Supporting Statement A for

ETHICAL DILEMMAS IN SURGERY AND UTILIZATION OF HOSPITAL ETHICS CONSULTATION SERVICE: A SURVEY

Revised 11/07/13

Project Officer:

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Supporting Statement for Request for Approval from the Office of Management and Budget (OMB) for "Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey."

Abstract

We request OMB to approve our project titled "Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey." This study involves a self-administered survey of randomly selected surgeons currently practicing in the US who will be contacted through the American Board of Medical Specialties mailing list. The sample size will be stratified so that surgeons representing: 1) both rural and urban locations, 2) all 5 geographical locations in the US, and 3) all 13 surgical subspecialties recognized by the American College of Surgeons will be included in this study. The survey instrument will be a 29 item questionnaire and take approximately fifteen minutes to complete. This survey is intended to collect information about the ethical dilemmas that surgeons have faced in their practices over the past year, and assess their experiences, if any, with their hospital consultation services. Specifically, the information gathered in this study will be valuable in understanding the ethical dilemmas that surgeons face, the utility of institution ethics consultations services for surgeons, and to identify what barriers, if any, discourage surgeons from utilizing these services. The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, they will provide a better understanding the ethical dilemmas that surgeons face in their practices. Second, they will provide understanding of factors that determine the current utilization of hospital consultation services by surgeons. Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to ethical dilemmas in their practices and how ethics consultation services could better support surgeons when faced with these dilemmas. Results of the survey will be de-identified, and the responses of individual surgeons will be kept private to the extent allowable by law.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Despite the mandates among U.S. hospitals to maintain ethics consultation services, the increasing standardization of the consultative process, and the consistent endorsement of ethics consultation in general, there is little empirical evidence regarding the perceived effectiveness of ethics consultation and the barriers that limit its use by surgeons. Previous studies have shown that ethics consultation services are used regularly by some doctors, but others appear to be reluctant or refuse to use these services.[1] This previous study showed a statistically significant decrease in the use of hospital ethics consultation services by surgeons as compared to non-surgeons. Another study assessed the experiences of US internists with ethical dilemmas and ethics consultation.[2] The American College of Surgeons Committee on Ethics has shown that surgeons face numerous ethical dilemmas during training and in practice, however to our knowledge no studies have been performed in the surgeon population to 1) identify the specific ethical dilemmas that surgeons encountered during their medical careers; 2) characterize the utilization of hospital ethics consultation service by surgeons; and 3) recognize the barriers to surgeons' use of ethics consultation services.

The proposed survey is designed to improve the understanding of the specific ethical dilemmas that surgeons encounter, the role of ethics consultation in their practices, and what barriers may exist that discourage surgeons to utilize these services. We plan to survey a random sample of surgeons who practice in the US drawn from the American Board of Medical Specialties list of physicians.

This project involving the collection of data represents an appropriate study for the Department of Clinical Bioethics at the Warren G. Magnusun Clinical Center at the NIH. First, the project falls within the authorized role of the NIH as a research institution within the Public Health Service, as expressed in 42 USC 241a. Second, the project is not duplicative of any research being conducted by other agencies within the DHHS. We have consulted with Carolyn Clancy, director of the Agency for Healthcare Research and Quality (AHRQ), and Ahmed Calvo, a representative of the Health Resources Services Administration (HRSA), and have received confirmation that our project is not duplicative. Third, the project falls within the more specific goals of the Department of Clinical Bioethics, which exists to serve the needs of the NIH staff

[1] Orlowski JP, et al. Why doctors use or do not use ethics consultation. J Med Ethics 2006;32:499-502.
[2] DuVal G, et al. A National Survey of U.S. Internists' Experiences with Ethical Dilemmas and Ethics Consultation. J Gen Intern Med. 2004; 19:253-260.

and patient population, and to conduct research on important ethical issues in medical practice and research. This study is consistent with these roles.

