

Manuscript Submission Guidelines and Policies for Tissue Engineering, Part C: Methods

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Journal Information

- Manuscript Submission Site: https://mc.manuscriptcentral.com/ten
- Editorial Office Contact: TEeditor@rice.edu
- Support Contact: prosupport@liebertpub.com
- · Journal Model: Hybrid (Open Access Option)
- · Blinding: Single Blind
- · File formatting requirement stage: Upon submission
- Instant Online Option (immediate publication of accepted version): Yes
- · Average time to initial decision: 35 days

About the Journals

Tissue Engineering (Part A) presents innovative tools and assays in scaffold development, stem cells, and biologically active molecules to advance the field and to support clinical translation.

Tissue Engineering Reviews (Part B) presents innovative tools and assays in scaffold development, stem cells, and biologically active molecules to advance the field and to support clinical translation.

Tissue Engineering Methods (Part C) presents innovative tools and assays in scaffold development, stem cells, and biologically active molecules to advance the field and to support clinical translation. The journal publishes methods and protocols in life and natural sciences relevant to tissue engineering and regenerative medicine. A method manuscript involves a novel research method that has not been published before. A protocol manuscript deals with a method that has already been used successfully in a wide range of experiments.

Manuscript Types and Guidelines

The ultimate decision regarding the assignment of manuscripts is left to the discretion of the Editors-in-Chief. At any time prior to publication, the Editors of *Tissue Engineering* may reassign an article from one part of *Tissue Engineering* to another. Language must conform to acceptable English usage and syntax. The contents must be clear, accurate, coherent, and logical. In accepting, rejecting or reassigning a manuscript to another Part of the journal, the editors will also consider its originality, teaching value, and validity.

Decisions concerning journal assignment, editing, revisions, acceptances, and rejections will be made by the editors. These may include reassigning an article from one part of *Tissue Engineering* to another, shortening the article, reducing the number of figures and tables, or changing the format. An accepted article may be published with an accompanying discussion if the editors so desire.

A)	 Unstructured abstract of no more than 350 words Impact statement: 100 words or less Structure: Introduction, Method, Experiment, and Discussion Maximum of ten (10) figures Maximum of six (6) tables
Review Article (Part B)	 4,000-word limit Unstructured abstract of no more than 350 words Impact statement: 100 words or less Structure: Introduction, Method, Experiment, and Discussion Maximum of ten (10) figures Maximum of six (6) tables
Methods Article (Part C)	 4,000-word limit Unstructured abstract of no more than 350 words Impact statement: 100 words or less Structure: Introduction, Method, Experiment, and Discussion Maximum of ten (10) figures Maximum of six (6) tables
Protocol Article (Part C)	 4,000-word limit Unstructured abstract of no more than 350 words Impact statement: 100 words or less Structure: Introduction, Method, Experiment, and Discussion Maximum of ten (10) figures Maximum of six (6) tables
Letter to the Editor	 500-word limit May include one (1) figure OR table Reference citations are identical in style to those of full original articles, but should not exceed five (5).
Technical Note	

Word limits do NOT pertain to the abstract, disclosure statements, author contribution statements, funding information, acknowledgments, tables, figure legends, or references.

Description

In general, the text should be organized under the headings: Introduction, Method, Experiment, and Discussion. A brief introduction should state the research problem, explain/define why a new method or protocol had to be developed, and justify the need for the new method or protocol with literature references. The method section should explain the methodological approach in a coherent way. In a protocol manuscript, the method section should provide clear instructions for all steps that have to be taken to perform the procedure. It is essential that as much information is provided to allow the reader to use the method or protocol for their own experiment. Furthermore, an accurate list must be provided of all essential equipment, facilities, materials, reagents, etc. that are used.

The method section must be followed by a section titled "Experiment". This section should provide a description of an experiment in which the method or protocol was used. Care has to be taken that the suitability of the method or protocol is indeed substantiated with experimental data. Depending on the method, controls have to be included in this experiment. For a protocol manuscript, reference has to be made to earlier publications of the author(s), in which the respective protocol was already used successfully.

In the discussion section, additional background information should be provided. How the method or protocol compares with other methods and protocols should be discussed and additional information provided about the possible wider application of the method or protocol. Pitfalls and problems that can be encountered should also be addressed in this section.

