

## Reporting Guidelines

*Archives* requires authors to submit the CONSORT flow diagram when submitting manuscripts reporting randomized controlled trials (RCTs). *Archives* also strongly encourages authors to use industry-recognized reporting guidelines such as PRISMA, STARD, and STROBE, when appropriate, to clarify that minimum reporting requirements have been met. Click here for links to the reporting guidelines, and for further information, visit [www.equator-network.org](http://www.equator-network.org)

Study Type	Reporting Guideline	Link to Guideline
Randomized Controlled Trial	CONSORT	Checklist: <a href="http://www.consort-statement.org/consort-statement/overview0/">http://www.consort-statement.org/consort-statement/overview0/</a>  Flowchart - <i>Required</i> : <a href="http://www.consort-statement.org/consort-statement/overview0/">http://www.consort-statement.org/consort-statement/overview0/</a>
Systematic Reviews  Meta-analyses of controlled trials	PRISMA	Checklist: <a href="http://www.prisma-statement.org/statement.htm">http://www.prisma-statement.org/statement.htm</a>  Flowchart - <a href="http://www.prisma-statement.org/statement.htm">http://www.prisma-statement.org/statement.htm</a>
Observational epidemiology studies	STROBE	Checklists: <a href="http://www.strobe-statement.org/index.php?id=checklists">http://www.strobe-statement.org/index.php?id=checklists</a>
Diagnostic accuracy studies	STARD	Checklist: <a href="http://www.stard-statement.org/">http://www.stard-statement.org/</a>  Flowchart: <a href="http://www.stard-statement.org/">http://www.stard-statement.org/</a>

## Clinical Trial Registration

The International Committee of Medical Journal Editors (ICMJE) and the Council of Science Editors support the registration of prospective clinical trials that involve human subjects "to study the cause-and-effect relationship between a medical intervention and a health outcome." *Archives'* editors have adopted in principle the spirit of the requirement to register clinical trials, at or prior to subject enrollment.

At this time, however, it is not a requirement of submission that authors whose studies meet the ICMJE criteria (criteria available at: <http://www.archives-pmr.org>) register their trials or, if they do, comply fully with the Minimal Registration Data Set. In the future and by prior notice, *Archives'* editors may make registration and compliance mandatory. Authors who have registered their trials should provide the trial registration number in the cover letter to their submissions. Registration numbers will appear in all content published in the journal.

## IRB and Animal Care Committee Approval

Research submitted to *Archives* must comply with accepted ethical standards for human and animal research. When submitting work to *Archives*, authors must certify (1) that their institution or the appropriate regional institution approved the protocol for any investigation involving humans or animals (or that the research complied with the Declaration of Helsinki and (2) that the conduct of all investigation conformed to the protocol and the ethical and humane principles of research.

## **Case Reports and Single-Case Studies**

With the implementation of the US Health Insurance Portability and Accountability Act (HIPAA), federal regulations now govern the privacy of patient data in the United States. To comply with HIPAA without comprising important clinical detail, authors submitting case reports (category Clinical Notes) or single-case studies (category Articles) are required to assure the anonymity of patients (including names, uniquely identifying personal descriptors, detailed family trees, and geographic location). Authors need to ensure subjects are not identifiable in the manuscript and photographs OR obtain from each patient a written consent to publish the manuscript and photographs. If patient consent for publication is obtained, the author must mention this in the cover letter that accompanies the manuscript submission. All manuscripts submitted to *Archives*, whether from domestic or international authors, must comply with this standard at submission.

## **Patients' Rights to Privacy**

Patients and research subjects have a right to privacy that should not be infringed without informed consent. Identifying information will not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific explanation and the patient (or legal proxy) gives written informed consent for publication. Informed consent for this purpose requires that the patient or proxy be shown the manuscript to be published.

Identifying details should be omitted if they are not essential, but patient data should not be altered or falsified to attain anonymity. Complete anonymity is difficult to achieve, and informed consent should be obtained when doubt exists. For example, masking the eye region in photographs of patients is inadequate protection of anonymity.