
Research Lecture
Government Grant Writing &
the PHS 398 Form

Edward P. Sloan, MD, MPH, FACEP 

Edward P. Sloan, MD, MPH FACEP

Professor

Department of Emergency Medicine
University of Illinois College of Medicine
Chicago, IL

Edward P. Sloan, MD, MPH, FACEP 

Attending Physician
Emergency Medicine

University of Illinois Hospital
Our Lady of the Resurrection Hospital

Chicago, IL

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Global Objectives

- Conduct successful research
- Improve EM patient care
- Live a fulfilled life with a great career
- Make the world a better place

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Specific Objectives

- Learn how to find, obtain federal grants
- Be a successful federal grant writer
- Obtain federal grants
- Complete the work outlined in the grant
- Be able to utilize the resources well
- Enjoy the process
- Repeat

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Session Plan

- Identify sources of federal grant funds
- Consider an example: TBI
- Look at grants.gov and the Internet
- Discuss how the PHS 398 is filled out
- Examine specific sections of PHS398 using a manuscript of published research
- Look at a biographical sketch

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**2007 Emergency Medicine Research Workshop
Government Grants and the PHS 398 Form
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**Government Grant Sources:
Some Considerations**

- Huge numbers of grants and resources
- All agencies need successful researchers, grant writers, and work completers
- Get global, think across the board
- Think about the many agencies that overlap and create opportunities and synergies

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**Government Grants, Contracts:
Necessary Perspective**

- You are getting paid to deliver a service
 - Salt and pepper shakers
 - Portable GPS systems
 - Study of motorcycle helmet use and effects on spine and CNS outcomes following TBI
- Contracts even more specific in required deliverables


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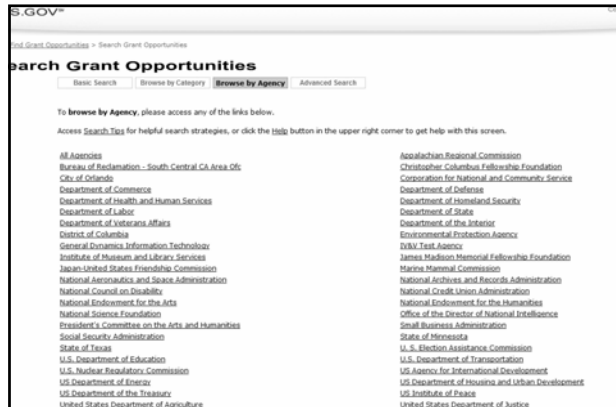
Government Grant Sources: TBI

- CDC: epidemiology, use of guidelines
- NINDS: Effect of new acute therapies
- DoD: Field (EMS) stabilization, Rx
- DHS: Mass casualty management
- CMS: Cost of initial evaluation and use of advanced neuroimaging
- United Healthcare: ditto

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**www.grants.gov
CRISP**

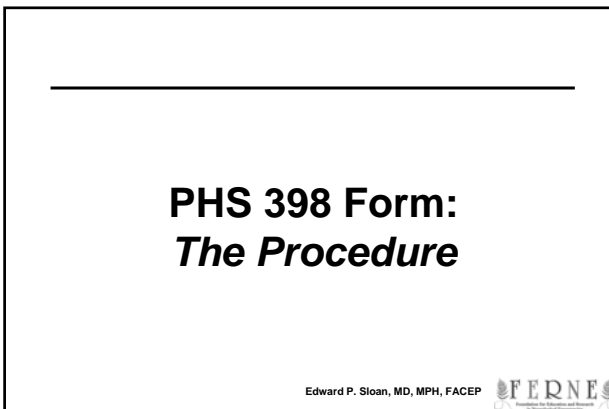
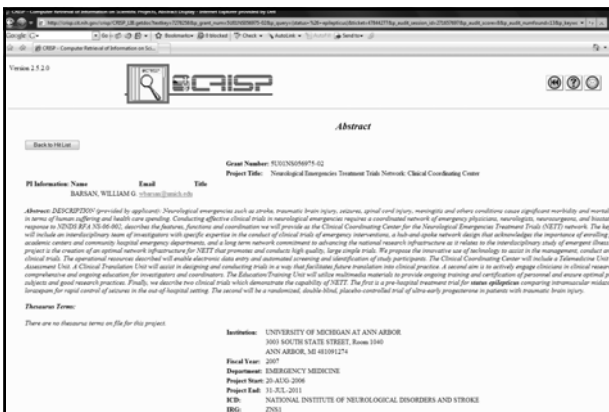
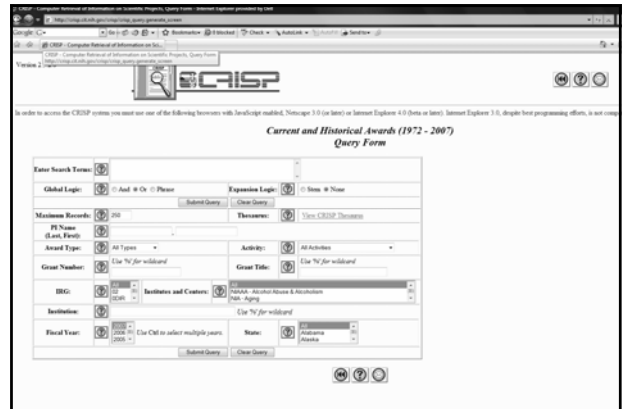
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Compelling Grant Writing: *Specifics*

