

Do I Need Institutional Review Board Approval? Applying the 2018 Institutional Review Board Revised Common Rule to Athletic Training Educational Research

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INTRODUCTION

In 2019, the 2018 Revised Common Rule (RCR)¹ for the protection of human subjects research went into effect. The RCR, approved in January 2017, was the first change to these guidelines that were established in 1991.² In response, educators, researchers, and institutional review boards (IRBs) are still adjusting to and interpreting these changes. The purpose of this editorial is to provide a brief overview of these changes and to discuss implications for educational research in athletic training and their impact on the *Athletic Training Education Journal*.

What Is the Common Rule?

The United States Department of Health and Human Services (HHS) establishes federal regulations that set standards for the protection of human subjects in research, including the definition of “human subjects research,” composition of the IRB, requirements for consent, protection of special populations, and types of IRB review (eg, exempt, expedited, full board).¹ The RCR established several changes to the review and approval of human subjects research, including streamlining the informed consent process, expanding the qualifications for exempt studies, and requiring a single IRB review for multisite studies (see Table).^{2,3} The goal of these changes was to increase flexibility for researchers, better inform potential participants about the research process, and allow IRBs to focus on higher risk studies.^{2,4} Two key changes affect educational researchers: (1) the addition of categories that are excluded as research and (2) the expansion of what is considered an exempt study.

What Is Research?

According to HHS, “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowl-

edge.”^{1(p6)} For a scholarly activity to be considered research it must meet these criteria. The RCR specifically identified 4 activities that are *not* considered research, including scholarly and journalistic activities (eg, oral history, historical scholarship), public health surveillance, collection and analysis of information for a criminal justice agency, and operational activities for national security purposes.¹ The first item, “scholarly and journalistic activities,” is most relevant to educational research.¹ If a researcher examines information about only one individual (ie, case report), the information is considered not generalizable and is therefore not considered human subjects research.⁵ The implication of this is that no IRB review would be required. Let’s say a researcher conducts a case study examining one athletic trainer’s transition to practice over the course of 2 years via individual interviews, or “oral history.” This would not be considered research according to the HHS definition.^{1,5} However, if a researcher examined multiple athletic trainers’ transition to practice over this same time period, this would be considered research and would require IRB review because the information would be considered generalizable.⁵

The publication of educational case reports is rare but useful to illustrate a specific pedagogical technique or unique situation. There is no doubt that case reports are valuable in the educational literature. However, case reports can pose a specific ethical challenge for journals, especially medical journals, because by their very nature individuals in reports are highly identifiable. Journals (medical and educational) must ensure proper consent for publication has been obtained and that the individual(s) who is being reported on is aware of the possible consequences of that reporting.⁶ There is no one-size-fits-all form, but the Committee on Publication Ethics does offer guidance for ensuring consent for publishing medical case reports, which can and should be adapted for educational journals such as the *Athletic Training Education Journal*.⁶

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Table. Summary of Key Changes in the 2018 Revised Common Rule

Expansion of what is not considered research
Oral history
Historical scholarship
Expansion of exemption criteria
Research conducted in established or commonly accepted educational settings
Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual/audio recording)
Consent
Broad consent
Focused summary
“Prospective agreement” instead of consent
Single IRB review for multisite studies
Many studies no longer need continuing review
Addition of limited IRB review focused on confidentiality

Abbreviation: IRB, institutional review board.

Expanded Exemption for Education Research

In addition to the activities no longer defined as research, the RCR broadened several categories for exempt research that affect education research studies. The RCR now specifies that “research conducted in established or commonly accepted educational settings” and “research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or audio recording)” are classified as exempt for IRB purposes.^{1(p7)} The RCR specifies additional criteria that need to be met, including that educational practices must be unlikely to negatively affect students or educators, so researchers should review these additional criteria to determine if their research may be considered exempt.¹ It is important to note that while some research activities may be considered exempt from federal regulations, they are still regulated by state laws, institutional policies, and other requirements for ethical research. Additionally, regulations differ when working with children or other vulnerable populations.¹ The determination of exemption must be made by an institutional authority other than the researcher, typically an IRB.¹ Researchers should consult with their IRBs to ensure they are appropriately following institutional expectations.

