Health Sciences south carolina
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Date: Wednesday, November 16, 2016 5:00:11 PM

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Pro00054122 : A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe

View: Study Identification - Identification

VIEW000072

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 * **Full Title:**

Enter the full study title

Physician use of cost and malpractice information in medical imaging decision making: A deeper look into the factors influencing physician ordering of head CT scans in patients with minor head trauma.

2.0 * **Short Title:**

Enter a short descriptive title for this study (65 characters maximum):

A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering.

3.0 * **Briefly describe the scientific or scholarly rationale:**

(i.e. purpose of research)

The purpose of the proposed research is to determine whether the introduction of information regarding litigation history and out-of-pocket cost to patients will influence head CT ordering behavior by Emergency Physicians in a simulated clinical encounter. This research is important as the literature suggests that financial motives and fear of malpractice are two of the most influential factors when Physicians order head CTs. Results from this study will advise future studies and the potential development of targeted clinical decision support for Emergency Physicians. Optimal medical image study ordering will enhance patient safety and potentially save the health system millions of dollars annually.

4.0 * **Brief Study Summary**

Non-scientific description of the research study, using 3 to 10 sentences:

Statements such as "see protocol" are not acceptable.

Note: Text entered in the Brief Study Summary field will be used to describe your study at www.SCresearch.org, an online directory designed to facilitate recruitment, if inclusion on this site is indicated later in the application.

There is a huge push to cut back on medical spending, lead by the changes in how Medicare reimburses hospitals for patient care. We aim to explore the effects of informing physicians about out-of-pocket patient costs of head CT scans, and educating physicians on the the history of malpractice cases involving failure to order head CT scans.

5.0 * **Is this a pilot study?**

○ Yes ◉ **No**

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket

View: Study Identification - Institutional Review Board

cost to patients and malpractice history influences ordering. - Steven Lowe

Institution

1.0 * **Select the appropriate Institutional Review Board (IRB) for review**:
Greenville Health System

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Study Identification - IRB Review Request

IRB Review Request for Multi-site Studies

The ***IRB of Record*** is the IRB with the primary responsibility for reviewing a study. For a multi-site study, the internal IRB may serve as the IRB of Record for other sites as well, or they may defer review to another IRB. **If you are requesting one of these IRB reviews, indicate the type below. Otherwise, click Continue on this page.**

IRB OF RECORD IS YOUR INTERNAL IRB

Central Review

1.0 The review model where your internal IRB has agreed to serve as the single, central IRB of Record for other sites involved in a multi-site study. Be sure to contact your local IRB to assure that appropriate authorization agreements have been or will be executed.

The institution that allows this in eIRB is MUSC.

* **Is this a Central Review?**
○ Yes ◉ **No**

IRB OF RECORD IS ANOTHER IRB

Facilitated Review

2.0 The review process used by your local, internal IRB as they make the determination whether or not to accept another IRB's review of a study.

All institutions allow this review in eIRB.

* **Is this a Facilitated Review (non-HSSC IRB, non-NCI CIRB, non-contracted IRB)?**

○ Yes ◉ **No**

Independent Review Model

3.0 The review model where the NCI CIRB is the sole IRB of Record responsible for both study review as well as review of local context considerations for enrolled institutions.

The institutions that allow this review in eIRB are MUSC, GHS, PH, AnMed and Self Regional.

* **Is this an Independent Review (NCI CIRB)?**

○ Yes ◉ **No**

External IRB Review

4.0 The review process used by your local, internal IRB where they defer IRB review to a contracted IRB. The external IRB becomes the IRB of record for all aspects of the study.

The institutions that allow this review in eIRB are MUSC, GHS, SRHS, AnMed and Self Regional.

