Ethical Issues to Consider: Approval for Studies Involving Human Participants

Academic Medicine Staff
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Ethical Approval for Studies Involving Human Participants: Academic Medicine’s New Policy

It is important for readers to know that human participants in any study reported in Academic Medicine have been treated in accordance with contemporary ethical standards. Consequently, the journal has added a new requirement: For studies involving human participants (including students, residents, and faculty), it is the author’s responsibility to state in the manuscript information about ethical approval for the research (preferably in the Method section). This information should include but not be limited to the name of the approving committee (e.g., institutional review board, research ethics board) and the name of the institution at which approval was granted.

Authors who do not have access to a formal ethical approval process must provide information in the manuscript about the treatment of human participants, including:

- how risks to human participants were minimized,
- why the risks were reasonable in relation to anticipated benefits,
- how the selection of participants was equitable.

Declaration of Helsinki (http://www.wma.net/e/policy/b3.htm). Also, it may be useful for authors to consult the statements on ethics of the American Educational Research Association, the American Psychological Association, the American Sociological Association, and/or other national and international organizations.

There are several reasons why the journal’s new policy is important. First, Academic Medicine is one of the journals that follows the Uniform Requirements for Manuscripts Submitted to Biomedical Journals maintained by the International Committee of Medical Journal Editors. Section II.F of that document states that when reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration (http://www.icmje.org).

The World Association of Medical Editors (WAME) supports this position and offers explicit guidance for individuals working in countries or institutions without ethics committees. Require formal verification that human subjects research on which a submission is based was approved by an institutional review board or complied with the Declaration of Helsinki and that the researchers conducted the study according to acceptable research standards, including obtaining informed consent (http://www.councilscienceeditors.org/editorial_policies/white_paper.cfm).

Second, in studies that involve students or residents as human participants, it is especially important to treat them with the same ethical consideration that we expect them to use when treating their own patients or study participants. Medical school faculty are important role models for students and residents at critical formative junctures – times when students and residents are formulating notions of how to treat patients, participants in clinical trials, and more junior learners. Experiencing the informed consent process as a study participant can provide a student or resident with an invaluable, first-hand learning experience that supersedes book learning or studying a Web-based module.
Protecting human subjects in research

- *Academic Medicine* follows policies regarding the treatment of human participants established by the International Committee of Medical Journal Editors.

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.
Does your study require ethical approval?

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<thead>
<tr>
<th>Questions about your study</th>
<th>Do you need ethical approval?</th>
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<tbody>
<tr>
<td>Did you or any coauthors have access to identifiable data?</td>
<td>YES</td>
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<tr>
<td>Did you or any coauthors evaluate or observe human participants?</td>
<td>YES</td>
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<tr>
<td>Did you or any coauthors survey people?</td>
<td>YES</td>
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<tr>
<td>Did you or any coauthors interview people?</td>
<td>YES</td>
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Next steps if you need approval

Does your institution have an institutional review board (IRB) or ethics committee?

**YES**

Contact your institution’s IRB to learn how IRB approval (or exemption) is received. This process varies.

**NO**

Authors who do not have access to a formal ethical approval process must provide information in the manuscript about the treatment of human participants.

The following should be addressed:
- how risks to human participants were minimized
- why the risks were reasonable in relation to anticipated benefits
- how the selection of participants was equitable
- whether adequate procedures were in place to ensure the privacy and confidentiality of participants
- the plan used to monitor the data and safety of the subjects
- how informed consent was sought and documented
- if applicable, what safeguards were used to protect vulnerable populations
- other relevant information

After review, your institution’s IRB will approve or exempt your study.

Submit approval or exemption letter with your manuscript submission to indicate you sought IRB review.
Final Thoughts

• Remember to include information about the ethical approval of your study in the Method section of your paper. Details should include:

  ➢ The name of the approving committee (e.g., Institutional Review Board, Research Ethics Board)
  ➢ The name of the institution at which approval or exemption was granted.

• If participants are surveyed or evaluated at multiple institutions, each institution’s IRB must grant approval or exemption.

• Include a copy of your IRB approval or exemption letter with your submission to the journal.
Need more information?

• Review our complete instructions for authors for more details about the journal’s ethical approval policy.

• Read the February 2009 editorial about the journal’s policy.

• Still need answers? Contact the editorial office at:
  Telephone: (202) 828-0590
  Email: acadmed_online@aamc.org
  Online: www.academicmedicine.org