So, how do these changes affect educational researchers? Several research studies conducted under the pre-2018 Common Rule likely required an expedited review but would now fall under the exempt category.³ For example, a researcher may desire to implement 2 different teaching strategies into 2 different course sections, Section A: traditional lecture, Section B: flipped classroom design. These are both *normal* educational practices in established educational settings. Implementation would be unlikely to adversely impact the students or educator. This meets the requirements of exemption category 1.^{1,3} Additionally, the researcher may choose to measure students’ satisfaction with these teaching modes using an anonymous survey. The RCR considers this to be a “benign behavioral intervention,” which would fall under the new RCR exemption category 3.^{1,3}

In another example, a researcher may choose to interview educators about their experiences teaching in a flipped classroom model. This *qualifies* as research because it is a systematic investigation that seeks to generalize the findings.⁵ The researcher audio records the interviews, which includes identifiable information. Before 2018 the research study would undergo an expedited IRB review.³ Following the RCR, this study would fall under the exempt category. An IRB may choose to conduct a limited review of the protocol, focusing on the privacy and confidentiality protections.³ A key consideration here is that IRBs may interpret the RCR differently and impose additional requirements on researchers. Additionally, the HHS recommends, and many IRBs require, that researchers are *not* permitted to determine their own exempt status.¹ Some IRBs may require the researcher to file with the IRB a simple checklist that determines exempt status, whereas others may require an administrative review or protocol submission. Therefore, researchers should review their own IRB requirements to determine how their scholarly activity may be categorized and what review, if any, may be required.

The HHS also states that many quality improvement activities are not considered research and therefore does not require IRB review.^{7,8} For example, Manspeaker and Wix⁹ published an educational technique article describing a learning module about dermatological conditions used for several years within one athletic training program. The authors summarized assessment scores over time as well as quotes from student course reflections. This educational technique did not require IRB review because it was considered typical educational practice and continuous quality improvement.

Other recent publications in the *Athletic Training Education Journal* demonstrate these evolving IRB requirements. Thrasher and Strapp¹⁰ described a laboratory activity for teaching wound packing. The educational technique article’s authors reported student feedback in the form of direct quotes obtained from discussions with instructors and course evaluations. Students provided consent to include their feedback. The authors stated that no IRB review was required because it was an educational technique that was not considered research. Another educational technique article looking at implementation of a class project, which published student quantitative and qualitative feedback, was not considered research by a different IRB.¹¹ The study of Rippon et al¹² examining programmatic factors and Board of Certification pass rates using deidentified data was also not considered research, therefore not requiring IRB review. These publications demonstrate that what may have previously required IRB review may no longer be considered research by the RCR.

Despite the RCR being in place for several years, IRBs, researchers, and the *Athletic Training Education Journal* are still trying to play catch up and determine to what extent and how the policies affect each stakeholder. The *Athletic Training Education Journal* has an ethical obligation to ensure research was conducted with ethical oversight, appropriate consent procedures, and adherence to relevant laws relevant to research.¹³ Therefore, while an organizational or institutional IRB may deem educational research “exempt,” authors wishing to publish in the *Athletic Training Education Journal* will be required to acknowledge that “no IRB approval” was

necessary based on the policies established under the RCR at their institution. This applies to “Educational Techniques” published in the *Athletic Training Education Journal* that report any level of data collected and reported in the manuscript.

