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Confidentiality concerns for surgical residents as educational research subjects: A pilot study☆

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ABSTRACT

Background: Research within the field of surgical education has been expanding rapidly in order to guide future curricula. However, education studies often have minimal IRB oversight and evolving concerns exist regarding issues of informed consent of trainees.
Methods: We conducted an electronic, single center, anonymous survey of general surgery residents. The survey study was IRB approved and subjects were provided with information and opt-out sheets.
Results: The response rate was 43.5% (37/85). Approximately 76% of residents felt that education research was important and that they should participate. If a faculty member conducted the study, 18% of residents would feel coerced to participate and 21% would feel uncomfortable refusing to participate. The majority (81%) felt uncomfortable with peers viewing their identifiable records and a sizeable minority (24%) were uncomfortable with peers viewing de-identified records.
Conclusion: Surgical residents believe that educational research is important, but researchers should be cognizant of unintended consequences on resident autonomy and confidentiality.

Introduction

With the advent of duty hour limitations along with many other confounding factors, changes in attending supervision requirements have contributed to decreased resident autonomy within the operating room. Potentially related to this, there has been developing controversy as to whether general surgery residents are prepared to go directly into practice in our current training environment.[1–4] Multiple factors may contribute to this loss of autonomy including: hour caps and decreased continuity of care; shifts in simple operations to surgical centers resulting in residents not learning basic skills; a push for increasing productivity; aging and increasingly more complex patient populations; and increasing use of changing technologies such as robotic surgery.[3] This, in turn, has created an increased focus on surgical education research. The current explosion of surgical education research, however, has an unknown impact on the research subjects, surgical residents. Furthermore, there is a paucity of studies on the implications on residents as research participants in graduate medical education (GME) research.

The ethical oversight of these educational research study can vary widely between institutions.[5,6] Many studies are often exempt from Institutional Review Board (IRB) review as they are considered minimal risk to participants, do not involve protected health information, are framed as quality improvement projects, or are deemed not to be human subjects research.[7] In this setting the consent process for surgical residents as research subjects can be widely variable.[8]

Without adequate oversight of the structure of educational research studies, the optimal consent process and preferred level of data privacy by subjects is unknown. The aim of this study was to assess any confidentiality concerns of general surgery residents as research subjects in educational research studies. We also sought to evaluate the overall comfort with resident participation in projects supervised by senior residents or attending surgeons. The findings of this study may help to inform the development of future oversight processes appropriate to ethical oversight of educational studies.

Abbreviations: Institutional Review Board, (IRB); Graduate Medical Education, (GME); Post Graduate Year, (PGY).

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Methods

Following IRB approval, an anonymous survey was distributed to 85 general surgery residents at Oregon Health and Science University using Survey Monkey (San Mateo, CA) in November 2015. All residents were provided with an informational email sent by our program coordinators prior to proceeding to the link for the survey. The recruitment email included an anonymous opt-out option.

Using input from content experts, we developed and pre-tested a survey consisted of 19 multiple choice questions split into 5 sections. Given the limited sample size of our target population, we did not pursue survey piloting. Each section assessed comfort level in varying situations on a 5-point Likert scale ranging from very uncomfortable to very comfortable and from strongly agree to strongly disagree.[9] Following this, one open ended question was provided at the end of the survey for any further concerns or comments in order to perform qualitative assessment.

Data was collected and underwent analysis using Fisher's exact test. Percentages for each response were calculated. There was only one response for the open-ended question and qualitative analysis was not able to be performed due to lack of thematic saturation.

Results

Thirty-seven of 85 general surgery residents responded to the survey (43.5% response rate, Table I). The majority (59.4%) of residents were junior residents (PGY1-3). Thirty-seven percent were interested in pursuing a career in academic surgery (Table 1). Ninety percent of residents felt surgical education was important and 76% of these residents felt they should participate and develop education research in comparison to 24% being indifferent ($p < 0.001$). Six of these participants did not want to be involved in education research as a subject.

In regards to consent, 53% of residents felt they should undergo verbal consent while 25% of residents did not believe that verbal consent to participate in educational studies was necessary (Fig. 1). Thirty-four percent of residents felt written consent should be obtained and another 34% of residents disagreed, with the remainder of residents reporting indifference on this matter (Fig. 1).

The majority (87.5%) of residents felt that education studies should not be mandatory in a training programs and 62.5% of residents would feel coerced to participate as a subject in an educational research study if their faculty or senior resident was an investigator (Fig. 1). Seventeen percent of residents that answered that they would feel coerced also answered that they would feel comfortable refusing to participate in these studies. However, 75% of residents who answered that they would feel coerced would not feel comfortable refusing to participate in these studies ($p = 0.074$).

