Delayed Splenic Rupture After Non-Operative Management of Blunt Splenic Injury
An AAST Multi-Institutional Prospective Trial

Principal Investigator: Ben Zarzaur, MD
University of Tennessee Health Science Center
910 Madison Avenue, 2nd Floor
Memphis, TN 38163

Co-Investigators: Martin Croce, MD
Timothy Fabian, MD

1. INTRODUCTION:

In this consent form, the word "you" means the patient with the injury.

You are being given the opportunity to participate in this research study. Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

You are being invited to participate in this study because you have been involved in an accident and have been diagnosed with a blunt injury to your spleen (meaning that your spleen has been injured after your body was hit by a large outside object such as a car or was injured in a fall) but you have not required surgery to repair your spleen. The purpose of this research is to study the non-surgical management of injuries of the spleen. Because a person may occasionally have to be taken to surgery to repair the spleen at a later time, this study will also help determine the factors that might have lead up to the need for surgery.

Approximately 1500 subjects will be participating in this study at approximately 15 centers around the country, and up to approximately 300 subjects will be participating locally. At this site the study will take place at the Regional Medical Center at Memphis.

Your participation in this study will last 6 months. It will take about 2.5 years to complete the entire study.

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2. PROCEDURES TO BE FOLLOWED:

This study involves a member of the study team monitoring your hospital record and collecting data about your injury, how you have been treated, how you are progressing, and what your outcome is. A member of the study team will monitor your hospital chart for any new information at least 5 times per week while you are in the hospital. If you have already been discharged from the hospital on day 5 and 10 following your injury, you will be contacted by phone to see how you are doing. After day 10 you will be contacted at 1 month, 3 months, and 6 months after your injury either in person if you have an appointment to come to the hospital clinic or by phone to determine if you have had any treatment or problems with your spleen since your last follow-up. The study team member will ask you questions that will give them information describing your activity level. Once you are 6 months from your injury day, your participation in the study will end.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There are no physical risks associated with this study because there are no medications or treatments being given to you specifically for this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Also, some of the questions we will ask you as part of this study may make you feel uncomfortable as they may remind you of your accident and cause you anxiety. You may refuse to answer any of the questions, and you may take a break at any time.

4. BENEFITS ASSOCIATED WITH PARTICIPATION:

Because this study does not change the way the doctors are treating your injuries, there is no direct benefit to you personally for participating. There is a potential, however, for gathering important new information regarding the way injuries to the spleen heal, and this could change the way these injuries are handled in the future.

5. ALTERNATIVES TO PARTICIPATION:

You will receive the same treatment for all your injuries, including the injury to your spleen, regardless of whether you participate in this study or not. If you choose not to participate in this research, no information will be gathered about you for the purposes of this study.

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6. CONFIDENTIALITY:

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel. All your electronic research records will be computer password protected and also accessible only to research personnel. Your research records will be entered into a computerized study database and will be labeled with a code. A master key which links your name with the code on your research record will be maintained at the local investigative site until the study has ended and all the information has been collected and verified with the hospital chart.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the researchers at the University of Tennessee to have access to your PHI collected in this study and to receive your PHI from your physician facilities where you have received health care. In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research and your medical insurance carrier. However, these latter organizations may not have the same obligations to protect your PHI. The Institutional Review Board (IRB) at the University of Tennessee Health Science Center may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used until the study is completed.

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study.

Information about your participation in this study will be placed in your medical record; as such, this information could be made available to your employer or insurer.

You will not be identified in any presentations or publications based on the results of this research study.

Finally, you should understand that the investigator is not prevented from taking steps, including disclosure of your research information to authorities, in order to prevent serious harm to yourself or others.

7. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, the Regional Medical Center at Memphis or the agents of either, from liability for negligence. Because there is no treatment or procedures involved with this study, there should be no research related physical injuries and neither the University of Tennessee nor the Regional Medical Center at Memphis has funds budgeted for treatment or reimbursement for such injuries or for compensation either for lost wages or for medical treatment.

You and/or your insurance carrier will be billed for the total costs associated with your hospitalization in the standard way.

There will be no compensation available for non-physical injuries that may be incurred as a result of research participation, such as exposure to criminal or civil liability, or damage to your reputation, financial standing, or employability.

8. QUESTIONS:

If you have any questions about this research study, you may contact Ben Zarzaur, MD at 901 448 8140 (academic office number where a message may be left after regular business hours and your call will be returned the following business day) .

You may contact Dr. Terrence F. Ackerman, Ph.D., UTHSC IRB Chairman at 901-448-4824 if you have any questions about your rights as a participant in this study or your rights as a research subject.

9. PAYMENT FOR PARTICIPATION:

You will not receive payment or gifts for participating in this study.

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10. COSTS OF PARTICIPATION:

There will be no additional costs to you for participating in this study. Your participation in this study will not affect your hospital bill and will not affect whether you or your insurance carrier is responsible for these costs.

11. PREMATURE TERMINATION:

Your participation in this research study may be terminated by the investigator without regard to your consent for the following reasons:

- if you do not qualify for the study
- the investigator feels it is in your best interest not to participate.

12. VOLUNTARY PARTICIPATION:

Your participation in this research study is voluntary, and your refusal to participate or your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

If you decide to stop taking part in this research study, you should tell your study doctor. Deciding to not take part in this research study will not change your regular medical care in anyway. If you decide to withdraw from the study, the information you have already provided will be kept in a confidential manner.

If you are a student, you understand participating or not participating in this study will in no way influence your grade in any course. If you are an employee of the university, you should realize that participating or not participating will not affect your employment status.

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13. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

Signature of Research Subject	**Date**	**Time**

Printed Name of Research Subject

Signature of Person Obtaining Consent	**Date**	**Time**

Printed Name of Person Obtaining Consent

In my judgment, the subject or the legally authorized representative has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Signature of Investigator	**Date**	**Time**

Signature of Legally Authorized Representative	**Date**	**Time**

Relationship of Legally Authorized Representative

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