

METRC Consenting Procedures

METRC has adopted a universal, comprehensive informed consent process that involves the treating surgeon, the clinical site research coordinators, and material and resources for patients and family members to facilitate informed decision making about research participation. The goal of the consent process is to provide each eligible patient or their legally authorized representative (requirements vary by study) sufficient information about the study, to adequately address their questions and concerns, and to give them time to make an informed decision about whether to participate.

General Consenting Approach

There are strong ethical and practical reasons for striving for quality consent processes. The decision to participate in a study is completely voluntary; decisions to enroll made in haste, without adequate thought or reflection are not in the participant's or investigator's interest, as participants may not understand the commitments expected of them as research participants. The consent process provides an opportunity for the participant and investigator to build their relationship, in addition to serving to inform the participant of their rights and responsibilities as research participants. The formation of a strong relationship between a study participant and the study investigator is of particular importance in studies where patients are asked to self-report sensitive information or outcomes and where participation extends over time.

Recruitment and enrollment materials are developed in conjunction with the Protocol Committee and consultants as required to ensure that they are accessible, informative and culturally sensitive. METRC works with experts in research ethics in this process as needed.

While the timing of consent varies by study, in general, recruitment begins at the time of screening in METRC. Sites are encouraged to incorporate screening into daily “checkout” or rounding procedures to (1) ensure all potentially eligible participants are considered for inclusion; and (2) maintain visibility of enrolling projects, such that the clinical team is aware of research activities and can help to reinforce support for METRC projects. Once a participant has been determined to be potentially eligible, the recommended procedures include initial contact by the treating surgeon, who helps explain the rationale of the study to each eligible patient and, if applicable, family member. The local research coordinators follow up to obtain the actual consent. Involvement of the attending surgeon in the consent process reassures patients, helps to avoid confusion, and promotes adherence to study procedures and follow up schedules. The research coordinator reviews the consent form with patients or their legally authorized representatives in detail. Recruitment aids such as standard brochures and flip charts are used by the research coordinator to walk through the consent process. For studies where recruitment is particularly challenging, videos are used that explain the treatments under study and the importance of randomization. The consent form explains the study rationale, what is expected of the patient if he/she decides to participate, and details about the intervention (where applicable). In studies where it is warranted, legally authorized representatives are allowed to consent on behalf of the patient.

Assessing Capacity to Consent and Consenting a Legally Authorized Representative

Whenever possible, the patient provides consent. There are times, however, when due to the nature of the injuries, the patient is unable to provide consent and a legally authorized representative (LAR) is required to consent on his or her behalf. Within METRC, the potential need for an LAR is assessed prior to approaching the potential research participant and as part of the consent dialog.

Prior to initiating the consent process, the Research Coordinator communicates with the patient's physician to confirm that the patient has the ability to understand the relevant study information and to both communicate and maintain a choice. If the physician indicates that the patient lacks the capacity to consent (either due to injury or due the fact that the patient is unresponsive or intubated and likely to remain so during the study), the LAR is contacted and the consent process proceeds.

When administering the consent forms, research staff endeavors to answer all questions posed by the patient and family to ensure their understanding of the protocol. Prior to completing the consent process, the study team member obtaining consent asks several questions of potential research participants assessing the person's understanding of the study and what it means to participate, their appreciation of the consequences of participation, and their ability to consider alternatives to participation (see below). This process may be conducted formally or informally, and the person obtaining consent will determine, based on the appropriateness of the responses, whether or not the person can provide consent. If the Research Coordinator is at all unsure about the patient's ability to consent s/he will consult with the study site PI.

If it is determined that an LAR is required, the research team seeks out an LAR according to the following order of priority: (1) legal guardian; (2) proxy (health care agent) named in an advance directive or durable power of attorney for health care; or (3) family member or other surrogate identified by the state law on health care decisions. The study team provides guidance to the LAR in making the consent decision, advising them to base the choice on the participant's expressed wishes, or, if these are not known, what they believe the participant would have desired under the circumstances of the injury, their beliefs and values. If the LAR does not know what the participant would have wanted, the LAR is advised to base the decision with the participant's best interest in mind. They are asked to carefully consider how much leeway the participant would likely give the LAR in making the choice about participation in the study. If the participant regains capacity to consent during the study period, the participant is re-consented using standard consenting procedures described above. Participants must be able to provide consent in order to take part in the performance assessments.

Evaluation to Give Consent

1. Is the respondent alert and able to communicate with you?
Yes ____ No ____ **(if condition not likely to change, seek proxy consent)**
2. Ask the respondent to name at least one thing that s/he will be asked to do as part of the study.

Describe:

3. Ask the respondent to explain how it will be decided which treatment s/he will get if s/he decides to join the study.

Describe:

4. Ask the respondent to explain what s/he could do if s/he decided s/he did not want to participate in the study.

Describe:

5. Ask the respondent to explain what s/he would do if s/he were experiencing distress or discomfort at any time during the study.

Describe: