

## Objective

Trauma induced coagulopathies (TIC) are a frequent cause of preventable death in those suffering severe traumatic injury. This multi-center study seeks to develop a comprehensive understanding of molecular and physiological processes to anticipate bleeding and clotting complications following trauma.

## Methods

Clinical data and blood samples will be collected from 400 patients with severe trauma at 4 different trauma centers. Serial blood samples are used to perform assays studying coagulation, inflammatory mediators, protein structure and function, and gene function.

## Results

During the pilot phase of this study, we found that challenges of acute care and resuscitation precluded informed consent in the emergency department, with only 3/23 patients agreeing to participate. We therefore amended the protocol, and due to the minimal risk of collecting blood samples from hospitalized patients, we obtained a waiver of informed consent for initial blood acquisition. Blood samples are now collected at the time of emergency department presentation, with a waiver of informed consent. Additional time points >24 hours from trauma require consent of the patient or assent from a surrogate. To date, of 15 patients screened, 4 were enrolled and informed consent was obtained from all subjects. Blood was spun and the plasma frozen at -80C for analysis.

## Conclusions

Waiver of initial consent from trauma patient has increased the feasibility of studying coagulation abnormalities in this population, without putting the patient at increased risk.