Use only standard abbreviations, which can be found in the AMA's Manual of Style for Authors and Editors, 10th edition or the Council of Science Editors (CSE) Style Manual, 8th edition. At first usage, spell out terms and provide abbreviations in parentheses. Thereafter, use only the abbreviations. It is not necessary to spell out standard units of measure. Use generic names for drugs if possible. If you wish to use a proprietary drug name the first time it appears, use the generic name followed by the proprietary name, manufacturer, and location in parentheses.

Statistical Analysis

If a statistical analysis is done, an explanation of how it was performed must be stated at the end of the section preceding the results. Unusual or complex methods of analysis should be referenced.

For Methods, please review these links for proper manuscript structure:

https://www.liebertpub.com/doi/10.1089/ten.tec.2020.0064 https://www.liebertpub.com/doi/10.1089/ten.tec.2020.0049

References

Tissue Engineering, Part C: Methods uses Mary Ann Liebert's **Vancouver** reference format. Templates are available in **Zotero** and through the CSL Style Repository. An EndNote template can be found **here**.

Liebert Vancouver Style: Order of Citation

- · Reference List: Prepared in sequential order as cited in text.
- In-text Citations: All references must be cited in text in numerical order, set in superscript Arabic numerals
 outside of any punctuation. Do not set reference numbers in parentheses or brackets. To cite several
 references at once, use commas to separate non-sequential citations and use dashes to separate sequential
 citations; do not include spaces. Ex: 3,7,12-15
- Journal titles should follow the abbreviation style of PubMed/Medline.
- Include among the references any articles that have been accepted but have not yet published; identify the
 name of publication and add "In Press." If the reference has been published online, provide the DOI number in
 place of the page range.

Style Examples for Reference List:

Type of Reference	Punctuation and Order of Elements in Reference List
l lournal article	Wang Q, Nambiar K, Wilson JM. Isolating natural adeno-associated viruses from primate tissues with a high-fidelity polymerase. Hum Gene Ther 2021;32(23-24):1439-1449; doi: 10.1089/hum.2021.055 [insert article-specific DOI if available].
	Pfister EL, DiNardo N, Mondo E, et al. Artificial miRNAs reduce human mutant Huntington throughout the striatum in a transgenic sheep model of Huntington's disease. Hum Gene Ther 2018;29(6):663–673; doi: 10.1089/hum.2017.199 [insert article-specific DOI if available].

Edited Book	Herzog RW, Zolotukhin S, (eds). A Guide to Human Gene Therapy. World Scientific Publishing Co. Pte. Ltd.: Singapore; 2010.
Chapter in an Edited Book	Nicklin SA, Baker AH. Adenoviral Vectors. In: A Guide to Human Gene Therapy. (Herzog RW, Zolotukhin S. eds.) World Scientific Publishing Co. Pte. Ltd.: Singapore; 2010; pp. 21-36.
Authored Book	Isaacson W. The Code Breaker: Jennifer Doudna, Gene Editing, and the Future of the Human Race. Simon & Schuster: New York, NY; 2021.
Website	Last name, first/middle initial(s) of author(s) [if available]. U.S. Food and Drug Administration. What is Gene Therapy? Silver Spring, MD; 2018. Available from: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy [Last accessed: month/date/year].
Personal communications	References that are unpublished (ie: personal communications, emails, letters) are not to be included in the reference list. Instead, insert "Personal communication; [name], date" parenthetically at the point of citation within text.
Using previously published images or tables as a reference	Reused/adapted images, tables, or any published material must be officially cited as a reference in the reference list, and the author(s) of the submitted work must obtain written permission from the copyright holder. Verbal approvals are not acceptable. Any fees associated with the reuse or adaptation of any material is the sole responsibility of the author(s).

PaperPal Preflight

The Paperpal Preflight service is available for this journal. PaperPal Preflight allows authors to check their Original Research manuscripts for common errors prior to submitting a manuscript for consideration. Please note that this does not guarantee that your paper will pass all submission or other checks, nor that it will be considered for review.

The checks are configured for Original Research manuscripts only and may not be applicable to other manuscript types. There may be additional requirements for submission. Please review the full instructions for authors for guidelines.

The basic service is free. PaperPal preflight offers an *optional* fee-based service that will provide a report showing tracked changes and potential modifications. Please note that if this service is used, a clean copy of the manuscript must be uploaded to the submission system.

