Executive Summary

Relationship of Trauma Activation Criteria to Utilization of High-Intensity Time-Sensitive (HITS) Interventions in Geriatric and Non-Geriatric Patients: A Multicenter Study

Coordinating Center:
Center for Trauma and Acute Care Surgery Research (CTACSR), HCA Healthcare, Nashville, TN

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Background

- Trauma activation criteria use the information communicated from the prehospital setting to determine whether an injured patient requires "activating" the trauma team such that a specialized group of healthcare providers are present in the trauma bay/ER to provide immediate and life-saving interventions when the patient arrives.
- The purpose of this retrospective multicenter study is to assess which trauma activation criteria, or set of criteria, are associated with the utilization of potentially life-saving high-intensity time-sensitive (HITS) interventions requiring the immediate presence of the trauma team.
- This study will evaluate the use of trauma activation criteria in geriatric trauma patients (i.e., those aged 65+ years) as compared to younger trauma patients (i.e. those aged 18-64 years) to determine if optimal criteria differ by age group.
- The CTACSR team submitted this study protocol to the Advarra IRB (https://www.advarra.com/) for review, and the decision letter is attached as **Appendix A**.

Participation from HCA and non-HCA Centers

- Participation in this multicenter study will involve both HCA trauma centers and non-HCA trauma centers.
- Participating sites are defined as a single center or group of centers that submit data; participating sites will provide retrospective (previously collected) data from their trauma registry from January 1, 2017 to December 31, 2019.
- Specific data variables requested align with the National Trauma Data Standard and are consistent with requirements for annual data submission to the American College of Surgeons and other entities for purposes of trauma center designation/verification. In addition, limited, select characteristics of the participating sites will be collected. A full set of variables requested is detailed in the protocol, and generally entails the following:
    - Participating sites' NTDS variables for the complete study period;
    - Identification of activation status for each patient record during the study period; and
    - A text document identifying how the participating site defined their activation criteria during the study period.

Data security

- Each participating site will submit a limited dataset from their trauma registry to the Coordinating Center via a secure protocol. Each participating site will be granted access to only its own designated, secure folder within the Coordinating Center SharePoint site such that they can view only their own folder and data.
- To de-identify submitted site data, files will be received and processed by a designated Administrative Honest Broker and a Data Honest Broker:
    - The Administrative Honest Broker will create copies of individual site data files and replace the original site filename(s) with a Study Site Number unique to this research such that individual site identity is protected and then store the original files in a secure location accessible only by them along with a key to provide reverse identification of data files if needed.
    - The individual study site identifiers will not be available to the research team at any time.
    - The Administrative Honest Broker will then transfer the renamed files to a secure server location available only to the Data Honest Broker.
    - The Data Honest Broker will perform any necessary data management to ensure participating site data files do not contain any site or individual patient identifiers (see **Appendix E**) and then create a de-identified Research Study Dataset (RSD) consisting of a merged file of all submitted non-HCA site data.
    - The RSD will then be appended to a comparable file of de-identified HCA trauma center data to create a Final RSD.
    - The study Biostatistician will have access only to the Final RSD containing the merged data from all participating sites, de-identified for both participating site and patient identifiers/PHI.
- Only aggregated, de-identified data in the Final RSD will be available to the research team at the Coordinating Center.
- After analysis by the Coordinating Center research team, only summary data results will be made available to researchers from participating sites for purposes of analysis, interpretation, and dissemination in publications.