A.2. <u>Purpose and Use of the Information</u>

The survey instrument will gather information in the following categories:

1. *Demographic information* (years in practice, gender, specialty training, board certification, type of surgical practice, type of location where surgeries are performed).

2. *Ethical dilemmas encountered* (insurance coverage, resource allocation, conflicts of interest, impaired colleagues, competing commitments, informed consent, confidentiality, mandatory reporting, end of life issues, appropriate training/credentialing, and/or surgical innovation).

3. *Ethics Consultation* (access to service, number of consultations requested, usefulness, reasons for not requesting service/barriers, what would make surgeon more likely to request consultations).

The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, through contribution to the medical literature we hope our study will provide a better understanding the ethical dilemmas that surgeons face in their practices. Second, we hope to characterize the current utilization of hospital consultation services by surgeons so that we can determine if respondents who report encountering a greater number of ethical dilemmas will report requesting a greater number of ethics consultations (if service is available to them). Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to how surgeons approach ethical dilemmas in their practices and how ethical consultation services could better support surgeons when faced with these dilemmas.

A.3. Use of Information Technology and Burden Reduction

This study provides a minimum of respondent burden as the survey will be self-administered via a paper mailing that contains the questionnaire and a postage-paid return envelope.

A.4. Efforts to Identify Duplication and Use of Similar Information

We performed a thorough review of the literature to identify any studies that have been published regarding surgeons' ethical dilemmas and ethics consultation. A previous study[3] examined the factors that led some doctors to use ethics consultations more frequently than other doctors. Although this study included surgeons in the sample studied, the questionnaire was administered at only one hospital location in Florida and did not publish how many of the respondents were surgeons. Another study[4], also performed at only one hospital location, examined the ethical issues encountered during patient care and the "team of origin" of the requestor, among which general surgery was listed. However, our study focuses on the surgeon population exclusively. It also involves a large, nation-wide sampling of surgeons representing all sub-specialties and from various geographical locations in the US, rather than drawing data from only one hospital location. We could not identify any previously published studies that examined the utilization of ethics consultation services by surgeons nationally. Further, there were several publications that discussed various ethical dilemmas faced by surgeons, but none attempted to categorize the types of ethical dilemmas faced, the relationship between the number of dilemmas encountered and the number of ethics consultations requested, or identify any barriers that surgeons may have when considering whether to order an ethics consultation. The project is not duplicative of any research being conducted by other agencies within the DHHS. We have consulted with Carolyn Clancy, director of the Agency for Healthcare Research and Quality (AHRQ), and Ahmed Calvo, a representative of the Health Resources Services Administration (HRSA), and have received confirmation that our project is not duplicative.

A.5. Impact on Small Businesses or Other Small Entities

We will be surveying practicing physicians. The burden involved in answering the survey is minimal, and the data gathered will be directly useful to these physicians.

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[3] Orlowski JP, et al. Why doctors use or do not use ethics consultation. *J Med Ethics* 2006; 32:499-502.
[4] Tapper EB, et al. Ethics Consultation at a Large Urban Public Teaching Hospital. *Mayo Clin Proc* May 2010; 85(5):433-438.

A.6. Consequences of Collecting the Information Less Frequently

All information will be collected in a single questionnaire per respondent.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project fully complies with the guidelines of 5 CFR 1320.5.

A.8. Comment in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. The 60 day Federal Register Notice was published in the Federal Register on November 28, 2011, Vol. 76, No. 228 on page 72955 – 72956 [FR DOC # 2011-30548]. The comments we received included one request from a survey firm that was interested in possibly administering the survey and one request from AAMC that was interested in knowing what items were in the survey instrument.

B. Within the DHHS, we have consulted to following agencies. They have assured us that this project is not duplicative of any work in their agencies.

