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Costs and inconsistencies in US IRB review of low-risk medical education research

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Abstract

CONTEXT—Advances in communication technologies over the last two decades have transformed the way medical education research is conducted, creating opportunities for multi-institution national and international studies. Although these studies enable researchers to gain broader understandings of educational processes across institutions, they increase the need for multiple institutional review board (IRB) reviews to ensure the protection of human subjects.

OBJECTIVES—This study describes the process of obtaining multiple IRB approvals of the same protocol for a multi-site, low-risk, medical education research project in the USA. The burden of obtaining those reviews and their consistency are assessed. The associated time and costs, and implications for the research process are detailed.

METHODS—Following review by the investigators' parent institution IRB, the project team circulated a uniform protocol for conduct of a low-risk, medical education survey to the IRBs of 89 US medical schools for review. The processes and time required to obtain approvals were recorded to estimate associated research team personnel costs.

RESULTS—Approval could not be obtained from five IRBs as a result of insurmountable procedural barriers. A total of 67 IRBs eventually deferred to the parent IRB determination. The remaining IRBs required a variety of additional procedural processes before ultimately agreeing with the original determination. The personnel costs associated with obtaining the 84 approvals amounted to US\$121 344.

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Contributors: MK is the first author and led the drafting and critical revision of this work and made substantial contributions to the orchestration of the overall project, including the acquisition, analysis and interpretation of data. CMG contributed to the acquisition, analysis and interpretation of data. CR tracked the acquisition of data, contributed to the organisation of the analysis, and supported the analytic efforts of the work presented. ALS served as lead qualitative researcher on the project and contributed to research design and to the analysis and interpretation of data. RLW served as principal investigator, developed the research design, oversaw the acquisition, analysis and interpretation of data, and was extensively involved in the drafting of the manuscript. All authors contributed to the critical revision of the paper and approved the final manuscript for publication. All authors have agreed to be accountable for all aspects of the work and to ensure its accuracy and integrity.

Conflicts of interest: none.

Ethical approval: this study was deemed exempt from further consideration by the Human Research Review Committee, University of New Mexico, Health Sciences Center.

CONCLUSIONS—Considering the value of multi-site designs to address a range of research questions, enhance participant diversity and develop representative findings, solutions must be found to counter inefficiencies of current IRB review processes for low-risk research, such as that usually conducted in medical education. Although we acknowledge that local review is an essential protective measure for research involving identifiable communities that are uniquely susceptible to social or economic harm, this report suggests that proposals to modernise and streamline IRB review processes for low-risk research are timely and relevant.

INTRODUCTION

Advances in information technologies over the last two decades have transformed the way medical education research is conducted, creating opportunities for broader understandings of educational processes through multi-institution national and international studies. Multi-site studies, however, carry with them the responsibility for and burden associated with obtaining multiple reviews in order to ensure human subject protection.

Human subject protection review requirements in the USA are standardised to assure the uniformity of ethical review of research, while incorporating local considerations. Local review of research in which human subjects are engaged is important to assure culturally appropriate protocols, particularly in communities in which members are uniquely susceptible to harms from research, such as those which include members of ethnic or linguistic minority groups, people with low levels of literacy and people who are socio-economically disadvantaged. The concurrent needs to include local perspectives and to minimise institutional liability result in the reviewing of multi-site studies by multiple institutional review boards (IRBs). Multiple reviews of the same protocol, however, increase the administrative and oversight burden of the individual institutions^{1–3} and, some argue, increase costs and delay research without enhancing human subjects protections.^{4–6}

This report describes our experiences in seeking approval to conduct a low-risk, medical education, multi-site survey with Year 4 medical students. After our home institution's IRB had determined the study to be 'exempt' (i.e. to pose less than or equal to minimal risk to participants and not to require further in-depth review) from the need for further review, we sought IRB approvals from 89 US medical schools to survey their senior students. Here, we report the inconsistencies in IRB review and the resource-related challenges we faced.