A sizeable number of residents (34%) felt concerned about their confidentiality as a participant in surgical education research with 82% agreeing that residents needed special protections in education studies, beyond what was provided by the IRB with 9% indifferent and 9% disagreeing ($p = 0.029$). When asked about specific components of their educational records, residents had varying responses on their level of comfort. Approximately 20% were uncomfortable with clinical or technical performance being filmed, 13% were uncomfortable with operation logs being accessed, and 20% were uncomfortable with feedback forms being analyzed. Eighty percent were uncomfortable with another resident viewing identifiable records and 20% were uncomfortable with unidentifiable records being analyzed by another resident (Fig. 2). One resident felt uncomfortable answering an anonymous survey.

Table 1
Demographics.

Variable	Percentage
Response Rate	43.5%
Post Graduate Year >4	40.5%
Participate in research year	28.7%
Academic Career Path	37.8%

Discussion

This needs assessment is the first of its kind in the education literature and focuses on the opinions of surgical residents who frequently and, often unwittingly, serve as subjects in medical education studies. Local IRBs have traditionally waived much of their oversight of these studies as they do not include protected health information and thus do not meet the definition of human subjects research, although this approach is beginning to be questioned.[7,10]

There is an imperative to optimize the graduate medical education of future surgeons and this often requires conducting high quality medical education studies within the framework of an existing residency program.[2] The tension between the need to optimize the education of surgical residents and the often cursory evaluation of the IRB drove us to perform this single institution pilot study to evaluate resident's degree of discomfort with participation as research subjects. The data presented in this study suggest the residents are generally supportive of the mission of educational scholarship, but do have significant privacy, data protection and coercion concerns. Addressing these concerns may require ethical oversight beyond what local IRBs are either able or willing to provide.

Despite being one of the largest general surgery programs in the nation, there was a sizeable number of our residents that were uncomfortable participating in certain aspects of education studies and felt their confidentiality was at risk. This can potentially create animosity or concern for retribution if a resident chooses not to participate in a study.[11] Along these lines, for studies involving operative skill or autonomy, this may create a lack of confidence in peers or attending surgeons that are conducting or reviewing data. Many residencies also consist of very few residents which may make confidentiality difficult, particularly for studies related to gender disparities, as there may be only one male or female per residency year. These identifiers need to be commonly used, however, blinding evaluators can be a way to ensure not only study validity but also confidentiality.[7] Despite these measures, many residents may not even be aware that blind evaluators are utilized due to lack of consent prior to a study.

Informed consent is an important aspect of minimizing coercion for research study participants.[7,12] The IRB generally governs this aspect of research with an importance held on protection of research subjects when warranted. However, many educational studies are considered minimal risk or not human subjects research and the majority of potential harm may not be detected by the researchers due to the qualitative nature of many analyses.[7] Noteworthy examples of risks that can be encountered include increased time requirements, fatigue, stress, loss of confidence, and loss of privacy which may impact their reputation or career.[7] Also, as demonstrated in our study, many residents would feel coerced in participating in research studies by a faculty member or senior resident, which may be attributed to a feeling that they may experience retaliation. A formalized consent process, even if not required by the IRB, could be considered to alleviate this effect by giving residents a way to opt out of a study without retribution. Along these lines, however, senior residents and faculty that are conducting the study may be the ones to obtain consent which may again create pressure on trainees to participate.

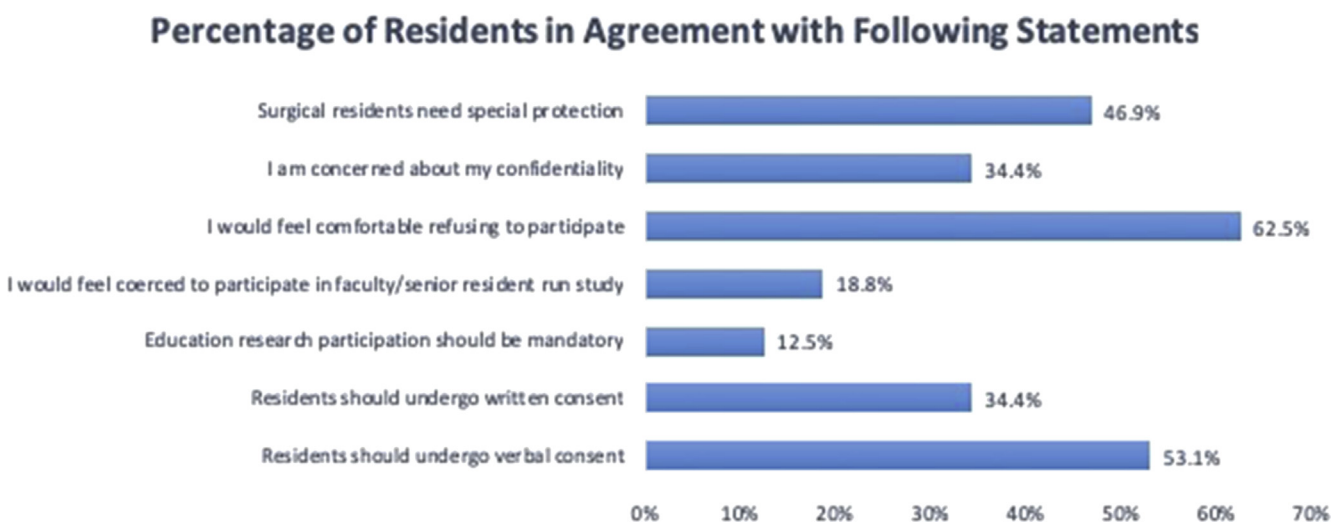

Fig. 1. Percentages of surgical residents that agreed with each statement.