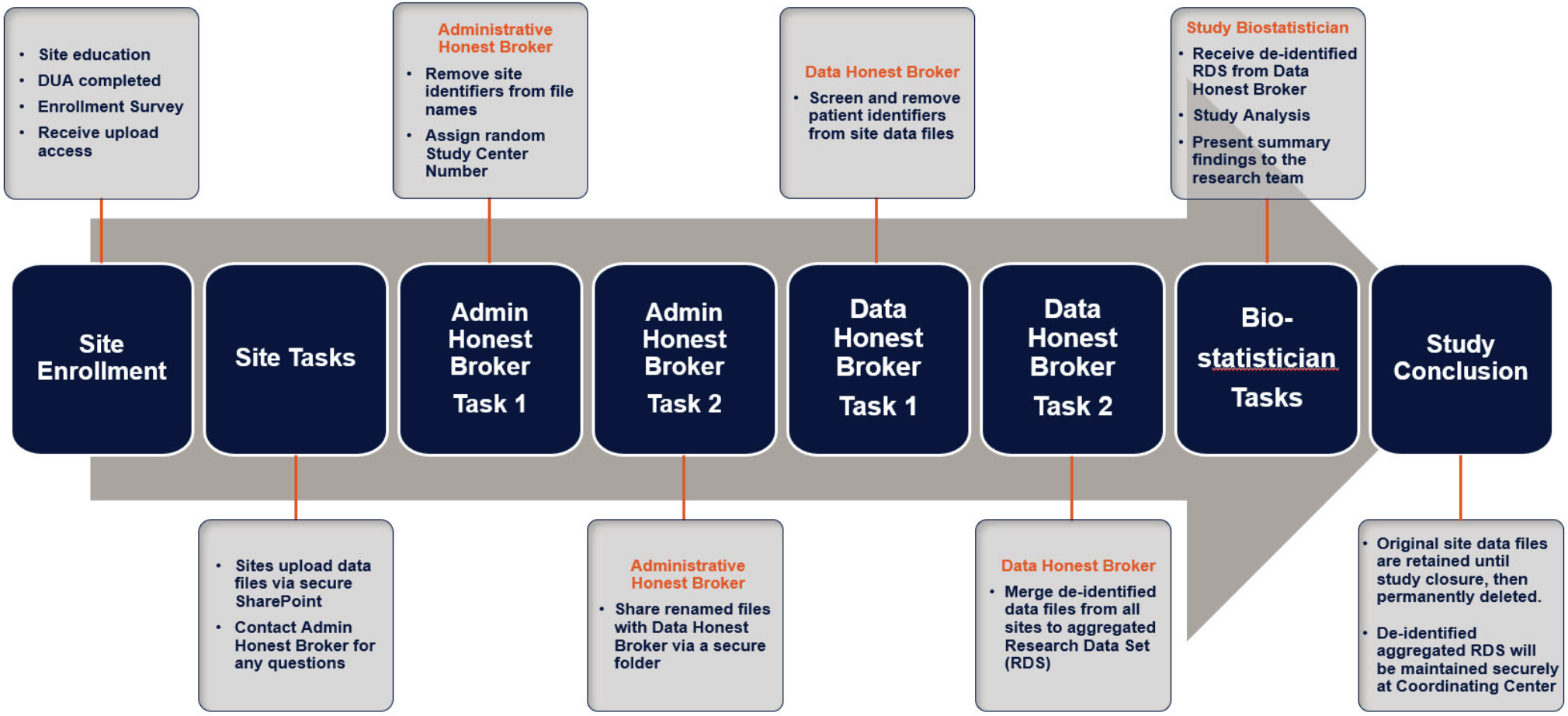
Data stewardship

- The Honest Brokers will store participating site data on a secure, designated HCA SharePoint site used exclusively for the study. The data stored will include the original submission files from participating sites. The Honest Brokers will be responsible for maintaining the original files as well as the de-identified merged files on the SharePoint site. All data will be retained for the length of the study, and as required by 45 CFR 46, and will not exceed 10 years from study initiation.

Data dissemination

- Data will be analyzed by the Study Biostatistician. Only aggregated, summary study output will be reviewed by other members of the research team.
- Study output in aggregate will be analyzed and interpreted by the members of the research team at CTACSR and at participating sites and disseminated via a suitable abstract and/or manuscript published in a peer-reviewed surgical journal following ICMJE guidelines for authorship.

Data Stewardship



HCA Healthcare

The Center for Trauma and Acute Care Surgery Research at HCA Healthcare