IC: Potential Case Subject Consent

Study personnel at each of the contracted CIREN sites review trauma registry data to identify potential case subjects based on the study's inclusion criteria. If the CIREN contractor team deems an individual to be a potential case subject, a study team member will approach the individual (or a representative) to obtain consent for participation in the data collection. Study teams obtain informed consent from eligible patients according to institutional policies and consent documents. Each study site (hospital) has its own consent form(s). The consent process generally requires thirty (30) minutes of the respondent's time, which includes explanation of the study risks and benefits and review of consent language. This burden would apply for every patient approached for consent, regardless of their ultimate decision to participate in the study.