Changes to the Consent Process

The RCR also implemented several changes to the informed consent process designed to better inform potential participants about the study details.¹ The RCR states that consent forms should include a focused summary of the study at the beginning of the consent form to better help potential participants decide whether or not they should participate.² Additionally, researchers are allowed to obtain broad consent, whereby participants can agree to have their identifiable information be used for future research studies as well as for the current study.¹ Of particular interest to educational researchers is that “benign behavioral interventions” involving adult participants may be able to obtain a “prospective agreement” instead of providing written consent.³ For example, a researcher may ask preceptors to watch a 30-minute video about providing effective feedback during clinical education and then interview them about their opinions of the video contents. As long as the researcher obtained oral consent from participants to watch the video and be interviewed, no written consent would be required.³ These revisions to consent requirements may help facilitate a more manageable consent process for both participants and researchers. Researchers have found that participants prefer a streamlined consent process and rarely asked for additional information about the study, when offered.¹⁴ Educational researchers may consider implementing these new standards for consent to streamline the process in their own research.

It is important to note that although some activities may not be considered research and therefore may not require consent, it may still be ethically appropriate to obtain consent and inform individuals involved in the activity. For example, in the case of the educational technique publications in which student reflection quotes were included in the published work, it would be appropriate, albeit not required, to ask permission of these students to include their words, as these authors did.^{10,11} This could be done when asking students for this feedback by adding a question in a feedback survey that states “please check *Yes* or *No* whether you are willing to have your deidentified feedback shared with others” or by asking students after the information is collected. My (S.L.N.) IRB also suggested putting a note in my syllabus that informs students how course assignment information may be used. I now have a statement in all my syllabi that states “Upon conclusion of this course, student information may be blinded and disseminated to contribute to the advancement of educational techniques in the athletic training profession. If you do not want your blinded student information to be shared, please contact the instructor prior to the end of the course.” Keep in mind that this may not be acceptable at all institutions, so it is important to check with your own IRB.

Not Research Determination

So, what if you determine that your scholarly activity is not considered research and therefore does not require IRB review? The RCR and many IRBs allow researchers to make

this determination.⁵ The HHS has several decision charts to help researchers determine if their activity is considered research.¹⁵ Many IRBs have modified these charts to meet their own institutional requirements. Researchers should review their own IRB resources to determine how their activity is categorized and what type of review, if any, is required.

Another result of the RCR is the emergence of “not research determinations” from IRBs. Many IRBs have a brief administrative review that determines whether a scholarly activity is considered research or not. An IRB may issue a “not research determination” letter with this decision for the scholar’s record-keeping purposes. Other IRBs may require that a full protocol is submitted to make this determination. This highlights the different processes among IRBs that authors need to consider. Additionally, some IRBs may issue a “not research determination” at any time during the research process, whereas others will only issue this before the scholarly activity occurs. Therefore, it is important that researchers determine their institution’s requirements before initiating any scholarly activity that might possibly be considered research.

Authors should be aware of their IRB requirements for “not research determinations,” in addition to scholarly journal expectations related to these determinations. Some scholarly outlets, such as the *Journal of Allied Health*, require documentation of a “not research determination” from an IRB to publish this type of work. Other journals, including the *Athletic Training Education Journal*, do not require a statement regarding IRB approval in the “Methods” section but does not currently require documentation of a “not research determination.” Authors are ethically bound to ensure the research being reported was conducted in an ethical and responsible manner, to comply with all relevant legislation, and to ensure proper storage of relevant materials, including all IRB correspondence.¹⁶

IMPLICATIONS

The RCR provides many benefits for researchers and participants that can save time and improve the clarity of the research process.^{2,4} If they have not recently done so, researchers should review their IRB requirements to determine how future scholarly activities should be categorized. Many educational research studies conducted pre-2018 would have required a detailed IRB application and lengthier expedited review, whereas now they may only require a brief application to obtain exempt status. As an experienced researcher I (S.L.N.) have a habit of reusing and updating older IRB protocols to fit the content of my current studies. I’ve realized that I may be creating extra work for myself and my participants, since many of these details are no longer required in consent forms and protocols according to the RCR. Researchers may experience more efficient and user-friendly IRB review processes if they review current IRB expectations.

Researchers or authors with additional questions or concerns should reach out to the *Athletic Training Education Journal*’s Editorial Office with their questions (atej@slu.edu). We also encourage authors to carefully review the author guidelines before submitting.

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