Problem Statement
I have a standing interest in the ethical quality of institutional review board (IRB) review. I had the
tportunity to conduct a pilot project regarding the conduct, review, and oversight of human subject
research on mental/behavioral outcomes related to manmade and natural disasters. While there is a
growing literature on the incidence and prevalence of mental and behavioral health outcomes in the wake
of a natural or man-made disaster (Kelen and Sauer 2008; Smith et al 2009), there will unfortunately be
additional opportunities to advance our understanding about the effect of disasters on individuals and
communities (Pfefferbaum et al 2010). In addition, there are gaps in the current evidence base that ought
to guide future research efforts to expand and deepen our understanding of post disaster effects
(Collogan et al 2004; Pfefferbaum and North 2008). Given the priority of meeting the immediate medical
and mental health needs of survivors of and witnesses to disaster, when and how to conduct mental and
behavioral health research with these populations is logistically and ethically challenging (Fleishman and
Wood 2002; Black 2003; Jacobsen and Landau 2003; Levine 2004; Rosenstein 2004; Pfefferbaum and
North 2008). It is important for institutions and individuals considering or actively engaged in such
research to be ready to review and approve the conduct of systematic data collection under these
circumstances. My specific aim was to describe and consider the ethical challenges encountered by
principal investigators and IRBs conducting and reviewing post disaster mental and behavioral health
research. The overall goal of the project is to iteratively combine empirical and normative methods to
identify key issues IRBs/PIs ought to consider in preparing for and reviewing proposals for the conduct of
mental and behavioral health research among adults and children affected by a natural or manmade
disaster. The ultimate goal of this effort is to determine whether these findings can contribute to
considerations regarding the quality of the ethical review human subject research.

Description of the Research
Methods: With the help of a professional librarian, a systematic review of the literature was conducted to
identify research reports published between 2005 and 2012 was conducted to identify a sample of IRB
and PI able to be key informants. Of the 557 research reports identified, 331 were identified as reports
on research conducted in the US and involved the recruitment and direct engagement with human
subjects. The majority of the publications reported on research conducted after the terrorist attacks on the
World Trade Center (43%) or Hurricane Katrina (42%). The resulting list of institutions and investigators
was sampled according to the volume of research they had conducted. In-depth interviews were then
conducted with eligible and willing subjects. 8 informants affiliated with 25 of the eligible IRBs were
interviewed and 9 informants among the 22 eligible investigators were sampled. All interviews were
conducted over the phone, audio recorded and transcribed. Analysis of the data focused on the
identification of themes and patterns among the themes identified.

Preliminary Findings: According to the IRB informant, IRBs adopt a range of models for the conduct of
their review of post disaster research. Primary concerns among IRBs in their approach to the review of
post disaster research include: the quality of research proposed; level of harm to which subjects may be
exposed; burden on subjects, avoiding confusion between research and service and the safety of
research staff. PIs report that IRBs are concerned with quality of research and the level of harm to which
subjects are exposed. PIs report a range of procedural and substantive challenges in the conduct of post disaster research including: identifying funding sources, access to populations and securing appropriate referral options for subjects.

Limitations: The primary limitation of this research is that it is pilot in nature. While informational redundancy occurred among core themes some unique themes may have been confirmed with additional data collection. This data will serve to drive hypotheses to drive both further qualitative and quantitative approaches to this subject matter.

Next steps: The next step for this project (the results of which will be presented) will be to consider whether any of the findings, in combination with additional normative analysis ought to be considered as clear recommendations for IRBs and PIs to consider when reviewing or conducting post disaster research.

Additional Information
References:

A Systematic Review of Placebo/Sham- and Lesion-Controlled Surgical Trials: Ethical Issues in Design, Conduct and Reporting

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Problem Statement
Placebo/sham controlled surgical trials (PCSTs) are valued for the level of evidence they offer. Three well-publicized PCSTs—conducted a decade or more—are widely discussed in the literature. The debate, which began with whether PCSTs can ever be ethically appropriate, now concerns when and how they are appropriate. Lesion controlled surgical trials (LCSTs)—generally more difficult to justify than PCSTs—have received little attention in the research ethics literature. Questions remain about both PCSTs and LCSTs: What are their risk/benefit profiles? What special human subject protection issues do they pose? Are subjects willing to participate? How feasible are PCSTs and LCSTs? Surgical researchers, IRBs, regulators, funders and prospective subjects would benefit from a more complete understanding of the ethical and methodological questions that arise in the design, conduct and reporting of randomized surgical trials that involve placebo/sham- and lesion-controls. The goals were to evaluate: the scope and frequency of placebo/sham- and lesion-controlled surgical and technical intervention trials; the magnitude and duration of the placebo/sham/lesion response; the risk profiles of the active vs. the placebo/sham/lesion arms; the relative risk of PCSTs vs. LCSTs; common pitfalls and best ethical and methodological practices.

