As one of our core missions, the Division of Trauma and Surgical Critical Care actively encourages research collaborations including physicians, nurses, pharmacists, respiratory therapists and nurse practitioners in both the Trauma unit & SICU.

To ensure patient safety, efficiency and productivity in research, we have instituted a research management model for all studies conducted in these ICUs. This process was created in response to the volume of studies, the desire to enroll critically ill surgical patients in clinical trials and the complexity of integrating studies. A number of practical issues supports this model, including:

- Protection of patient rights and safety.
- Adherence to the IRB minimal risk policy in the setting of co-enrollment in multiple studies.
- Avoidance of consent fatigue for the patient/family.
- Introduction of numerous extra-clinical individuals into patient care and family communication in an environment where patient/family stress is already high.
- Assurance that the primary teams are knowledgeable about ICU research and that their concerns are communicated to, and addressed by, the research team.
- Conflict resolution where co-enrollment in multiple studies may be inappropriate or enrollment windows overlap.
- Industry adversity to trial co-enrollment, unless negotiated up-front.

Our goal is to facilitate safe and effective collaborative research in the Trauma Unit and Surgical ICU. The process is as follows:

Initiation of projects (including observational trials):

- Contact Judy Jenkins RN, MSN, Division of Trauma and Surgical Critical Care Research Supervisor, to facilitate review and integration of the project.
- All proposed studies must be reviewed and approved by the Medical Director of the respective unit (Trauma: Oscar Guillamondegui, MD; SICU: Addison May, MD).
- For studies seeking to enroll patients on the Trauma service or in the SICU, the proposed study will be presented for approval to the Trauma faculty and/or the MDSCC.
- For studies in the SICU, information regarding the proposed study, recruitment, consent and safety will be presented to the primary attendings who admit patients to the unit. This will usually be accomplished by an e-mail summary to Division chiefs and faculty with the opportunity for the faculty to ask questions or provide input prior to trial initiation.
- Once approved by the faculty/MDSCC and IRB, the research team may screen.

Screening and enrollment process:

- All requests for enrollment must be paged to the Trauma/SCC research pager **835-4015** after 10:00a, 7 days/wk. The research nurse will evaluate and adjudicate competing trials, evaluate and assure the continued safety and minimal risk of overlapping trials. The Medical Director of the respective unit will assume final responsibility for adjudicating difficult situations.
- For any study that requires consent, prospective research subjects must be approved by the Critical Care Attending & also the primary attending, if the patient is in the SICU, ***prior to*** approaching the patient or family for consent.
- Communication regarding trial enrollment, research management & trial progress should be documented in StarPanel & communicated to the ICU care providers.
- It is expected that collaborating teams conduct research according to IRB policy & the Code of Federal Regulations.

Should you have questions, please contact Addison May, MD at 936-7188 or the Trauma/SCC Research pager (835-4015).