* **Is this an External IRB Review (e.g., WIRB, etc.)?**

○ Yes ◉ **No**

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GHS Institutional Review Board Selection

1.0 * **Select the appropriate committee:**

	Name	Description
◉	**IRB/Committee A - Greenville Health System**	**Cardiology, Vascular Surgery, Plastic Surgery, General Surgery, Orthopedics, Rehabilitation, Neurology, Nursing, Women's, Internal Medicine, Infectious Disease, Pharmacy, General (non-pediatrics/non-oncology)**
○	IRB/Committee B - Greenville Health System	Pediatrics (all). If IRB/Committee A has reached its limit of 6 new studies for any given month, the following research may be reviewed by IRB/Committee B: Women's, Orthopedics, Internal Medicine, HIV/Infectious Diseases, Neurology, General (non-adult oncology).
○	IRB/Committee C - Greenville Health System	Adult Oncology

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Study Identification - Study Personnel Affiliation

Study Personnel Affiliation

1.0 * **Are all personnel on this research study affiliated with the institution of the designated IRB? If no, the next screen will contain a**

list of HSSC eIRB users for all institutions.

○ Yes ◉ **No**

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View: Study Identification - Study Personnel

Study Personnel

1.0 * **Principal Investigator:**
Click the Select button and choose a PI
Steven Lowe

2.0 **Study Coordinator**
Click the Select button and choose the individual who will assist in coordinating the overall activities of the the research study.
Ronald Gimbel

3.0 **Co-Investigator(s)**
Click the Add button and select the Co-Investigators for this study:
PI must obtain agreement of co-investigators prior to submitting their names to the study.

Name	Organization
Zachary Connor	Greenville Health System
Ronald Gimbel	Clemson University
Ronald Pirrallo	Greenville Health System

4.0 **Other Study Team Member(s)**
Click the Add button and select any other team members (other project assistants, students, etc.):

Name	Credentials	Organization	Role on Study	Edit Permission
Blackhurst, Dawn Dr.P.H.	Dr.P.H.	Greenville Health System		no

5.0 **Guest List**
Click the Add button and select any user to have read-only access to study information:

Name	Credentials	Organization
Ronald Gimbel		Clemson University

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View: Study Identification - eIRB Communication Coordinators

eIRB Communication Coordinators

1.0 * **Select those study team members that will handle eIRB communication for this study.**

	Person
☐	Dawn Blackhurst

Person
☑ **Zachary Connor**
☐ Ronald Gimbel
☐ Steven Lowe
☐ Ronald Pirrallo

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Study Identification - Study Sites

Study Sites

1.0 * **Indicate all affiliated sites that will be involved in the research study.**
Check all that apply:

GMH
Greer Memorial Hospital
Hillcrest Memorial Hospital
Clinic
Oconee Memorial Hospital

List any other affiliated facilities where research activities will take place:
Laurens County Memorial Hospital

2.0 * **Does this study involve other non-affiliated institutions, organizations or sites?**
○ Yes ◉ **No**

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Study Identification - Another IRB

Another IRB

1.0 **Have the Investigators listed on this application presented this research study to another IRB?**
○ Yes ◉ **No**

2.0 **If YES, provide a copy of the IRB's decision:**
Click the Add button to upload the copy

Name	Version	Orig. Author	Orig. Created	Last Modified
There are no items to display				

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Human Subjects Research - Human Subjects Research

Human Subjects Research

The following questions will assist you in determining whether this research study meets the federal requirements for Human Subjects Research.

1.0 * **Is this research study a systematic investigation, including research development, testing, and evaluation, designed to develop or to contribute to generalizable knowledge?** Note: Please check 'Yes' if the study involves a Humanitarian Use Device (HUD).

(•) **Yes** ( ) No

Note: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

2.0 * **Does this research study involve the investigator obtaining data about living individuals through 1) intervention or interaction with the individual; or 2) identifiable private information?** Note: Please check 'Yes' if the study involves a Humanitarian Use Device (HUD).