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Problem Statement

- What is the problem, and why do we care?
- Is there an opportunity to solve the problem and make a positive impact?

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Needs Assessment

- Answer the question: what do we need to do? Why?

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Global Objective

- What are we trying to do?

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Specific Objective

- What specifically are we trying to do in order to meet the global objective?

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Project Plan

- How are we going to meet the specific objectives?

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Assessment

- How are we going to measure the success in meeting our global objectives?

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PHS 398 Form: *The Procedure*

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Abstract

- Tell the whole story in 250 words or less:
 - What is the problem?
 - What is the study question?
 - What will you do to answer it?
 - What will be the implications?
 - Do you have the means to get it done?

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Specific Aims

- Specific aims are not global aims
- Specific aims relate to the study question, the research, and the deliverables
- Specific aims are designed to answer specific questions

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Background and Significance

- Why should we care?
- What is the issue?
- Where are the treatment and outcome problems?
- How can this work address those issues?
- What prior research gaps exist?

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Preliminary Studies or Progress Report

- Have you done any work that matters in this research area?
- Did the preliminary work lead to the methods of this proposed project?
- Does this work suggest that you will succeed in this work?

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Research Design & Methods

- What question are you asking?
- What are the baseline assumptions?
- How do these assumptions lead to the design and methods proposed?

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Framework for Achieving Aims

- How will you deliver on answering the specific questions identified in the Specific Aims section?
- What is the overall structure of the work?

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Data Collection and Analysis

- What data, what statistics, what questions answered with the data?
- Include sample size calculation here based on initial assumptions

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Novel Methods or Technologies

- Are you going to use a noteworthy method or testing technology?
- What are the implications that would enhance the likelihood that funding will take place?
- Does this make success more or less likely? Why?

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Potential Limitations

- Acknowledge that all work has limitations and strengths
- Identify briefly 2-3 limitations that could impact the ability to answer the question or the generalizability of the results

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Potential Hazards or Risks

- Be realistic, identify all patient risks
- Confirm IRB approval and patient safeguards
- Address all human subject issues completely
- HIPAA issues addressed here

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Human Subject Issues

- Linked to potential hazards and risks

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Study Sequence or Timeline

- What will take place in what order, over what period of time? Why?
- What will take place in series or parallel?
- What happens if one step cannot be completed?
- What stopgap measures might be used?

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Budget

- Tie the budget to people costs, other direct costs, and specific activities that will lead to the ability to provide the deliverables
- Include all of the costs needed to deliver on the obligations
- If you wouldn't pay for it, don't put it in!

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Budget

- Cost per patient
- Cost of doing the business
- Who do you have to hire to get the job done?
- Think of building a home. You are the general contractor.

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Budget

- What are the IRB costs?
- What will tests cost?
- What will it cost to collect the data?
- What will it cost to analyze the data?
- What will it cost to present and publish the data?
- What are space and storage costs?

