

# Development of a Health Professions Education Research-Specific Institutional Review Board Template

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## Abstract

### Problem

Health professions education (HPE) has become a core component of the mission of academic health centers (AHCs) nationwide. The volume of HPE research projects being reviewed has increased, presenting new challenges for institutional review boards (IRBs). As HPE research becomes increasingly sophisticated in its design and methods, IRBs and researchers alike have a duty to better understand its unique characteristics. Researchers must be better able to conceptualize and describe their research to IRBs, and IRBs should be able to provide timely review and assure protection of research subjects (or participants).

### Approach

The creation of HPE research-specific IRB templates may be one way to improve the interactions between education researchers and IRBs. This report describes the development and early implementation of an HPE research-specific IRB template at Duke University from 2013 to 2014.

### Outcomes

Early adopters have noted increased ease of preparation and submission, while IRB staff have reported improved proposal clarity and more attention to protecting learners as research participants. Focus during educational or

training sessions about the new template has shifted—from merely a description of the new submission process to a more comprehensive education series that includes discussion of regulatory definitions, examination of case studies, and opportunity for audience feedback.

### Next Steps

Continued collection of quantitative and qualitative data regarding the implementation of this IRB template will help its developers more precisely describe its effects on HPE research projects. Formalizing and streamlining the interactions between HPE researchers and IRBs is an important goal for all AHCs.

### Problem

Health professions education (HPE) has become a core component of the mission of academic health centers (AHCs) nationwide, and, consequently, HPE research has become increasingly prevalent and more sophisticated in both its design and methods. The growing volume of HPE research projects presents particular challenges for institutional review boards (IRBs): Does HPE research constitute human subjects research? If so, do these projects qualify as exempt, or are they subject to review? The majority of medical school IRBs, whose members have dealt

primarily with basic science, biomedical, or clinical research projects, may be ill equipped to respond to this emerging need. The continued development of high-quality HPE research will require the professional development or training of educators and reviewers alike—academics who can competently design and assess HPE research with the same rigor they apply to basic and/or clinical research. In this report, we describe an effort to meet this need at the institution level through the development and dissemination of an HPE research-specific IRB submission template.

HPE research projects present unique challenges, including the following: (1) educators may not identify their planned educational observations, innovations, or interventions as research (even when they truly are), or they may need assistance in framing them as such; (2) determining whether education research projects meet the regulatory definition for human subjects research, and if that research requires informed consent of participants, is sometimes difficult<sup>1,2</sup>; (3) the research methodologies common in HPE, especially qualitative methods such as segmenting and coding of interview transcripts or analysis of ethnographic

observations, are often unfamiliar to IRB members<sup>3</sup>; and (4) most IRB submission forms include entry fields or questions that are not relevant to HPE research projects. There is also renewed cognizance of the ethical issues surrounding the inclusion of students and residents at AHCs as participants in HPE research.<sup>4,5</sup> Some commenters have even questioned whether students should be considered a vulnerable population,<sup>6</sup> given both the pressure to perform (and, at times, to participate in studies) at most AHCs and the concerns surrounding potential coercion of learners.

A number of developments have led to increased contact between educators and local IRBs. For one, more AHCs have formalized education-specific tracks for faculty development.<sup>7</sup> Further, the 2014 Institute of Medicine report on graduate medical education described new funding linked to educational innovation,<sup>8,9</sup> so fostering high-quality HPE research now carries an important financial incentive for AHCs. The report also encourages researchers (and the institutions that employ them) to seek external funding.<sup>8</sup> Additionally, AHC leaders and HPE researchers may be seeking opportunities for wider dissemination of local HPE

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work. Further, a recent literature review has suggested that HPE researchers should be seeking early guidance from their local IRB when contemplating education research so that they formally, a priori, consider research design, proposed methodology, human subjects research requirements, and possible regulatory requirements.<sup>10</sup> Finally, most, if not all, HPE journals require a statement regarding ethical approval of submitted research. For all of these reasons, careful and efficient IRB oversight for HPE research has become a necessity.

HPE research and its relationship with the IRB is complicated by the fact that IRBs do not review HPE research proposals uniformly. A recent multicenter study revealed that among six different IRBs reviewing the same proposal, there was significant variability in both the content of the reviews and the time to approval.<sup>3</sup> Some boards required up to two months to complete their reviews.<sup>3</sup> This problem, not unique to HPE research, has been described elsewhere—specifically in the review of multicenter research network proposals in pediatrics.<sup>10</sup> Although most health professions educators agree that multicenter studies will be necessary to move the quality of education research forward, these inconsistencies make HPE research projects that reach across institutions especially problematic.

### Approach

Recognizing the challenges described above, we (an interdisciplinary group of educators) began discussions with the local IRB regarding the creation of an HPE research-specific IRB template, guided by the following principles:

- To provide early guidance to educators in recognizing their planned education observations, innovations, or interventions as research.
- To encourage the use of sound research practices by educators.
- To ensure that sufficient and appropriate information is included in proposals so that the IRB is equipped to determine whether a research project is either exempt or a study involving humans and thus subject to IRB review.
- To ensure proper consideration of the protection of the well-being of learners as human subjects or research participants.

### Template development

This template included critical components of HPE research design (Figure 1). We used, as a framework, an extant IRB template that had previously been approved for the submission of quality improvement (QI) proposals at Duke University. We chose the QI template as our starting point for several reasons. Firstly, it was the only alternative template available. Secondly, we saw the development and implementation of the QI template, which had occurred prior to our project, as a model for working with the IRB to come to consensus on (1) template elements necessary for achieving sound review of HPE research proposals and (2) questions regarding which QI projects qualify for exemption. Lastly, QI projects and HPE research face similar dilemmas regarding questions about exemption, scholarship, and dissemination.