A Further challenge demonstrated during this needs assessment is the concern with co-residents conducting these studies. Many residents in this study felt uncomfortable with a resident analyzing their techniques, operative logs, and feedback forms. This raises an important point that third party educators and blind evaluators could be an integral part of educational research analyses to alleviate discomfort felt by trainees. When focusing on improvements to conducting ethically sound educational research, these third-party educators along with anonymous data analysis, consent processes that occur beyond the IRB, and further review by an education committee can help protect resident confidentiality.

There are multiple limitations to this study. This was a single center pilot survey study with a 50% response rate with three reminder emails sent to participants in an attempt to increase response rate. This may lead to data which may not be generalizable to other institutions or other specialties. Additionally – given the size of our target population and the specificity of the questions, we were not able to identify a target group for pilot testing of the survey – potentially leading to confusing questions that were not apparent to the research team. We are also aware of the irony in putting a study focused on describing the failings of IRB oversight of educational scholarship into the IRB for approval – but at the time of study initiation, no better mechanism existed. Furthermore, the lower response rate may reflect an even larger number of trainees not comfortable participating in education research. Lastly, the study participation email was sent by our program coordinator at our institution as we were unable to obtain third party researchers. This could likely create concern over assurance of data security and privacy as this was not through an unaffiliated third party. Overall, some residents may have felt more comfortable answering one question versus another, especially since this study was directed by both a critical care fellow and faculty member.

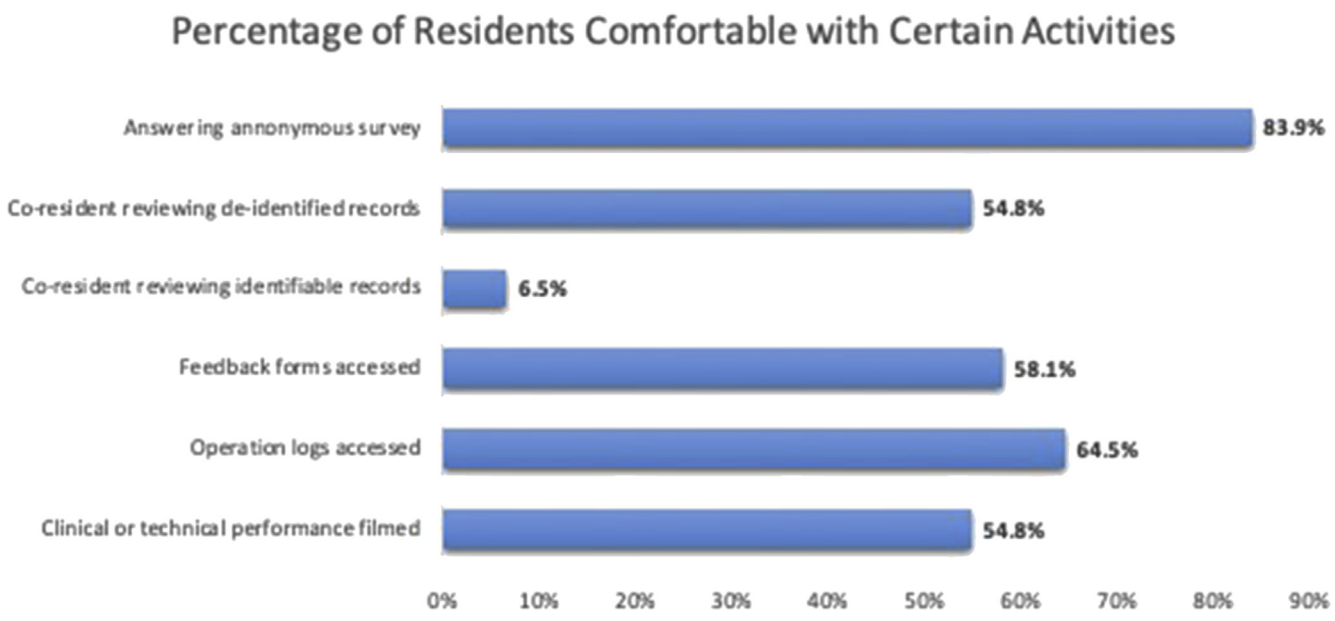

Fig. 2. Percentage of residents that were comfortable with the stated activities.

Conclusions

Surgical residents who participate, either intentionally or unintentionally, in educational research studies report a greater desire for anonymity, data protection, and informed consent than is typically required by IRB oversight. These data support the development of a national survey focused on the same questions – to test the reproducibility of these findings and further explore specific concerns for surgical trainees as educational research subjects. This survey should also include the opinions of IRB representatives as local practices likely vary. Educational researchers should be thoughtful about developing protocols to assure these goals, although best practices are far from clear.

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