

## Undergraduate Research with Human Subjects: IRB Guidelines

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**M**y vision is that *SPUR* be the scholarly voice of the undergraduate research, scholarship, and creative inquiry (URSCI) community. As such, I am committed to ensuring that *SPUR* publishes papers that inspire, inform, educate, and challenge us in our own URSCI endeavors. To do this, it is critical that the work we publish is well done, has archival value, and deserves the trust of our community. Readers then can be confident that the work published here is of high quality and worthy of emulation, adoption, or adaptation.

Over the past year, I have realized that we need to advance some of *SPUR*'s practices and policies to accomplish this. You have seen some of these changes codified in the new Author Submission Guidelines. Many of these changes bring us in line with accepted practices and policies of other journals that publish the scholarship of teaching and learning (SoTL), which is the thoughtful, systematic study of teaching and learning informed by the work of others in the field and intended to inform and improve student learning. One important area for refinement is in human subjects research. Specifically, we need to ensure that the educational studies we publish meet the accepted standards when these studies involve humans as research subjects.

The objectives of this editorial are twofold: (1) to ensure that *SPUR*'s readers, future authors, and reviewers appreciate the importance of securing approval or exemption by a local institutional review board (IRB) or ethics board for their research study *before initiating any studies of undergraduate research practices* that they seek to publish in *SPUR*; and (2) to clarify the types of studies that do and do not require IRB or ethics board review and approval. I hope that this increases the number of quality SoTL submissions we receive that use students as research subjects in a deliberate, humane way that benefits us all.

Any research activities involving humans, irrespective of where they are undertaken around the world, must abide by a series of principles that ensure research participants' rights to health, safety, privacy, and welfare. These principles were originally set out in the Declaration of Helsinki

in 1964. The US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research subsequently published "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (1979), often referred to as the Belmont Report. This document outlines the ethical framework for the current federal human subjects research regulations based on three fundamental principles: respect for persons, beneficence, and justice. The principle of respect for persons embraces the idea that humans should be treated as autonomous, and those with diminished autonomy should be protected. Beneficence recognizes the obligation of researchers to protect the health and well-being of everyone who agrees to be a research subject. Last, justice acknowledges the responsibility of researchers to ensure that the risks of research are shared equally by everyone in our world who is likely to benefit. The Common Rule, 45 Code of Federal Regulations (CFR) part 46 subpart A, outlines the criteria and mechanisms for the IRB's work. Institutional Review Boards determine whether studies are designed and will be carried out according to the principles of the Belmont Report. Thus, IRB review of human subjects research protocols, or plans for the design and implementation of human subjects research, protects not only the people who participate in the research but also the researchers by providing an unbiased, outside perspective on the extent to which the research is ethical. Outside the United States, local, regional, or national ethics boards perform essentially the same function according to the relevant national or international codes and regulations, always with a focus on ensuring respect for persons, beneficence, and justice.

Quality, peer-reviewed journals that publish research involving humans, including *SPUR*, require evidence that researchers have designed and executed their research study while providing for the participants' rights under federal and institutional guidelines. *This evidence is typically an IRB review number provided in a letter or other certification indicating that the research plans and protocols have been reviewed and approved, or determined to be exempt from review. In most cases, this review must take place before the initiation of any data collection by the research team.* In the United States, 45 CFR Part 46 outlines this requirement. *IRBs cannot retroactively evaluate or approve research that has already been completed*, so it is critical that researchers using human subjects or data obtained using human subjects be reviewed and either approved or evaluated as exempt *before the initiation of the study.* Also, this requirement is in place for all human subjects research regardless of

whether the research project is funded. Authors submitting manuscripts to *SPUR* are expected to upload their letter of certification and to include a statement in the manuscript indicating that the study has been reviewed and approved or determined to be exempt, also including the name of the institution whose IRB or ethics board has made the determination.

