

# Informed Consent for Research: A Survey of Current Practices in Osteopathic Academic Emergency Medicine Departments

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## Abstract

**Background:** The emergency department (ED) environment presents unique barriers to the process of obtaining informed consent for research. **Objectives:** To identify commonalities and differences in informed consent practices for research employed in academic EDs. **Methods:** Between July 1, 2006 and June 30, 2007 an on-line survey was sent to the residency directors of thirty seven academic emergency medicine residency training programs identified through the American College of Osteopathic Emergency Physicians (ACOEP). Residency directors had the opportunity to complete the survey on-line or in person at the annual Program Directors meeting in Naples, Florida. **Results:** Thirty (81%) responded. The average number of simultaneous clinical ED-based research projects reported was 5.7 (95% CI: + 1.52). Over three quarter (77.5%) of respondents reported that emergency medicine (EM) residents are responsible for obtaining consent from research subjects. Eight (26.6%) participating institutions do not require documentation of an individual's knowledge of the specific research protocol and consent procedure before he or she is allowed to obtain consent from human subjects. **Conclusions:** It is common practice in academic EDs for clinical investigators to rely on on-duty health care personnel to obtain research informed consent from potential research subjects. This practice raises questions regarding the sufficiency of the information received by human subjects and further study is needed to determine the compliance of this consent process with federal guidelines.

\* Marcin Kociuba was an emergency medicine resident at the time of data collection.

Dr. Arthur Calise served as residency director and his trainer.

This work was performed as a joint project between the emergency departments at Yale New Haven Hospital and Saint Michael's Medical Center.

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## INTRODUCTION

Ever since the Board of Trustees of the American Osteopathic Association approved the creation of the American Osteopathic Board of Emergency Medicine (AOBEM) in 1980, academic EDs pursued research opportunities involving human subjects. [1] While some

emergency medicine (EM) research is conducted in the out-of-hospital setting, most EM research is conducted within the confines of the academic ED. Wherever it occurs, EM research continues to rely heavily on human subjects to advance the field.

Since the Belmont Report, clinical researchers have been expected to recognize that patients have legitimate interests in what happens to their bodies in both clinical and research contexts under the bioethical notion of respect for persons, a manifestation of the principle of respect for patient autonomy. [2] To this end, it is necessary for human research subjects to receive sufficient information to make an informed decision before enrolling in a research protocol. Federal oversight agencies enforce regulations protecting the rights of research subjects. Noncompliance has resulted in sanctions against the offending institution, monetary penalties and civil litigation. [3] EM researchers have known for years that the emergency setting presents unique challenges to the process of informed consent. [4] Some of

these challenges were brought to the fore in the Institute of Medicine's (IOM) 2006 report entitled the Future of Emergency Care which described the state of emergency care as fragmented and overcrowded with decreasing number of EDs in the face of increasing demand. [5] These findings along with pragmatic staffing issues, the necessity for around the clock coverage, delegation of duties to housestaff, nursing shortages, few NIH funded investigators that can devote significant resources to human subject enrollment, lack of research staff and ED research infrastructure impede compliance with ethical and legislative guidelines governing the informed consent process of human subjects.

Despite these hurdles, all reports seem to indicate that osteopathic medical research is growing as witnessed by increased submissions to the Annual AOA Research conference and the increase of extramural funding to osteopathic clinical training programs. [6] The admixture of academic demands to conduct research amidst the current ED chaos begs the question as to how carefully informed consent is being obtained in the extant academic ED milieu. Our objective is to describe current practices in the process of obtaining informed consent for research conducted in academic emergency departments in the US.

## **METHODS**

### **STUDY DESIGN AND POPULATION**

After approval of the research by the Saint Michaels' Human Investigation Committee, we posted an on-line survey targeting program directors at academic emergency departments identified through the ACOEP residency programs 2005-2006 database. All programs were considered eligible for participation by virtue of the research provision contained in the Basic Standards for Residency Training in Combined Osteopathic Emergency Medicine/Internal Medicine Manual. [7] Surveys were sent to the program directors at each program identified.