Carolyn Clancy, MD
Agency for Healthcare Research and Quality (AHRQ)
Phone: (301) 427-1200

Dr Ahmed Calvo, MD, MPH
Health Resources and Services Administration
Phone: (301) 594-4293

We have consulted the following individuals as advisors in developing the instrument. They have written extensively, and are experts in the fields of: medicine, bioethics, survey research, sociology, public health sciences, and/or surgery:

Steven D. Pearson, MD, MS

Department of Clinical Bioethics
Clinical Center
National Institutes of Health
Phone: (301) 435-8717

James Ellis, PhD
Director of Research, Center for Survey Research
University of Virginia
Phone: (434) 243-5224

Thomas M. Guterbock, PhD
Professor of Sociology, and Research Professor of Public Health Sciences
Founding Director, Center for Survey Research
University of Virginia
Phone: (434) 243-5223

Luke P. Brewster, MD, PhD, MA, RVT
Assistant Professor of Surgery, Division of Vascular Surgery
Department of Surgery
Emory University School of Medicine
Phone: (404) 727-8413

A.9. Explanation of Any Payment or Gift to Respondents

An unconditional incentive ($2 bill) will be mailed along with the questionnaire and a cover letter inviting the randomly selected surgeon to participate in the project. We believe that this is likely to yield a higher response rate than a conditional incentive that is sent after completion of the survey.

A.10. Assurance of Privacy Provided to Respondents

We will ensure complete privacy of all responses by removing any identifying information (if necessary) from the survey responses as they are entered into a database. Data collection will be

performed by the Center for Survey Research, and only de-identified data will be reported to us. The CSR plans to use the SensusWeb survey system from Sawtooth in the form of several files that store the data and are managed by the software as a relational database. The data will then be extracted by CSR to SPSS, text, and/or Excel format for handling and processing. CSR will own and operate the database. SensusWeb operates and stores data on the CSR's web server, which is part of their information technology system and will comply with their Information Technology guidelines for security and backups. The CSR network requires logins and passwords to access it. The SensusWeb system has additional login and password security before users can view or download data. In addition to SensusWeb for data collection, the contact list will be stored in an MS-Access database and CSR will manage the survey invitation and reminder process. The SensusWeb system has the capability to retrieve information about survey respondents in order to contact them for follow-up, but a "confidential" protocol will be employed. This "confidential" protocol will use MS-Access/Word/Outlook to allow CSR to link completed surveys to information on the contact list for follow-up or for the purpose of attaching administrative data in the contact list to the survey data records, but will be accessible only by qualified individuals of CSR. Only the de-identified data will be reported back to us, and it will be impossible for us to connect a particular response or group of responses to any individual. As required by 45 CFR 46, this project has also been reviewed by the Office of Human Subjects Research Protection (OHSRP) at the NIH. OHSRP has found this project to qualify for exempt status (Appendix 1). Karen Pla, NIH Privacy Act Officer has reviewed this project and determined that the Privacy Act does apply: "I have reviewed the Clinical Center submission to OMB to improve the understanding of the specific ethical dilemmas that U.S. surgeons encounter, the role of ethics consultation in their practices, and the barriers that exist to discourage them from utilizing consultative services.

The Clinical Center contracted with the University of Virginia Center for Survey Research (CSR) for survey instrument expert review, and cognitive testing and validation of the survey instrument. The Clinical Center will contract with the University of Massachusetts CSR for implementation of the full scale survey project. The scope of work performed under contract will include subject enrollment, database entry, mail-based communication with survey participants, data management, including the collection and reporting of the raw data to NIH.

The survey instrument will be sent by the UMass CSR via a paper mailing to randomly selected surgeons who they will contact through the American [Board of Medical Specialties] mailing list. The questionnaire will gather demographic information that is personally identifiable (i.e., gender, board certification, type of surgical practice, years in practice, specialty training).

I have determined that the Privacy Act will apply to this data collection. Personal information will be collected using a "confidential" protocol and reported to the Clinical Center as de-identified information (e.g., raw data). If a question arises during the analysis of the data, UMass would serve as a proxy to access the protected information.

