Issues in Law and Medicine Research Ethics Policy

Protection of Research Participants

Issues in Law and Medicine complies with the recommendations of the International Committee of Medical Journal Editor regarding Protection of Research Participants:

> "All investigators should ensure that the planning, conduct, and reporting of human research are in accordance with the Helsinki Declaration as revised in 2013. All authors should seek approval to conduct research from an independent local, regional, or national review body (e.g., ethics committee, institutional review board). 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 local, regional, or national review body explicitly approved the doubtful aspects of the study. Approval by a responsible review body does not preclude editors from forming their own judgment whether the conduct of the research was appropriate.
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> Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived with the journal, the authors, or both, as dictated by local regulations or laws. Applicable laws vary from locale to locale, and journals should establish their own policies with legal guidance. Since a journal that archives the consent will be aware of patient identity, some journals may decide that patient confidentiality is better guarded by having the author archive the consent and instead providing the journal with a written statement that attests that they have received and archived written patient consent.
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> Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are deidentified, authors should provide assurance, and editors should so note, that such changes do not distort scientific meaning.
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> The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained, it should be indicated in the published article.
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> When reporting experiments on animals, authors should indicate whether institutional and national standards for the care and use of laboratory animals were followed."

Human Subject Research Policy

Clinical Trial Research

Issues in Law and Medicine does not publish clinical trial research in human subjects. We use the ICMJE definition of a clinical trial, which is described as:

> "The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention *and* a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."

Observational/Retrospective Chart Review Research in Human Subjects

Issues in Law and Medicine recognizes the ICMJE understanding that research which is purely observational in which the exposure or intervention is not dictated by the researchers, is not a clinical trial.

The Editors of Issues in Law and Medicine may consider publication of such nonclinical trial human research manuscripts. If such manuscript is accepted for peer review, ILM will require documentation of IRB approval or waiver.

Clinical Case Reports

The Editors of Issues in Law and Medicine may consider publication of case reports which adhere to CARE Case Report Guidelines. Authors should follow instructions for creating the case report as outlined in CARE Writing a Case Report.

Policy for Corrections, Retractions and Expressions of Concern

Plagiarism, falsification of data, misrepresentation of data, fabrication of data, violations of human subject research ethics and other ethical violations are taken seriously by the Editors of Issues in Law and Medicine.

Allegations of breach of Research Ethics will be investigated by Issues in Law and Medicine. The Editors of Issues in Law and Medicine will then make a decision regarding further action which may include no further action needed, publication of a Correction, publication of an Expression of Concern or a retraction of the manuscript or published paper.

Corrections or Expressions of Concern for existing articles submitted by the authors will be published at the end of the existing article, with the date, time and authorship of the correction noted.

Articles published in previous editions of Issues in Law and Medicine may also be subject to retraction at the discretion of the Editorial Board.

Articles which may not qualify for retraction but are deemed worthy of editorial clarification of the substance of the article, may qualify for an “Expression of Concern”. Such expressions of concern will be appended to the end of the article at the discretion of the Editorial Board.