We adapted the existing QI template to better reflect the language and elements of an education project. For example, we replaced the term “subject” with “learner” where appropriate. Between May and June 2014, we circulated the draft to expert health professions educators and IRB members for review and comment,

and we made edits based on their feedback. Our team then met with the IRB chairs to review the template again. At this meeting, we made further edits and reached an agreement that two of the IRB chairs would be designated to review HPE proposals using the template. Subsequently, we began a pilot, submitting three HPE proposals to the new submission template and review process. After this stage (during which we made no further edits), we shared the template with the larger HPE community at our institution in July 2014. The complete template, available from the authors upon request, includes the following elements: an explanation of what qualifies as “exempt” research and fields for authors to provide the title of their project, a statement of the problem, a literature review and references, project goals and methods (including design, setting, analysis, timeline, etc.), the process for obtaining consent, and the plan for collecting and securing data.

### Training and education

Next, we organized education sessions to promote the use of the new HPE research-specific process to multiple key stakeholders across the institution including the Duke Academy for Health



**Figure 1** Components of health professions education (HPE) research design, considered and included in the Duke University School of Medicine institutional review board template for HPE research-specific proposals.

Professions Education and Academic Development (Duke AHEAD); clinical research support organizations (e.g., the Duke Office of Clinical Research [DOCR]) and multiple other clinical research units; and HPE schools (e.g., the schools of medicine and nursing). These sessions, which took place in the fall of 2014 through the spring of 2015, included small-group, case-based discussions and the dissemination of personal laminated pocket guides for HPE researchers. We offered additional small-group or individualized faculty and trainee development sessions as part of a campus-wide Education Conference Day. Participating in this event allowed for one-on-one HPE research troubleshooting in a high-volume venue. Our team also met with small groups of educators through informal sessions such as the School of Nursing's "Teaching Conversations" series; the monthly graduate medical education program directors' development series, Medical Education Grand Rounds; and the monthly, interdisciplinary, DOCR "Research Wednesdays."

## Outcomes

We anticipated a six-month timeline for full rollout of the new template and the completion of various trainee and faculty development sessions. As of April 2014, stakeholders at our institution seem to have received the new template and process positively. According to informal feedback, early adopters of the template have noted that it has streamlined the submission process and made the overall preparation of documents for IRB review easier. In turn, the IRB has reported in informal conversations that the clarity of proposals has increased and that researchers are giving extra attention to protecting human research participants. Anecdotally, we have heard (and experienced ourselves) that submissions have been more efficient and that questions back and forth between the IRB staff and primary investigator have decreased.

Some common questions that educators have brought to our design group during the ongoing implementation process have focused on whether their planned educational observations, innovations, or interventions are actually research and, as before, whether education research projects meet the regulatory definition

of "human subjects research." Our emphasis during the education sessions has therefore shifted—from merely a description of the new submission process to a more comprehensive series that includes discussion of regulatory definitions, examination of case studies, and opportunity for audience feedback.

The rollout of this HPE research-specific template at our institution has taught us that, rather than being a one-sided affair with the onus on the investigators, complete process improvement requires targeted education, resource allocation, and professional development for IRB members as well as researchers.

## Next Steps

We are currently collecting data on the number and type of HPE research proposals submitted to the Duke University School of Medicine IRB, the overall use of the template in the submission process, and any barriers to its use, including causes of delays. Additionally, we continue to assess whether the template requires further clarifying edits so that investigators can better communicate their proposals to the IRB. Although conducting a cost-benefits analysis is difficult, we anticipate—after full implementation of the new template—substantial reductions in time spent by investigators on proposal preparation, reduced time spent in review by IRB members, and ultimately, an increased number of submissions. Continued collection of such quantitative and qualitative data will help us more precisely describe the effects of the new IRB template on HPE research-specific projects.

In terms of sustainability, continued success will require our group to continue to educate a core group of IRB members and HPE research leaders so that they, in turn, will continue to educate HPE investigators in their own departments or divisions. Indeed, this innovation entails a comprehensive faculty development process in which the HPE template plays only a role. We believe this process is already well under way, as evidenced by the multiple education and development sessions that faculty and others have requested (and we have provided) so far. We are also planning a system to offer presubmission reviews of proposals, through Duke AHEAD.

One important question concerns who on the IRB will review HPE research proposals. No dedicated education researcher is appointed to our IRB routinely at this time; however, at our institution, select IRB chairs who are knowledgeable about HPE research have been identified as the chairs who will review most expedited or exempt proposals. Some academics have suggested creating an entire separate board at the IRB specifically for HPE research<sup>3,9</sup> under the auspices of an institution's HPE community, especially if the school has no stand-alone medical education (or other such) department. Such an IRB could no doubt incubate expertise in HPE research design and methodology within board members; however, some benefit may accrue from relying on the opinions of "traditional" IRB members—basic and/or clinical researchers who examine HPE research with the same rigor they apply to clinical or biomedical projects. In any case, such boards would certainly benefit from members with expertise in sociological or education research methodologies; their perspectives on HPE research have been noted to be constructive in most cases.<sup>9</sup>

Formalizing and streamlining the interactions between HPE researchers and their IRBs is an important goal for all AHCs. HPE researchers have a duty to improve their own knowledge of issues related to investigative research so that the rigor of their methods matches that required of basic or clinical science research projects. Likewise, the IRB must expand its available expertise to adequately understand the unique characteristics of HPE research proposals so that members can evaluate them in a fair and timely manner—and perhaps more important, so that the IRB is best equipped to protect the learners participating as research participants in these education projects.

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