(•) **Yes** ( ) No

Note: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

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View: Training - CITI Training Records

CITI Training Records

Review this information when considering if human subjects research education/training is complete for all investigators and study staff. Personnel training displayed are the current and historical records required by the institution associated with the team member's eIRB user account.

NOTE: All study team members must be in compliance with training requirements prior to beginning any role in the study.

If training is missing or expired:
1. Instructions for completing research education requirements can be found at www.citiprogram.org.
2. Verify this institution's affiliation has been added to the CITI user profile and complete the required training.
3. Verify the first name, last name and preferred email of the CITI user profile matches the eIRB user profile.

The content on this page is provided as a tool to display research training records in real time. These data are routinely updated and are, therefore, current at the present viewing of this content.

1.0 Principal Investigator CITI Completion Records

Name Organization Completed CITI Training

		Curriculum	Group	Stage	Date Earned	Date Expires
Steven Lowe	Greenville Health System	Human Subjects Protection	Biomedical/Clinical Research	Basic Course	12/17/2015	12/16/2017
		Human Subjects	Biomedical/Clinical Research	Refresher Course	12/18/2013	12/18/2015

Protection

2.0 Study Coordinator CITI Completion Records

Name	Organization	Completed CITI Training
Ronald Gimbel	Clemson University	

3.0 Co-Investigator(s) CITI Completion Records

Name	Organization	Completed CITI Training

		Curriculum	Group	Stage	Date Earned	Date Expires
Zachary Connor	Greenville Health System	CITI Conflicts of Interest	Conflicts of Interest	Stage 1	7/7/2015	7/6/2017
		Human Subjects Protection	Biomedical/Clinical Research	Basic Course	7/7/2015	7/6/2017

Ronald Gimbel	Clemson University

		Curriculum	Group	Stage	Date Earned	Date Expires
Ronald Pirrallo	Greenville Health System	CITI Conflicts of Interest	Conflicts of Interest	Stage 1	12/9/2015	12/8/2017
		Human Subjects Protection	Biomedical/Clinical Research	Refresher Course	7/22/2015	7/21/2017

4.0 Other Study Team Member(s) CITI Completion Records

Name	Organization	Completed CITI Training

		Curriculum	Group	Stage	Date Earned	Date Expires
		CITI Conflicts of Interest	Conflicts of Interest	Stage 1	3/3/2015	3/2/2017
Dawn Blackhurst	Greenville Health System	Human Subjects Protection	IRB Members IRB and ORCA staff	Basic Course	8/1/2015	7/31/2017
		Human Subjects Protection	IRB Members IRB and ORCA staff	Refresher Course	8/6/2013	8/6/2015

5.0 Mentor CITI Completion Records

Name Organization Completed CITI Training

6.0 Collaborating Institutions PI(s) CITI Completion Records

Name Organization Completed CITI Training

There are no items to display

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences ordering. - Steven Lowe View: Training - CITI Course Completion Record - Upload

CITI Course Completion Record - Upload

1.0 A copy of the CITI Course Completion Record for each investigator must be uploaded with this application.

Name	Version	Orig. Author	Orig. Created	Last Modified
RGimbel Citi Training (Both)	0.01	Zachary Connor	4/11/2016 10:12 AM	4/11/2016 10:12 AM
ZConnor Citi Conflict of Interest	0.01	Zachary Connor	3/30/2016 4:58 PM	3/30/2016 4:58 PM
ZConnor Citi Human Subjects Protection	0.01	Zachary Connor	3/30/2016 4:57 PM	3/30/2016 4:57 PM

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Study Review Type

Minimal Risk means that the risks of harm anticipated in the proposed research are not greater -- considering probability and magnitude -- than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests.

1.0 * Requested Review Type

Select the type of IRB review you are requesting.

Exempt

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View: Review Type - Exempt Research Category v2.0

Exempt Research Category

Conducting Exempt Research

Research that is exempt from IRB review is not exempt from the ethical principles pertaining to human subject research. All research involving human participants must follow the provisions of applicable regulations and standards regardless of the level or category of review.