### **SURVEY CONTENT AND ADMINISTRATION**

The Web-based, self-reported survey was developed by the authors (EM, LD). Survey development methods were based on consensus opinion. Item content was selected based on information deemed important to detecting potential barriers to research informed consent. Primary content areas targeted issues pertaining to program demographics, research output, institutional research policy, and information transfer of research protocol and consent procedures. Preliminary items

were assessed and reviewed by the authors and by an ethics consultant. Items that were retained were those judged by the authors to be the most clear and concise and to most effectively assess previously identified constructs related to research informed consent. Next, this version of the survey was pilot tested for clarity with an allopathic emergency residency program. No additional refinements were made based on the results of pilot testing.

Data were obtained using a web-based survey tool (SurveyMonkey.com, Portland, Ore). Questions focused on the following topics: faculty demographics, ED staffing patterns, type of research conducted, number of concurrent research projects, institution-specific investigational review board (IRB) requirements and policies, and informed consent practices. An initial e-mail invitation to participate was sent to each program director followed by up to 5 reminders to non-responders. If the fifth reminder failed to result in a completed survey, program directors were provided the opportunity to complete the survey at the 2007 annual Program Director's meeting in Naples, Florida. Survey data collection took place between July 2006 and June 2007. The survey instrument attempted to distinguish members of the research team from other potential consent personnel. Since information sufficiency and retention will be explored in future studies, the present survey did not explore what information was relayed from investigator to consent personnel.

### **DATA ANALYSIS**

Descriptive statistical analysis was used to summarize the survey findings.

### **RESULTS**

Thirty seven emergency residency programs were identified through the AOBEM database. Thirty (30) responses were received from program directors. Total response rate was 81%. The characteristics of the EM programs represented in the survey are outlined in Table 1. The percentage of time personnel not identified as part of the research team were used to obtain consent was EM resident (92.4%), other resident (26.9%), ED nurse (30.8%), and ED attending (15.4%).

Emergency Department programs that used consent personnel that were not part of the research team (delegators, N=26) were compared to programs that limited research consent responsibilities to the research team (nondelegators, N=4). There was no significant difference in clinical full

time equivalents (FTEs) between delegators (median = 3) and nondelegators (median = 3.0) (Nonparametric Wilcoxon rank sum test,  $p = 0.91$ ). Delegator and nondelegator programs also did not significantly differ in all other categories including the number of clinical papers published, number of residents, and number of patient visits.

Eight program directors (26.7%) indicated there was no institutional policy that required individuals with research consent responsibilities to demonstrate a baseline level of knowledge regarding the research protocol or its informed consent procedures. Training programs that reported having such policies indicated the policy originated from the institution's IRB (96.0%) of the time.

## Figure 1

Table 1: Physician Survey of Informed Consent (IC) Practices for Research in the Emergency Department (ED): Overall and by IC Delegator or Nondelegator Status