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Personnel, Bio Sketch

- Only put people on the grant who can deliver on their role in providing deliverables
- Use the Bio sketch to promote who you and other are, and why you will succeed
- Venture capitalist: what matter most?
- Not the idea or the process, but the people who will pull it off!

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Institutional Support

- Are the institutional pieces in place to allow the deliverables to be produced?
- Have all collaborators stated support?

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Assurances & Certifications

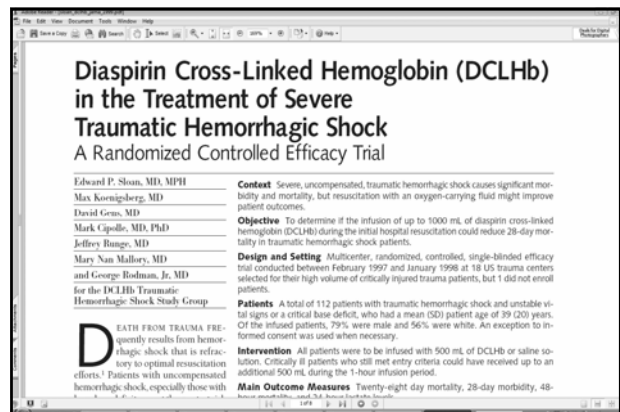
- Boilerplate materials available from grants and contracts office
- Be aware of what you are certifying and assuring to be true

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PHS 398 Form: An Example

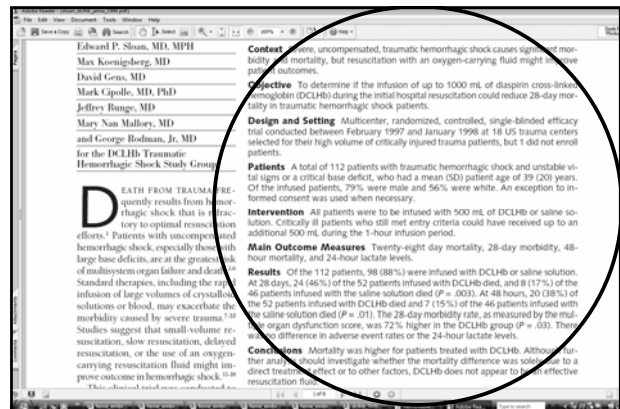
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be easily stored in the emergency department and immediately infused in trauma patients without the need for cross-matching.

The primary objective of this efficacy trial was to reduce 28-day mortality of traumatic hemorrhagic shock patients by 25%, from 40% to 30%, through the additional infusion of 500 to 1000 mL of DCLHb during the initial hospital resuscitation period. The study also attempted to demonstrate a significant reduction in 28-day morbidity, 48-hour mortality rates, and 24-hour lactate levels.

METHODS

Study Design

This was a multicenter, randomized, single-blinded, normal saline procedure-controlled, efficacy and safety study of DCLHb in severe traumatic hemorrhagic shock (FIGURE 1). This clinical trial was conducted in compliance with the regulations governing good clinical trials and good clinical practice. Study

rollment in this study.

Patients with significant traumatic brain injury, as determined by clinical criteria (ie, posturing, blown pupil) that suggest a space-occupying lesion, were excluded. Patients whose death was thought to be imminent, suggesting a futile resuscitation effort, were also excluded, as were patients whose injury occurred more than 4 hours prior to infusion. Also excluded from the protocol were minors, pregnant women, and patients who opposed to study participation or those of blood or blood products. Although there was an attempt to enroll eligible patients into this study, the data do not reflect a consecutive patient series. Outcome data for patients who either refused participation or were missed as potential study participants were not collected.

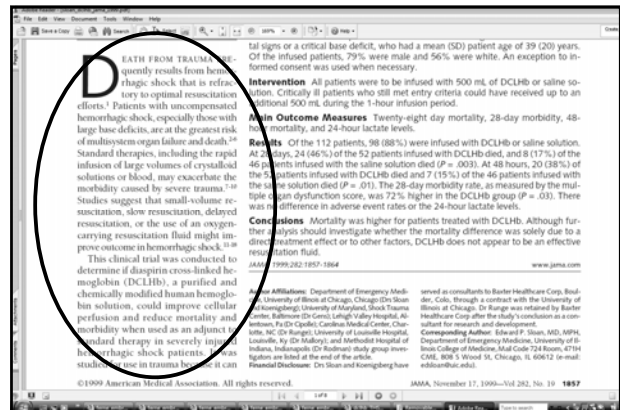
Randomization was stratified by clinical site, using permuted blocks of 4 or 6 patients.²¹ The investigators were informed of this randomization scheme in the study protocol. Each site was provided with a sequential set of sealed en-