Description of the Research
We searched PubMed, Google Scholar, Clinicaltrials.gov and the Cochrane Central Register of Controlled Trials for PCSTs and LCSTs posing greater than minimal risk. We identified and systematically reviewed 79 trials reported in English between January 2000 and March 2012. These trials enrolled more than 8,000 subjects, were performed in more than 20 countries, 50% were performed in the US (in part or in whole), were approved by hundreds of IRBs, and were funded by numerous companies, government agencies and foundations. The studies included novel as well as established interventions and ranged from early feasibility studies through Phase II/III trials. They occurred most often in cardiac surgery and neurosurgery. Pre-determined assumptions about the placebo response varied widely. The magnitude of the placebo response was frequently underestimated often resulting in underpowered trials. Assumptions about the magnitude of the lesion effect were rarely reported. More than twice as many studies used lesion controls than used placebo/sham surgery controls. The mortality rates and SAE rates varied markedly both between the active and control arms and between PCSTs and LCSTs. In general, LCSTs posed higher risks and additional types of risks. We observed a pattern of risk in lesion arms that was not evident in single trials. Open-label extension studies and long-term follow-up studies were common strategies for minimizing risks and increasing benefits. A few reports discussed special ethical considerations involving such matters as informed consent practices and deception. IRBs and regulators imposed ethical constraints on trials, some of which appeared misguided and damaged the integrity of the trial designs. In the absence of agreed upon terminology, reporting practices, and descriptors that can reliably facilitate a successful search of the medical literature for PCSTs and LCSTs, our review may not be fully representative of these trials. Moreover, the trials in our study are disparate in design and reporting style, which may limit our conclusions. This review did not survey investigators or review consent forms and other trial materials, but relied on published reports. Our findings and recommendations will enhance the guidance available to surgical researchers, IRBs, regulators, funders, prospective subjects and journal editors regarding the ethical design, conduct and reporting of PCSTs and LCSTs—some of the highest risk, highest cost and highest impact clinical research conducted. The unanticipated findings regarding LCSTs necessitate further methodological and ethical guidelines for this type of surgical research.
Subject Protection in Surgical Innovation and Research: A Survey on Surgical Innovation Committees
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Submission Type: Scientific Submission
Topic: Ethics & Risk
Funding/Sponsor: None

Problem Statement
A continual challenge in the field of surgery has been the distinction between surgical practice, surgical innovation, and true surgical research (which requires institutional review board (IRB) review). In this area, more so than in many other types of biomedical research, it may be difficult to differentiate between a surgeon’s use of an innovative procedure, and evaluation of a new procedure as a research study intended to contribute to generalizable knowledge. Therefore, the possibility that activities that should truly be categorized as research may not be recognized as such remains a concern. In 2008, a Task Force of the Society of University Surgeons issued recommendations that academic institutions create Surgical Innovation Committees (SIC) to review proposed procedures that were considered to be innovative. The SIC’s role would be to determine whether the activity constituted research that required IRB review, or if the activity was considered innovation, whether additional elements of informed consent might be required above the usual practice standard.

Description of the Research
Methods: An electronic survey was developed to assess the awareness and implementation of the Task Force recommendations among the Surgery Departments Chairs of academic medical centers in the United States/Canada. The brief survey was designed to determine whether an institution had created an SIC, and if so, what the SIC looked like in (activity, membership). If the institution did not have an SIC, the survey assessed why, and what other mechanisms within the institution were assumed to have oversight of innovative surgery. Additional non-identifying information was collected regarding institution size and characteristics. Our College of Pharmacy and Health Sciences IRB determined that the protocol was exempt from IRB review.