Good research design dictates careful consideration of risks/benefits, protections, and informed consent, even if review by the convened IRB does not occur. Moreover, the research design should meet applicable research ethics standards of the investigator's professional association or society. In all cases, the standards of respect for persons, beneficence, and justice enumerated by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report) apply to research involving human subjects, whether reviewed or certified as exempt from review.

1.0 * **Exemption Category**

Choose the exemption category that applies to this research study

- [ ] None of these categories apply to this research study

- [ ] **Category 1**
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- [x] **Category 2**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (I) information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the subjects; **AND** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. **Note**: Surveys, interviews, or observations involving children **cannot** be exempt.

- [ ] **Category 3**
Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption Category (2) of this section if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes require, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- [ ] **Category 4**
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐	**Category 5** Research and demonstration projects which are conducted by or subject to approval of [federal] department or agency heads, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under these programs; (iii) possible changes or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs.
☐	**Category 6** Tests and food quality evaluation and consumer studies, (i) if wholesome food without additives is consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

Note: To qualify for exemption, at least one must be selected

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View: Review Type - Exemption Category Justification

Exemption Category

1.0 * **Enter Justification**

Provide the IRB with information describing your study design and methods. Provide rationale for the exempt criteria chosen on the prior page.
Design:

Our research team will be measuring a series of outcome measures related to physician ordering of medical imaging study through a computerized case simulation.

Baseline measure: After presentation of clinical case participants will be asked to select one of three medical imaging study options – two variations of CT scan, and no imaging. Participants have no evidence or other information to advise their selection. The selection of an initial medical imaging study is the baseline measure.

Measure #2 – study ordered when exposed to the Canadian Head CT decision rule: Participants will be provided with information on the sensitivity, specificity, and validation studies that have supported this decision support rule. They will then be given the same imaging options to choose from as the baseline measure – two variations of CT scan, and no imaging.

Measure #3 – study ordering when exposed to malpractice data: Participants will be provided the history of all the cases where physicians were sued for not ordering a head CT scan for patients. With this information, they will be given the option to change which imaging order they would choose in the same case.

Measure #4 – study ordering when exposed to cost information: Participants will be provided information on the cost of a CT order to the patient taken from billing data from the parent institution. They will then be given the three imaging options, and asked what they would choose given

the new information.

Measure #5 – demographic information: We will be collecting basic demographic information on the participants including status (e.g. attending or trainee, military or civilian), age (scaled response not specific age), gender, and years of practice (scaled response from attending physicians).

All data will be collected during the experiment with no planned follow-up activity or engagement with the research participants. The study data, de-identified, will be secured by password in the PI's computer.

Rationale for Exempt criteria:

Simulated cases, presentation of evidence based medicine, and educational opportunities are not only part of medical culture, but are expected to take place at medical centers offering residency training programs in the United States.

Reviewing medical decision making, cost data, and discussing malpractice are topics that are well within the scope of a normal work day for a medical provider.

For these reasons, our research team asserts that there is no more risk to participants of our research study than they would encounter on any given day working in an emergency department.

2.0 Justification Document

Click the Add button to upload document(s) to support justification, including any data collection forms and/or information sheets/letters to be provided to research subjects:

Name	Version	Orig. Author	Orig. Created	Last Modified
Appendix A	0.01	Zachary Connor	4/29/2016 9:09 PM	4/29/2016 9:09 PM
Decision Tree	0.01	Zachary Connor	3/31/2016 8:44 PM	3/31/2016 8:44 PM
Information Sheet/Consent	0.03	Zachary Connor	3/30/2016 5:27 PM	4/4/2016 11:47 AM
Simulation Slides	0.01	Zachary Connor	4/29/2016 9:08 PM	4/29/2016 9:08 PM

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View: Protocol - Study Protocol

Study Protocol

1.0 * Select the category that applies to your research study protocol:

Investigator generated protocol/research plan

2.0 Protocol document, grant application, or research protocol

* Click the Add button to upload these document(s). (**Note: Do NOT upload consent or any other documents here.**)

Name	Version	Orig. Author	Orig. Created	Last Modified
ZConnor Total Protocol	0.02	Zachary Connor	3/30/2016 5:35 PM	4/1/2016 7:39 PM

3.0 Protocol Summary Information (as applicable):

3.1 Study Protocol Version: 1 **Dated:** 3/30/2016

3.2 Sponsor Assigned Amendment Number: Dated:

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View: Study Populations - Study Subjects

Study Subjects

1.0 * Estimated Local Enrollment Goal
Enter the anticipated number of subjects to be enrolled at local site:
75

2.0 Estimated Study-Wide Enrollment Goal
Enter the anticipated number of subjects to be enrolled at all sites:
200

3.0 * Briefly describe the setting in which the research will be conducted.
The research will be available online at an NIH website, which can be accessed by study participants at their choice of location and electronic device.

4.0 * Participant Remuneration (Payment/Academic Credit)
Will subject(s) receive remuneration?
○ Yes ◉ **No**

5.0 * Will prospective participants be vulnerable to coercion or undue influence?
○ Yes ◉ **No**

If yes, briefly describe additional safeguards included in the protocol to protect the rights and welfare of participants likely to be vulnerable.

6.0 * Identify targeted subject population(s) involved in this research study (**Note:** The purpose of this question is to determine equitable selection of subjects and to identify vulnerable populations.)
Select all that apply:

- ☑ **Adults (18+)**
- ☑ **Males**
- ☑ **Females**
- ☐ Pregnant Women
- ☐ Human Fetuses or Neonates
- ☑ **Minorities**
- ☐ Children (<18 years of age)
- ☐ Prisoners
- ☐ Comatose persons
- ☐ Cognitively Impaired persons

- [ ] Terminally Ill persons
- [x] **Employees of the principal investigator's institution**
- [ ] Students enrolled at the principal investigator's institution
- [ ] Non-English speaking persons
- [ ] Socially/Economically disadvantaged persons
- [ ] Caregivers
- [ ] Elderly/Aged persons
- [ ] Institutionalized Individuals

7.0 * **Study Population**
Briefly describe the study population? (e.g. healthy volunteers, adults with Type II Diabetes, children with Asthma):
Emergency Department providers: Doctors, Nurse Practitioners, and Physician Assistants

8.0 * **Describe the selection criteria (inclusion/exclusion criteria):**
a. Inclusion Criteria: Regardless of assignment to group, basic inclusion criteria include:
1) Licensed physician or physician trainee;
2) Board certified, board eligible or trainee in Emergency Medicine; and
3) Serve as an attending physician or trainee affiliated with the Greenville Health System.

b. Exclusion Criteria: All others not meeting inclusion criteria are excluded.

9.0 * **Describe recruitment procedures, including how subjects will be contacted, by whom, and how eligibility will be determined.**
Participants will be contacted by the Academic Vice Chair, Ronald Pirallo MD, through their work email address with information about the study and a link to the website where the simulation may be completed.

Eligibility will be determined by an employee roster provided by Bill Harvey, the business operations coordinator of the Emergency Trauma Center.

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Study Funding Information

1.0 * **Primary Funding Source (Active or Pending)**
Select primary (active or pending) funding sources for this study:
Internal Funding

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Study Sponsorship

1.0 Sponsor(s)
Click the Add button and select the sponsor(s)
Name
There are no items to display

2.0 Other Sponsor(s)
If sponsor(s) is/are not in the above list above, enter name(s) here:
GHS and Clemson University

3.0 External Identifier (if applicable):
(e.g. agency/sponsor assigned numbers)

4.0 Internal Identifier (if applicable):
(e.g. proposal or award Number)

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View: Funding and Sponsorship - Study Costs