METHODS

We proposed an anonymous, Internet-based survey of senior medical students to study influences on student medical decision making. The survey consisted of a series of eight clinical vignettes. Students were asked to select one of two options for each vignette.

We followed a similar process for seeking IRB approval at every school. After contacting IRB staff to discuss local review requirements, we forwarded copies of an executive summary of the study, the survey and our home IRB determination. Each school received identical protocols, with the exception of the survey distribution method, which was decided by the school administration (i.e. directly to the student or through local intermediaries). Additional application materials and steps were completed as required.

We systematically tracked the process of review at each institution, maintaining a communications log. When the approval process required contacts with other parties (e.g. local faculty members identified to serve as local principal investigators), we logged those as well. We tracked personnel efforts devoted to approval processes on a monthly basis.

RESULTS

Institutional review board approval

The processes of obtaining IRB approval at the 89 schools varied widely. We were unable to obtain approval in five schools as a result of lack of access to the forms required or inability to meet a condition for a local investigator. In the remaining 84 schools, 14 IRBs requested additional information and 12 others required a complete local application. Based on submitted materials, 67 deferred to our IRB's initial determination of exemption, a decision often delayed by conflicting perspectives among local IRB staff. The remaining 17 independently determined the study to be 'exempt'. One IRB required the use of an informed consent document developed by its staff and two others reduced the allowable number of solicitations of their students. No other changes were required to the original protocol or consent documents.

Staffing resources

In reviewing contact logs and communications from the project database, we calculated that obtaining IRB approvals required a total of 53.6 person-months over a 16-month interval. Four team members were involved in seeking IRB approvals. Overall efforts to attain IRB approvals at the various schools cost the project US\$121 344 including salaries and fringe benefits, exclusive of overhead expenses.

DISCUSSION

The process of obtaining IRB approval for this low-risk, multi-site survey of senior medical students was costly and time-consuming. Findings from this report lend credence to proposed modifications for IRB oversight in the USA that are intended to address the disconnect between human subjects risk in certain types of low-risk research and the cost and time burden of current review processes. Advances in information technologies have brought this contrast into sharp relief.

In July 2011, the Office of the Secretary of the Department of Health and Human Services in coordination with the Office of Science and Technology Policy issued an 'Advance Notice of Proposed Rule-making' requesting 'comment on how current regulations for protecting human subjects who participate in research might be modernised and revised to be more effective'.⁷ The proposed changes in IRB operation would directly address two aspects of the research described here. Firstly, low-risk studies that present only informational, not physical, risk could be excused from IRB review under the conditions of a data and informational security standard. Secondly, review by only one IRB of record would be required for domestic multi-site studies. Our experience suggests that in the case of such low-risk research, the use of a single IRB for multi-site studies would save substantial cost and labour resources for both IRBs and investigators and sponsors without apparent loss of

quality of human subjects protections. As of February 2014, however, no further steps have occurred to revise the IRB regulations (personal communication, Jerry Menikoff, Director, Office for Human Research Protections, US Department of Health and Human Services, Washington, DC, USA).

Although this study focuses on one US-based, multi-site research effort, these challenges are not unique to this study and in fact may be magnified in international research designs that collect data across institutions and borders. Proposed efforts to streamline human subjects review could promote international research collaborations by reducing the regulatory burden to such projects.⁸

CONCLUSIONS

Considering the value of multi-site designs in addressing greater ranges of research questions, in enhancing participant diversity and in developing more representative research findings, solutions must be found to counter the inefficiency of current IRB review processes for low-risk research, such as that usually conducted in medical education. At the same time, we acknowledge that for health research in identifiable communities that are uniquely susceptible to social or economic harms, local review is an essential protective measure. This report focuses exclusively on contemporary multi-site, low-risk research opportunities, demonstrating how such efforts are hampered by time and resource challenges as investigators work to meet current human subjects review requirements. This report suggests that proposals to modernise and streamline IRB review processes for low-risk research are timely and relevant.

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