# Primer for Submitting Health Professions Education Research to the IRB

Rebecca D. Blanchard, PhD, senior director, Educational Affairs, Baystate Health, and assistant professor, University of Massachusetts Medical School-Baystate; Stephen DeMeo, DO, MEd, attending neonatologist, WakeMed Health and Hospitals, and adjunct professor, Duke University Medical Center; and Alisa Nagler, JD, EdD, assistant director, Accreditation, Validation and Credentialing, American College of Surgeons, and adjunct professor, Duke University School of Medicine

Health professions education (HPE) research often represents a gray area for institutional review boards (IRBs) since HPE projects are variably categorized as research, quality improvement, or educational evaluation that is not research, depending on a number of considerations. Below, we address common questions asked by HPE researchers, define key IRB terms, and offer tips for successfully navigating the IRB review process.

| Common Questions | Answers |
|---|---|
| Does my project need to be submitted to the IRB? | HPE scholarship is considerably different than clinical research,[1] and can often be difficult to categorize as research. A detailed description of your project—including what data you will be collecting and how you will collect those data—should be provided to your institution's IRB to help IRB members make that determination. |
| How do I know if my project is research or not research? | To be categorized as "research" with the IRB, the project must be both a systematic investigation (deliberate plan for studying an outcome) and generalizable (intending results to be representative of what would happen at another institution with the same intervention).[2] |
| Who are the subjects in HPE research? | "Subjects" are likely to be learners or teachers in HPE research and not likely to be patients. |

| Key Terms | Definitions |
|---|---|
| Human Subjects Research  | • Human subjects research (HSR) is defined as any systematic investigation, either by intervention or interaction, designed to contribute to generalizable knowledge through the collection of data—from human subjects or living individuals, or from identifiable private information.[3]<br>• In the case of HPE research, "interaction" could include any communication or interpersonal contact between investigator and subject (likely learners). Institutions vary greatly on their determination of which educational activities are considered HSR. For example, learner surveys, curriculum evaluation, and longitudinal analysis of standardized exam outcomes may be considered HSR at one institution and not at another. |
| Risk  | Risk is the possibility of a negative consequence of participating in a study, including physical or psychological harm, or breach of privacy or confidentiality. "Minimal risk" is defined as risk that exceeds risk encountered in daily life or routine examination. The determination of minimal risk serves as the basis for the type of IRB review (exempt, expedited, or full).[2] |
| Exempt or Expedited Review  | • In an *exempt* review, a study usually involves no more than minimal risk, and an investigator may waive documented informed consent from participants, but (1) must have an appropriate process of informed participation, (2) must protect privacy and confidentiality, (3) must adhere to institution-specific policies and procedures, and finally, (4) is exempt from ongoing monitoring unless the protocol changes.[3]<br>• In an *expedited* review, a study may involve more than minimal risk; a protocol may include direct contact with subjects (including recordings or transcripts), noninvasive procedures, or potential for breaches of privacy.[3] These studies may be reviewed by the IRB chair only, but are subject to ongoing monitoring. These usually require subjects' written informed consent for participation. |

**Tips for Successfully Submitting HPE Research to the IRB**

1. Engage in a dialogue with the IRB early in the process (especially if you are unsure if the project meets criteria for HSR) and throughout with any updates, questions, or concerns regarding your project.
2. Find medical education mentors and collaborators to help you navigate the process.
3. Consider tools and templates to aid the process and to ensure in practice and documentation that learners are protected (at the institutional and national levels).[4]
4. Remind the IRB that your subjects are *learners*, and state clearly if no patient data are being collected, especially if your intervention occurs in a clinical space!
5. Be sure to collaborate with your IRB. HPE research can evoke many questions, and IRB processes and decisions vary by institution!

**References:**
1. Blanchard RD, Artino AR Jr, Visintainer PF. Applying clinical research skills to conduct education research: Important recommendations for success. J Grad Med Educ. 2014;6:619–622.
2. U.S. Department of Health and Human Services, Office for Human Research Protections. 45 CFR 46. Protection of Human Subjects. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/. Accessed July 21, 2016.
3. Johansson AC, Durning SJ, Gruppen LD, Olson ME, Schwartzstein RM, Higgins PA. Perspective: Medical education research and the institutional review board: Reexamining the process. Acad Med. 2011;86:809–817.
4. DeMeo SD, Nagler A, Heflin MT. Development of a health professions education research-specific institutional review board template. Acad Med. 2016;91:229–232.
**Author contact:** Rebecca.BlanchardPhD@baystatehealth.org; Twitter: @rdblanchard1

First published online October 4, 2016