Study Costs
Study Associated costs funded by:

1.0 Drug(s):
Sponsor

If OTHER, specify:

2.0 Device(s):
N/A

If OTHER, specify:

3.0 Supplies:
N/A

If OTHER, specify:

4.0 Laboratory Fees:
N/A

If OTHER, specify:

5.0 Hospital Fees:
N/A

If OTHER, specify:

6.0 Physician Fees:
Sponsor

If Other, specify:

7.0 Other:
N/A

If OTHER, specify:

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Application Checklist

1.0 Will the following be involved in the research study?
Select all that apply

- [x] **Waiver of the Requirement to Obtain Written and Signed Consent from Subjects**
- [ ] Medical Record/Chart Review
- [ ] Use of survey, questionnaire, focus group/interview questions
- [ ] Interviews/Group Discussion
- [ ] This research study is being conducted by other investigators in other countries
- [ ] Videotaping, audiotaping, filming or photographing research subjects
- [ ] Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse ?

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Clinical Trials

1.0 * What is the phase of the clinical trial?
This study does not involve a clinical trial

2.0 If OTHER, describe:

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Study Procedures
(Blood draw, Imaging, Lab Tests, Physical Exam, Medical History)

1.0 * Briefly describe the procedures to be performed solely as part of this research study.
N/A

2.0 * Briefly describe the procedures being performed already for diagnostic or treatment purposes (standard of care).

N/A

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View: Consent Process - Waiver of Written or Signed Consent

Consent Process - Waiver of Written or Signed Consent

If a waiver of written signed informed consent is requested, please provide justification.

1.0 * **Check one of the following and explain your choice:**

The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.

* **Explain:**

Simulated cases, presentation of evidence based medicine, and educational opportunities are not only part of medical culture, but are expected to take place at medical centers offering residency training programs in the United States.

Reviewing medical decision making, cost data, and discussing malpractice are topics that are well within the scope of a normal work day for a medical provider.

For these reasons, our research team asserts that there is no more risk to participants of our research study than they would encounter on any given day working in an emergency department.

2.0 * **If signed documentation is waived, will the subjects be provided with a written statement/explanation regarding the research?**

(●) **Yes** ( ) No

If YES, attach a copy of written statement.

Name	Version	Orig. Author	Orig. Created	Last Modified
Information Sheet	0.01	Zachary Connor	4/4/2016 11:49 AM	4/4/2016 11:49 AM

If NO, explain below why a written statement is not necessary or appropriate.

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View: Privacy - Privacy and Confidentiality

Privacy and Confidentiality

1.0 * **Describe the procedures and safeguards that will be implemented to protect the privacy and confidentiality of the participants' data. Include details, as applicable to the study, such as: privacy of interview site, procedures for coding/de-identifying data, provisions to avoid public identification/embarrassment of participants; persons with access to private identifiable data, etc.**

Storage, Access, and Transmission:

Storage:
1. On the GHS server, or on a GHS approved laptop that has been secured by the GHS Information Services department
2. GHS SharePoint Rad Team page owned and operated by Zachary A. Connor, approved by GHS Information Services.
http://share.ghs.org/SiteDirectory/eduservices/radteam/default.aspx
3. GHS RedCap web application, username zac15a

Access:
Zachary A. Connor, the owner of these projects, controls the GHS SharePoint Rad Team page and Redcap application page. Access will be granted to individuals who have documented approval from GHS to view the data in question.

Transmission:
Data with protected health information may be transmitted to individuals who have approval from GHS to view the data in question by means of:
1. GHS outlook secure email
2. Sharing access through the aforementioned GHS SharePoint Rad Team page
3. Approving access to the GHS Redcap application
4. Sending files securely through the GHS Redcap application

Authorization expiration: upon contract end date

Zachary A. Connor, MD

2.0 * **Where will study records and data collected at this site be stored**
Select all that apply:

Password protected network storage

If OTHER, describe:

If information will be stored on an end-user/portable device, describe the security on the end-user/portable device that will be used to prevent unauthorized access to the data in the event the device is lost or stolen:

3.0 * **Will the study use a National Institutes of Health (NIH) Certificate of Confidentiality?**

○ Yes ◉ **No**

If YES, what is the NIH Certificate of Confidentiality status?

