma and is being evaluated for known or suspected exposure to blunt trauma regardless of whether or not injuries were sustained and meet one of the following criteria: (a) undergoing trauma team evaluation, (b) transported from the scene to site facility by EMS, (c) undergoing cervical spine imaging at site facility, or (d) transferred to site facility with cervical spine imaging. If the patient meets the eligibility criteria the RC completes the Screening Form and continues to step 2.

(b) RC does not identify patient: On a regular basis, the RC reviews the ED census reports for potential patients not identified at point of ED arrival/treatment. For patients who meet inclusion criteria, the RC completes the Missed Eligible Form.

2. RC launches the appropriate provider forms for eligible subjects based on patient presentation to the ED.

(a) For patients who arrive by EMS from the scene of the injury: The EMS provider transfers patient care to the ED provider, and is approached by the RC to participate in the study. If the EMS provider agrees to participate, the RC launches the EMS Provider Form for the provider to

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complete. Once the form is complete, or if the EMS provider declines or is not available to approach, the RC continues to step 3.

(b) For patients who arrive by private vehicle, EMS transfer, or other means: The RC continues to step 3.

3. The ED provider completes the initial physical exam and history on the patient and the RC launches the ED Provider Form for the provider to start. If the ED provider confirms the patient is eligible, the observational section of the form is completed and the RC continues to step 4. If the patient is not eligible, the form ends and no further action is required.

4. For eligible subjects, if a surgical provider is available and agrees to participate in the study, the RC launches the Surgical Provider Form for the provider to complete. Once the form is completed, or a provider is not available or does not agree to participate, the RC continues to step 5.

5. Prior to the patient leaving the ED, the RC provides the family with the Consent, Parental Permission & Authorization Cover Letter that explains they may be contacted at 21-28 days for a phone follow-up. All families will receive this information sheet since at time of hospital discharge it will be unknown if the patient will qualify for a telephone follow-up. (A patient qualifies for phone follow-up if they did not undergo diagnostic imaging at the study site or its affiliates within 21 days of child's hospital visit.) The RC then completes the Demographics and Disposition Form and the RC continues to step 6.

6. On days 21-28 post ED enrollment, the RC reviews the patient's medical record and completes the Patient Status Form. The RC also reviews the chart for cervical spinal imaging and completes the appropriate form.

(a) If cervical spine imaging is NOT documented in the record: The RC conducts a phone interview and completes the Phone Follow-Up Form.

(b) If cervical spine imaging is documented in the record: The RC and the PI complete the Imaging/Consultation/Surgery Form.

7. For subjects who had abnormal cervical spine imaging, the study adjudicator completes the Patient Diagnosis Form.

The investigator needs to clearly outline the study procedures including a description of how the Waiver of Parental Permission and Authorization is used.

Request for Waiver or Alteration of Consent

We are requesting Waiver of Consent (Parental Permission/Assent) for the prospective observational data collection and medical record review that is part of study Methodology 1.

This study is a prospective observational study. We will be obtaining observations from clinicians regarding factors that place children at risk for CSI. To ensure that these observations are not biased, they must be obtained before diagnostic testing is obtained.

The decision to obtain diagnostic testing will not be influenced by enrollment in the study. Diagnostic testing for these children should not be delayed for study procedures.

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Explain why the research could not practicably be conducted without the waiver or alteration.

The research could not practicably be carried out without the waiver or alteration. The research proposed in this application would be impracticable to conduct if informed consent is required. This study investigates a rare disease, cervical spine injury (CSI). CSI occurs in less than 2% of children who sustain blunt trauma. We determined the feasibility of the proposed projects sample size 22,222 by using the enrollment rates and incidence of CSI in the pilot study and applying it to information regarding this study's participating sites obtained from PECARNs core data project.

Prior similar work in children with head injury and abdominal trauma has demonstrated that we are able to achieve enrollment rates of 80% only with waiver of consent. If written informed consent had been required for these prospective cohort participants, enrollment would have decreased by 45% due to lack of an available parent or legal guardian during the emergency visit. Further, we have concern that the established cohort would not be representative of the spectrum of children at risk for CSI and thus would result in ascertainment bias. Our prior work has demonstrated that those patients at highest risk for severe injury will be more difficult to consent (e.g. absent guardian, time critical injuries, etc.) while lower risk patients will be easier to consent (e.g. arrive with guardian, stable injuries etc.). Additional considerations regarding the impact of written informed consent on the study's scientific integrity:

1. Pivotal to the scientific integrity of developing a decision tool is that observational data collected from proxies is collected before diagnostic testing is obtained and/or reviewed. Observational data obtained after the ED provider is aware of testing results introduces recall bias. It would be unethical, however, to delay patient care in order to obtain written informed consent for collection of survey data from EMS and ED providers. Thus, either we delay collection of survey data for the written informed consent and risk the introduction of recall bias OR we conduct the collection of survey data under waiver of consent.
2. In trauma situations, parents may be under considerable duress given the critical nature of their child's injuries. While it is not uncommon for parents/patients to be approached for consent under these circumstances, particularly for studies and clinical procedures that may have substantial benefit to the patient, it would be inappropriate to solicit informed consent for a minimal risk study during this sensitive period of time when parents are facing more pressing decisions.
3. Data are to be collected from EMS pre-hospital personnel, who are required to return to service within 30 minutes or sooner of hospital arrival. It is implausible that we would be able to obtain written informed consent from a parent or legal guardian prior to EMS departure from the ED. Thus, we would be unable to collect prospective information from the EMS provider which threatens an important aim of the study.
4. For missed eligible subjects, we will not know who is eligible until review of the ED daily census reports, at which juncture, the patient will no longer be in the ED making consent procedures impossible.

The investigator needs to clearly outline the consent process, as applicable.

Consent Process

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For the prospective observational study, at the time of ED evaluation a site research coordinator will provide a Consent, Parental Permission and Authorization Cover Letter describing the phone follow-up procedure. 21 days after the ED visit, a site research coordinator will obtain verbal consent at a telephone follow-up only for qualifying patients who did not undergo diagnostic imaging at the study site or its affiliates.

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