Results: The survey was distributed to 140 persons. Sixty-five completed surveys were returned (46% response). 84% reported their institution promoted innovative surgery as an institutional strength, but 56% of respondents were unaware of the SUS recommendations. 23% reported that their institution has an SIC, and 20% more said their institution has discussed or plans an SIC. Existing SICs have a median of 10 members. 93% of the SICs had reviewed fewer than 10 procedures in the prior year, and 57% reviewed 3 or fewer. Most reported alternative mechanisms of oversight (morbidity/mortality conferences (88%), peer review (77%), and outcomes registries (51%)) for innovative surgery. Conclusions: Most respondents reported surgical innovation was an institutional strength, but only 23% have created an SIC to provide formal oversight. Although most of the respondents were from high-volume surgery centers, the existing SICs reviewed surprisingly few procedures. This raises concerns about whether the SICs are being recognized and, since part of their role is to ensure that surgical research is identified and directed to the IRB, if surgical research is occurring that is not recognized as such.

Limitations: Although the response rate was good, since only 23% of institutions (n=14) have an SIC, it is difficult to make conclusions about the SIC role and function. There was no assessment of the perceived effectiveness or value of the SICs.

Next Steps: Results will be reported in the surgical literature/conferences, with the intention of promoting additional discussion among surgeons. A follow-up survey may be considered to assess, at institutions that do have an SIC, why the reported use is so low and what the institutional education and training has been about the role of the SIC.
Ethical Challenges and Solutions Involved in Reviewing a Protocol with Sex Offenders as Participants: The Concerns and Solutions Identified for Protecting a Highly Controversial Population

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Problem Statement
In reviewing research, the three basic tenets IRBs are expected to abide by are beneficence, justice and respect for persons. The IRB was challenged in meeting these tenets during the course of a recent review. Given the highly controversial participant population of sex offenders and the methodology initially proposed, there were a multitude of ethical challenges uncovered that required unique solutions. The protocol presented to the IRB was developed to investigate the use of networked technologies and communications for the purpose of human trafficking. To do so the researchers proposed recruiting “Johns” or individuals convicted of soliciting sex and interviewing them to discover how they use the internet and networked technologies to find victims online. Ultimately, the research intends to provide technology-based tools for combatting trafficking of minors. So the question for the IRB was how to go about protecting “Johns” while protecting the potential victims and meet the criteria for approval?

Program Description
When working with participants who are convicted of a crime that has high amounts of recidivism with children as victims, there is an inherent human nature to protect the possible victims. However, the regulations require a refocus to protecting the “Johns”. The initial protocol was effective in de-identifying the data and maintaining confidentiality. However, upon further review we identified several areas that were lacking in protections and worked with the researcher in addressing the three major concerns; participant’s awareness of risk; legal obligations for reporting suspected child abuse; and maintaining confidentiality when a Certificate of confidentiality (CoC) is not obtainable. Managing participant risk was the impetus for putting into place several of the protections. During the 60-90 minute interview of the “Johns” there was the possibility that the participant would not only speak of the convicted offenses but also of the intent to commit additional criminal activity. To manage the risk for legal action the IRB committee agreed to the following protections:

1. Strong language in the consent that identified the risk of legal action
2. Language in the consent and interview process that encouraged hypothetical responses
3. Exacting guidances on how to record data.

The second major issue was the legal obligation for reporting suspected child abuse in states with three different laws. The project is funded in the State of New Jersey while the researchers proposed recruiting in New York and Oregon. Across the three states the laws regarding reporting of child abuse vary significantly. In New Jersey it is a crime if any citizen does not report sexual abuse of a minor; while in New York only specific professionals (teachers, social workers, etc.) are required to report under the state law. The IRB agreed that the most conservative approach to reporting would be required in an effort to meet the regulations across the country and to protect potential victims. Finally, research involving drug use or sexual behavior is often protected under a CoC. This research did not meet the criteria for a CoC and thus the data and researchers would be subject to subpoenas and other legal actions. Subsequently, the committee and legal counsel generated appropriate language for the consent that would provide the participants with all risks.

Additional Information
There was little precedent available for the reviewers to refer for this type of research. The novelty subsequently elongated the review process at our institution. On the other hand, the IRB is now prepared with the appropriate protections in place for additional research in this area. Other institutions may use this model for reviews with a similar population of participants at times when a CoC is unattainable.