veloped envelopes containing the random red blood cells from volunteers whose blood had been found to have negative results for surface antigen, human immunodeficiency virus 1 and 2, and hepatitis C virus. The 500- to 1000- (50 to 100 g of hemoglobin) study provided 714 to 1428 mg of DCLHb to a 70-kg person. Patients were less likely to become ineligible to be infused for other clinical reasons. Trauma patients with specified criteria within 60 minutes of arrival received up to 10% of either the 10% DCLHb normal saline through a distal or peripheral intravenous infusion was to begin no later than 60 minutes after the patient first arrived at the study site. The entire dosing of the study was to be completed within 2 hours of arrival at the hospital for more than 2 h

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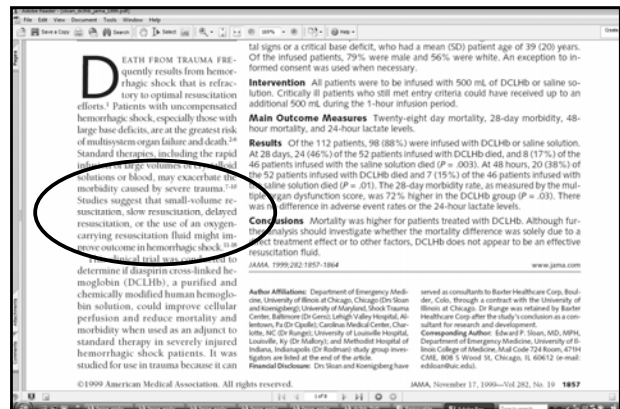
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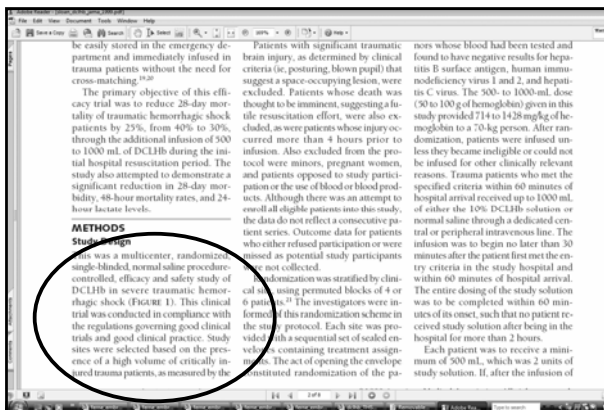
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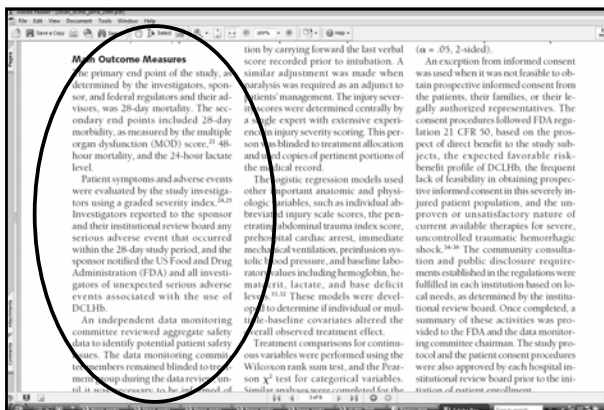
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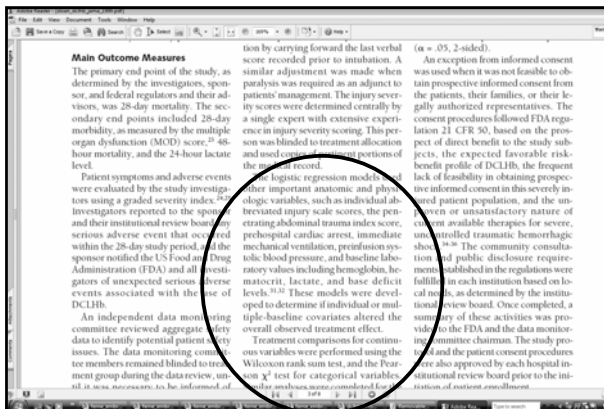