	Total	Delegator	Non-Delegator
	Median (IQR)	Median (IQR)	Median (IQR)
Total # annual visits to your ED	52000 (34000-88000)	48000 (31500-88000)	75000 (3400-9500)
# residents in EM residency program	16.5 (10-26)	17 (10-26)	32 (2-48)
#FTEs EM faculty with clinical responsibilities who conduct their own research	3 (2-5)	3 (2-4)	3 (0-14)
# Basic science research publications	0 (0-1)	0 (0-1)	2 (0-3)
# clinical research publications involving human subjects	0 (0-1)	0 (0-1)	3 (0-10)
# other publications	0 (0-1)	0 (0-1)	0 (0)
# publications Basic + Clinical + Other	1 (0-2)	0 (0-0.5)	6 (0-12)
# FTEs faculty and attending staff	36 (29-40)	36 (30-40)	35 (15-42)
Residents Per Shift	2 (1-3)	2 (1.5-2.5)	3 (1-7)
Physician Assistants Per Shift	0 (0-1)	0 (0-1)	1 (0-2)
Students per shift	1 (0-2)	1.5 (1-2)	2 (1-4)
Clinical Research Projects in Progress in ED	3 (3-8)	3 (3-8)	8 (0-13)
# FTEs EM NonClinical Staff who Conduct Their Own Research	0 (0-1)	0 (0-1)	0 (0-1)
	N (%)	N (%)	N (%)
Type of Patients Treated			
Adult Only	0 (0)	0 (0)	0 (0)
Adult and Pediatric	30 (100)	26 (100)	4 (100)
Protocol knowledge required to obtain informed consent	22 (73.3)	19 (73.1)	3 (75.0)
Have policy governing who may obtain informed consent	23 (76.6)	20 (76.9)	3 (75.0)
Utilize Assent for Pediatric (N/A Adults)	8 (26.6)	6 (23.1)	2 (50.0)
Conduct emergency research with a consent waiver	6 (20.0)	4 (15.4)	2 (50.0)
EM Faculty Member on IRB	13 (43.3)	12 (46.2)	1 (25.0)
Abbreviations:			
ED = emergency department			
EM = emergency medicine			
FTE = full time equivalent			
Hrs = hours			
IQR = inter-quartile			
N/A = not applicable			

## DISCUSSION

Before World War II, clinical research was largely unregulated. [8] Investigators set the bar determining what, if any, information human subjects received about a research protocol. [9] The human experimentation atrocities committed by the Nazis led to codified standards of research conduct in the form of the Nuremberg Code and the Declaration of Helsinki. [10] In the 1970's Congress further protected human subjects by enacting the comprehensive regulations known as the Common Rule which governs research today. [11] To comply with these regulations consent

personnel must be able to explain the purpose of the research, describe research procedures, alert human subjects to foreseeable risks and benefits and disclose appropriate alternative treatments or procedures.

The emergency department presents unique barriers to informed consent both because of the time frame in which the research is performed and because patients in the emergency department are a vulnerable population. [12] While investigators and other members of the research team may have extensive knowledge of a project, not everyone who is involved in the clinical care of ED patients would necessarily have extensive familiarity with that project. Who should act as consent personnel and the sufficiency of information these personnel relay to human subjects has been a focus of concern by commentators in the field of ethics and human research. Some advocate a movement away from using ad hoc consent personnel to dedicated consent teams [13] or consent personnel with "experience in the field of study". [14]

This study provides insight into the current state of research informed consent practices in academic emergency departments. Previous studies on research informed consent have examined various issues including patients with diminished capacity, [15] vulnerable populations, [16] and the researchers' understanding of federal guidelines. [17] No study to date, however, has examined practices used by clinical investigators in academic EDs. It was anticipated that academic EDs use a variety of healthcare personnel to obtain informed consent for research. The reliance upon nonstudy personnel may be a heretofore unrecognized barrier to research informed consent because nonstudy personnel have other priorities and may be unlikely to consistently administer adequate informed consent.

Our survey demonstrates that almost 90% of all academic EDs in our sample rely on on-duty healthcare personnel to explain research protocols to potential human subjects and obtain their consent for participation. This occurs for a number of reasons: the 24/7 nature of the ED environment, and concerns about enrolling patients on all shifts; the cost of having research staff present in the ED on a consistent basis; concerns about selection bias and providing opportunities for the spectrum of ED patients to enroll in research studies. Given the survey results, on average, ED personnel in many institutions, including residents and students, must have sufficient knowledge about 5.7 concurrent research protocols to obtain informed consent for

each of them. While our survey did not explore research protocol knowledge and its relationship to obtaining informed consent, it does raise questions about the depth of knowledge that some personnel may have about specific projects. This may be another unrecognized challenge to obtaining research informed consent in the ED. The need to assess knowledge of multiple research protocols might help delineate the reasonable capacity of housestaff and faculty and should be an area for future inquiry.

