INTRODUCTION

The purpose of the Shands at the University of Florida is to improve the understanding and care of trauma patients in the region. The purpose of this document is (1) to define the procedures by which interested parties can gain access to the data in the registry and (2) to outline a process to assure that any publication derived from the registry is a high quality report such that the data are accurately presented, not prejudicial to any person, nor in violation to the confidentiality of any person or hospital.

ETHICAL STANDARDS

Successful applicants who intend to use material obtained from the Shands at the University of Florida Trauma Registry (SUFTR) have the responsibility to seek honestly and promulgate ethically the truth in all phases of work. This responsibility extends to all phases of research and creative activities that may result from data obtained from the registry.

The Trauma Medical Director and Trauma Program Manager will review all applications and review for:

1) Scientific integrity will be inherent in all anticipated activity.

2) Fabrication and falsification of information that an applicant claims is based on registry data is unethical.

3) Intentional selection or treatment of data to present views known by the applicant to be false is unethical.

4) Dissemination of tangible information under the applicant’s name which is derived
From data from another individual's work without due credit will be considered plagiarism.

5) Applicants must list co-authors of a work to be disseminated in any form, but only with the co-authors’ express consent. The unwarranted inclusion of co-authors that have not been substantially involved in the work is unethical.

6) Observations must be recorded in such a manner that individual institutions and human subjects can not be identified, either directly or through inference.

7) Observations should be recorded in a manner such that conclusions can not be judged as prejudicial to any institution or individual.

THE PROCEDURE TO ACCESS DATA

Any request for SUFTR data by an individual (called the “primary investigator”) must be made through a sponsor, the trauma medical director or designee. The sponsor may serve as a primary investigator him/herself or oversee the application for data by other members within his/her department.

A sponsor has the responsibility for 1) evaluating all applications for access to SUFTR data; 2) for serving as a liaison between a primary investigator and the SUFTR for each project application or to serve as the lead or secondary author of the project; 3) for identifying the project participants and their roles in the project; 4) for assuming the responsibility of assuring project quality from initial conception to submission and completion; and 5) for initiating the application process.

Frivolous, poorly conceived or incomplete applications are unlikely to ever come to meaningful fruition and should be discouraged by sponsors.

No data, which risks the breach of patient or hospital confidentiality, will be made available to any investigator. It is the responsibility of the sponsor to assure the appropriate use of any data that is obtained from the registry and to see that investigators using the data are aware of its potential strengths and weaknesses.

No publication or major presentation shall be made by any party regarding the results of any data analysis without going through the appropriate approval processes, outlined below:

Origin: 2006, revised 2007
THE PROCESS TO OBTAIN DATA

a. **Routine Data:**

   Often, an individual may require straight facts (e.g., for benchmarking or policy-making purposes) from the registry, requiring no interpretation of data. In this case, the individual must submit only a completed “Routine Data Request” form to the SUF Trauma Program Manager. Whenever possible, SUF Trauma Program Manager should respond to all such requests within 15 business days.

b. **Scientific Project Data:**

   A “Scientific Project Application for Data” form (Attachment B), is to be completed for each major request for project data. The application must be typed and include all required information, including a sponsor’s signature and that of the primary investigator, verifying he/she will abide by all publication policies.

   The Trauma Registrar will immediately distribute the copies to the Trauma Program Manager and Trauma Medical Director.

**SUMMARY OF STEPS/TIME FRAMES FOR APPROVAL OF TRAUMA REGISTRY RESEARCH**

A) Routine Data (basic facts off the registry):

Complete a “Routine Data Request” form and forward to SUFTR for their response in ten days or less.

B) Scientific Project Data:

Initial Requests:

Complete a “Scientific Project Application for Data” form and forward to SUFTR.

Special Note: All scientific projects must have an IRB Approval # and letter on file before release of data.