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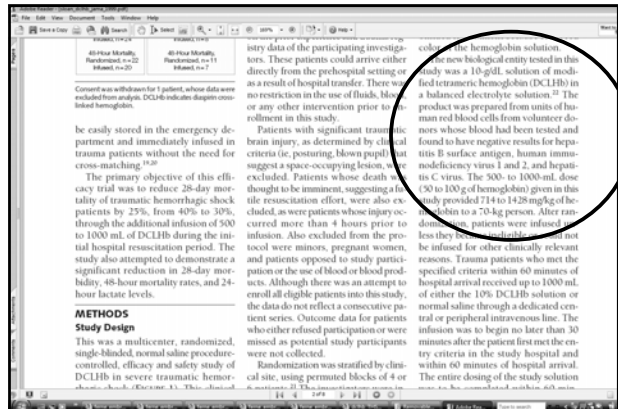
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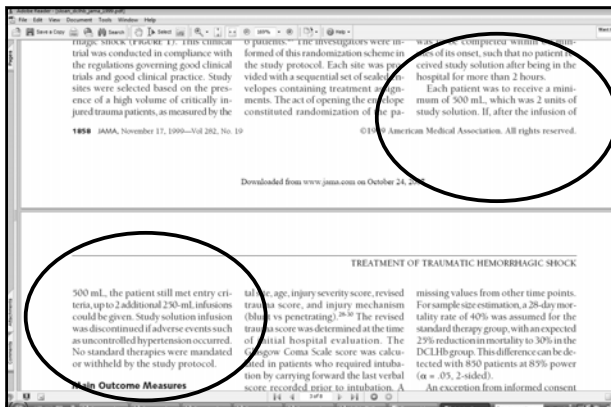
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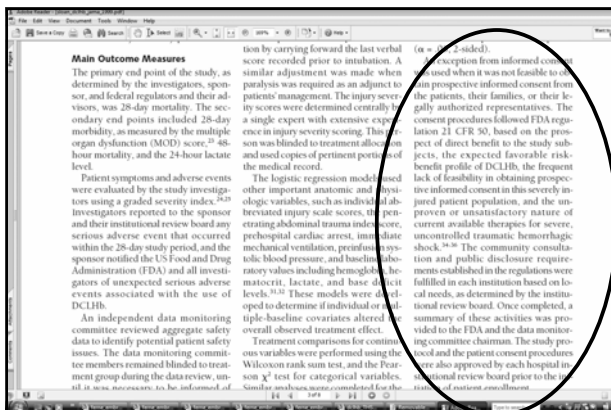
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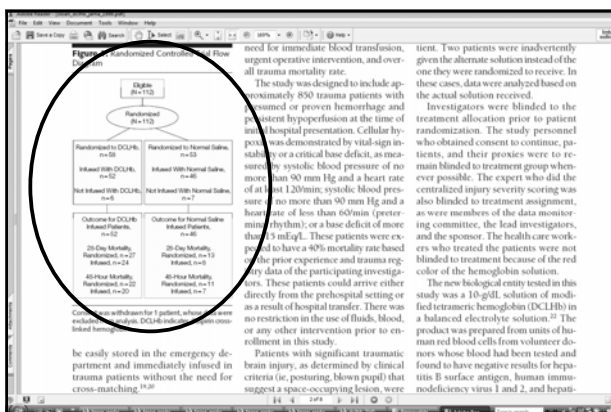
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Conclusions

- Government grants are abundant
- PHS 398 form allows for systematic application process
- Need to provide a detailed report of the work and the deliverables
- Websites such as grants.gov assist in the process

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Recommendations

- Become facile at doing government grant writing
- Know what is out there, and think global
- Consider how multiple federal grants can be obtained and utilized, promoting success in the research enterprise
- Be able to complete the PHS 398 form

Edward P. Sloan, MD, MPH, FACEP



Thank you.

www.ferne.org
ferne@ferne.org

edsloan@uic.edu
312 413 7490

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Edward P. Sloan, MD, MPH, FACEP