## **LIMITATIONS**

There are several limitations to this study. While we lack detailed data on the nonrespondents, we believe the sample to be representative of most academic EM programs, especially given that the overall mean number of EM residents per program nationally does not differ significantly from the mean number of residents per program in our respondent sample. We were only able to survey academic EDs with EM residency programs, however, most EM research tends to emanate from such centers. Another limitation is our reliance upon self-report data. While fraught with potential reporting and recall biases, self report data here would be anticipated to bias the results toward a more flattering description of a program's performance, not less. Hence, we would reasonably assume that any direct measures or direct observation of ED consent practices would uncover more barriers to research informed consent than the survey conducted herein.

## **CONCLUSION**

We found that medical staff on duty in the emergency department are frequently relied upon by investigators to obtain research informed consent from potential ED subjects. The finding that consent delegation is more common in academic centers with fewer FTE's may be due to faculty oversubscription, but further inquiry is required to resolve this issue. Documentation of information sufficiency during delegated consent may highlight future opportunities for improvement in EM research consent policy and

practice.

## **References**

1. AOBEM About AOBEM July 1, 2007. Available at: [www.aobem.org](http://www.aobem.org). Accessed February 28, 2008.
2. Beauchamp, T.L., Childress J.F.. 1994 Principles of Biomedical Ethics, 4th ed. New York: Oxford University Press.
3. Robert J. Levine, 1981 Ethics and Regulation of Clinical Research, Baltimore: Urban and Schwarzenberg.
4. Schmidt TA, Salo D, Hughes JA, et al. Confronting the ethical challenges to informed consent in emergency medicine research. *Acad Emerg Med*. 2004; 11:1082-89.
5. Institute of Medicine. Committee on the Future of Emergency Care in the U.S. Health System. Hospital-Based Emergency Care: At the Breaking Point Washington, DC: National Academy Press; 2006.
6. Guillory JV, Sharp G. Research at US Colleges of Osteopathic Medicine: A Decade of Growth. *JAOA*. 2003; 103:176-81.
7. Basic Standards for Residency Training in Combined Osteopathic Emergency Medicine/Internal Medicine. Revised, BOT 7/2002. Available at <http://www.acoi.org/Com.EM.IM.pdf>. Accessed March 3, 2008.
8. Blustein J. The history and moral foundations of human-subject research *Am J Phy Med Rehabil*. 2007; 86:82-85.
9. Slovenko R. The evolution of standards for experimental treatment or research *J Psychiatry Law* 2005; 33:129-174.
10. Marrus M. The Nuremberg War Trial, 1945-46: A Documentary History. Boston St. Martin's Press.
11. The Common Rule, Title 45, Code of Federal Regulations, Part 46. U.S. Department of Health and Human Services, National Institutes of Health and Office for Human Research Protections 2001.
12. Moskop JC. Informed consent and refusal of treatment: challenges for emergency physicians *Emerg Med Clin North Am*. 2006; 24:605-18.
13. May T, Craig JM, Spellecy R. Viewpoint: IRBs, Hospital Ethics Committees, and the Need for "Translational Informed Consent" *Acad Med* 2007; 82:670-4.
14. Stiffler HL. Guidelines for obtaining informed consent for clinical research 2003; *Appl Clin Trials*
15. Coats TJ. Consent for emergency care research: the Mental Capacity Act 2005 *Emerg Med J*. 2006; 23:893-4.
16. Baren JM, Fish SS. Resuscitation research involving vulnerable populations: are additional protections needed for emergency exception from informed consent? *Acad Emerg Med*. 2005; 12:1071-7.
17. Sanders AB, Hiller K, Duldner J. Researchers' understanding of the federal guidelines for waiver of and exception from informed consent. *Acad Emerg Med*. 2005; 12:1045-9.

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