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View: Privacy - Protected Health Information (PHI) for Research

Protected Health Information (PHI) for Research

Protected Health Information (PHI) is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future physical or mental health or conditions of an individual.

Covered Entity - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form.

1.0 * **To determine if this research study is using/disclosing PHI, select any of the following 18 elements that your study will require access to, as defined by the Health Insurance Portability and Accountability Act (HIPAA), as identifiers. If none of these 18 identifiers will be used/disclosed, then select the final option.**

Electronic mail addresses

If the study requires access to any of the 18 identifiers but will not be linked to PHI, please select those that are applicable to the left. On the next screen, you will be able to select "Study where health information is not linked to identifiers".

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Access to Protected Health Information (PHI) for Research

1.0 **Indicate the sources of health information to be used**

Select all that apply:

There are no items to display

If OTHER, indicate any other source(s) of health information to be collected/used:

2.0 **How will PHI be accessed for the research study?** (Check all those that apply)

Study where health information is not linked to identifiers

Pro00054122: A simulation study to assess whether informing physicians of out-of-pocket cost to patients and malpractice history influences View: Privacy - Use of De-Identification to Access Protected Health Information (PHI)

ordering. - Steven Lowe

Use of De-Identification to Access Protected Health Information (PHI)

1.0 The Privacy Rule permits covered entities, depending on IRB approval, to use and disclose data that have been de-identified without obtaining an authorization. The Principal Investigator must receive the data from the covered entity in a de-identified format. A covered entity may de-identify PHI in one of two ways. The first method requires the removal of every one of 18 identifiers enumerated at section 164.514(b)(2) of the Privacy Rule. Data that are stripped of these 18 identifiers are regarded as de-identified. The second way to de-identify PHI is to have a qualified statistician determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information.

The Privacy Rule permits a covered entity to assign to, and retain with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

* **Will you be receiving de-identified information from a covered entity for the purpose of this project?**

○ Yes ◉ **No**

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Institution Impacted Services

Prior to IRB approval, the investigator for this research study must obtain authorization from any services impacted by the research. Many studies require significant levels of support or collaboration from staff and departments in order to fully execute the proposed study.

1.0 * **Will the research study use any property, facilities, equipment, or services of the institution?**

○ Yes ◉ **No**

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General Comments

1.0 **Add any additional comments to assist in the review of this research study.**

2.0 Add any miscellaneous documents that do not fit in other sections of the study application.

Click Add to upload document(s)

Name	Version	Orig. Author	Orig. Created	Last Modified
CV of Ron Gimbel	0.01	Zachary Connor	4/11/2016 10:11 AM	4/11/2016 10:11 AM
CV of Ron Pirallo	0.01	Zachary Connor	4/2/2016 9:16 AM	4/2/2016 9:16 AM
CV of Steve Lowe	0.01	Zachary Connor	4/4/2016 2:06 PM	4/4/2016 2:06 PM
CV of Zachary Connor	0.01	Zachary Connor	4/2/2016 9:16 AM	4/2/2016 9:16 AM
Signature Page 1	0.01	Zachary Connor	4/29/2016 9:06 PM	4/29/2016 9:06 PM
Signature Page 2	0.01	Zachary Connor	4/29/2016 9:06 PM	4/29/2016 9:06 PM

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Final Page

This is the end of the application. Click the Finish button to close the forms and return to the Application workspace. Click Edit Application Forms in the Application workspace to return to the forms at any time.

NOTE: Clicking Finish does not submit the application for review; this activity can only be executed in the Application workspace by the PI.