Not all research studies involving human subjects require IRB review and approval. Studies presenting minimal or no risk to humans, such as those examining instructional activities or curricular changes or using data collected in standard education settings, may be evaluated by an IRB or ethics board and deemed exempt provided they meet certain criteria. For instance, studies using de-identified data from publicly available sources are often exempt, such as data from the US Census Bureau or the National Center for Education Statistics. In addition, evaluations for internal purposes only (i.e., not for publication) are exempt from review. They may not even be eligible for a determination of exemption since the data will not be public. However, researchers cannot unilaterally decide whether their research protocols are exempt. Approval and exemption decisions can be made **only by the institution's designated IRB or ethics board**. It is critical for anyone seeking to publish data from human subjects to **file a formal IRB application for any research study involving human subjects before initiating any research involving human subjects**.

The absence of an IRB or ethics board on campus does not exempt researchers from the requirement to seek IRB review and approval or determination of an exemption. If your institution does not have an IRB or ethics board, you should consult with senior officials on your campus about how IRB approvals or exemption determinations are obtained. In many cases, nearby institutions with standing IRBs or ethics boards will consider research plans from neighboring institutions and provide approval, exemption determinations, or feedback.

An important element of an IRB application is the certification that everyone involved in the research has completed human subjects research training. Many US institutions offer this training, typically called “social and behavioral research” training, through the online Collaborative Institutional Training Initiative (CITI) program. Any human subjects research involving children or the use of the Internet requires additional training. All research involving vulnerable populations, including children, pregnant women, individuals who are disabled or mentally disabled, and prisoners, as research subjects receives additional scrutiny during the review process. This may not seem applicable to much of the research we do, but it is important to remember that undergraduates may be minors (under 18) and so considered children. In addition, researchers

studying their own students are in positions of authority as instructors, research mentors, or program directors. Extra steps must be taken to avoid coercing our students into participating in our studies. For instance, someone who is not in a position of authority could carry out the process of informing potential participants about the study and getting their consent.

Since some of us seek to publish studies that involve undergraduate researchers as collaborators rather than as subjects, we also have the important responsibility of teaching and mentoring undergraduate collaborators about meeting these standards for the ethical conduct of human subjects research. Olszewski recently published an excellent article in the *Journal on Excellence in College Teaching* outlining how faculty can integrate education and training in human subjects research both in the classroom and in student research. This article provides several case studies illustrating how to integrate individual students and teams of students into the IRB process in creative and effective ways, benefiting all involved. Two other excellent resources for those new to SoTL research include McKinney's *Enhancing Learning through the Scholarship of Teaching and Learning: The Challenges and Joys of Juggling* and Dewar, Bennett, and Fisher's *The Scholarship of Teaching and Learning: A Guide for Scientists, Engineers, and Mathematicians*.

In conclusion, studies of undergraduates involved in research are inherently studies involving human subjects. As such, as authors of these studies, we have a legal and moral duty to ensure the health, safety, privacy, and welfare of student participants. This responsibility requires training and planning that must include the submission, review, and approval or determination of exemption by a qualified IRB or ethics board application before initiating any empirical work. For this reason, documentation (letter or certificate uploaded to the journal submission site and an in-text statement that includes the application number and name of the institutional IRB or ethics board) evidencing this review and approval or exemption is required for all human subjects studies published by *SPUR*.

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## Introducing our new Editorial Advisory Board Member



Dr. Edray Herber Goins

Dr. Edray Herber Goins is Professor of Mathematics at Pomona College. After obtaining his BS in mathematics from the California Institute of Technology (Caltech), he obtained his Ph.D. in number theory from Stanford University. Dr. Goins did post-doctorals at the Mathematical Sciences Research Institute and the Institute for Advanced Study. He then served as the Irvine Visiting Professor and Taussky-Todd Instructor at Caltech before moving to Purdue University where he rose through the ranks to full Professor before moving to his present position at Pomona College. Dr. Goins is a passionate advocate of undergraduate research and has mentored many undergraduates at several universities including Caltech, Miami University, and Purdue. He serves as the current director for Pomona College's NSF-funded REU Program in mathematics. Dr. Goins is active in the American Mathematical Society, the Mathematical Association of America and previously served as President of the National Association of Mathematicians, which is dedicated to promoting excellence in the mathematical sciences and the mathematical development of all underrepresented minorities. Dr. Goins' work has been published in many high-quality, peer-reviewed journals including the *International Journal of Combinatorics*, the *International Journal of Number Theory*, and the *International Journal of Pure and Applied Mathematics*.