Although identifying information about the surgeons will be removed from the survey responses before they are entered into a database owned and operated by the CSR, the Clinical Center owns the data. The CSR will retain the ability to retrieve information about the survey respondents in order to contact them for follow-up, and the Clinical Center, as the contracting agency, can audit the records at any time.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD" [published in the Federal Register on Friday, January 20, 1995, Vol. 60, No. 13]. If you have any questions, please contact my office at (301) 402-6201. Karen M. Plá"

A.11. <u>Justification for Sensitive Questions</u>

No sensitive questions will be asked as part of this project. All questions involve the professional role of the individuals and de-identified. Personally identifiable (demographic) information will be collected to control for covariates that may impact responses to the questionnaire. This information will be gathered using a "confidential" protocol administered by the CSR, who will report the de-identified data to us.

A.12. <u>Estimates of Hour Burden Including Annualized Hourly Costs</u>

A. We estimate the time burden to be 15 minutes per respondent based on cognitive testing of the survey instrument with less than 10 respondents.

Table 1: Estimated Total Annual Burden Hours

Type of Respondents	**Estimated Number of Respondents**	**Estimated Number of Responses per Respondent**	**Average Burden Per Response (in Hours)**	**Estimated Total Annual Burden Hours Requested**
Surgeons	598	1	15/60	150
Total	.....	.....	.....	**150**

B. The annualized cost to respondents is based upon our estimate of the hourly wages of surgeons in the US, obtained using mean income reported by the US Government Bureau of Labor Statistics.[5] There are no other costs that might be incurred by respondents for this collection of information.

Table 2: Estimated Total Cost to Respondents

Type of Respondents	**Estimated Total Annual Burden Hours Requested**	**Average Hourly Wage Rate**	**Total Cost**
Surgeons	150	$111	**$16,650**

A.13. <u>Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers</u>

There are no additional costs to respondents other than the cost of their time.

[5] Occupational Employment Statistics: 29-1067 Surgeons. US Department of Labor. Bureau of Labor Statistics. May 2011. http://www.bls.gov/oes/current/oes291067.htm

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government is estimated to be $50,000 which includes the following: 1) costs associated with the survey instrument expert review and cognitive testing (approximately $4,000); 2) costs associated with the survey instrument including purchasing participant contact information/mailing lists, paper mailings and online survey support, $2 bill incentive for participants, costs associated with 1 CME credit offering, data collection, and biostatistical analysis of results (approximately $46,000).

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The data will undergo statistical analysis. Hypothesis testing will be performed in addition to reporting of descriptive statistics, and analysis of variance will be utilized to identify any associations between the type of ethical dilemmas encountered and the frequency of ethics consultations requested. Multiple linear regression will be used to identify and control for any possible independent covariates associated with our outcome, such as demographic or geographic factors. We plan to submit the results of this study for publication in a peer-reviewed academic journal within the next year.

A.17. Reason Display of OMB Expiration Date is Inappropriate

None

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

None

APPENDIX 1:

OHSRP RECOMMENDATIONS

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX: 301-496-0760 **Exempt: #:** 5933
To: Danis, Marion
CC
10/1C118

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Cognitive testing of survey instrument. Involves showing questionnaire to 12-24 physicians and gathering responses to questionnaire to determine how well questions/items perform, understanding of survey instructions and if questionnaire successfully addresses scientific question of the survey.

Original Request Received in OHSR on: 8/30/2011

Responsible NIH Research Investigator(s): Marion Danis, MD CC

OHSR review of your request dated Wed, Aug 24, 2011 has determined that:

☐ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☒ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☒ Amendment 6/11/11 HB

☐ Other

Office Person SPC Admin Assist. CB

Note:
6/11/12 AMENDED: To proceed to the next phase of the project to survey approximately 5000 surgeons via the UVA Center for Survey Research. hb

Heather Bridge for

Charlotte Holden, JD — Acting Director, OHSR — 10/7/2011
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6