There is no obligation to use either the free or paid service. No editorial, review, nor any other decisions will be dependent on its use.

All manuscripts must be submitted through the journal's ScholarOne Manuscripts site.



General Manuscript Submission Guidelines and Policies for Mary Ann Liebert Journals

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Submission Preparation

All manuscripts must be prepared in accordance with the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (icmje.org). Please consult your specific journal's requirements for additional information.

All Mary Ann Liebert, Inc. journals follow the standards, guidelines, and best practices set forth by the Committee on Publication Ethics (COPE; publicationethics.org), the International Committee of Journal Medical Editors (ICJME; www.icmje.org), the World Medical Association (WMA); www.wma.net), and the American Medical Association (www.ama-assn.org).

Mary Ann Liebert, Inc. recommends that submissions follow standard relevant reporting guidelines. Please consult The Equator Network for more information.

PaperPal Preflight

The Paperpal Preflight service is available for most journals. PaperPal Preflight allows authors to check their **Original Research** manuscripts for common errors prior to submitting a manuscript for consideration. Please note that this does not guarantee that your paper will pass all submission or other checks, nor that it will be considered for review.

There may be additional requirements for submission. Please review the full instructions for authors for guidelines.

The basic service is free. PaperPal preflight offers an *optional* fee-based service that will provide a report showing tracked changes and potential modifications. Please note that if this service is used, a clean copy of the manuscript must be uploaded to the submission system.

There is no obligation to use either the free or paid service. No editorial, review, nor any other decisions will be dependent on its use.

All manuscripts must be submitted through the journal's ScholarOne Manuscripts site. Please refer to the individual journal's instructions for more information and to access the service.

Manuscript Formatting

Please check your journal's requirements for file formatting. Many journals require formatting compliance only on revision; however, unless stated, the file formatting should comply with the following requirements on submission.

Manuscript Files

The main text file, figure legends, and tables should be prepared in Microsoft Word. Some journals may accept LaTex. Please consult your individual journal instructions for guidance.

File Naming

- · All file names should be in English and contain only alphanumeric characters.
- · Do not include spaces, symbols, special characters, dashes, dots, or underscores.
- Title each file with the type of content contained in the file (e.g., manuscript.doc, tables.doc, FigureLegends.doc, Fig1.tif, SupplementalData.pdf, etc.).

Figures

- · Submission of high resolution .TIFF or .EPS figure files is preferred. Please upload as individual files.
- Cite figures consecutively in text within parentheses.
- Images should not reveal the name of a patient or a manufacturer.
- · Note: Figures that will not be reproduced in color must be readable and interpretable in black and white.

Figure Legends

- · A legend should be provided for each supplied figure.
- · All legends should be numbered consecutively.
- Figure legends may be included at the end of the main text file or uploaded as a separate, double-spaced
 Word file.
- In each legend, provide explanations for any abbreviations or symbols that appear in the figure.
- If the figure is taken from a copyrighted publication, permission must be secured by the author(s) and supplied at the time of submission with appropriate credit listed in the legend. Permissions and associated fees are the responsibility of the author.

Tables

- Tables may be included after the references at the end of the main text file, or uploaded as a single, separate Word file. All tables should be editable.
- · Provide a title for each supplied table.
- · Cite tables sequentially in text within parentheses.
- Explain abbreviations used in the body of the table in footnotes using superscript letters, not symbols.
- If a table is taken from a copyrighted publication, permission must be secured by the author(s) and supplied
 at the time of submission with appropriate credit listed in the legend. Permissions and associated fees are
 the responsibility of the author.

Supplemental Files

- Supplemental files should be uploaded as individual files. Most text, photo, graphic, and video formats are accepted. Ensure that patient identities are not revealed.
- · Supplemental Information will not be copyedited or typeset; it will be posted online as supplied.
- For journals that publish accepted versions of papers prior to copyediting and typesetting, supplemental
 files will not be posted with the paper until after production has been completed.

Manuscript Structure

Specific journal requirements will vary, however the general order of elements in each manuscript should be

- Title page* with full manuscript title, all contributing authors' names and affiliations, a short running title, a denotation of the corresponding author, and a list of 4-6 keywords/search terms,
- · Abstract,
- Main text without embedded figures or tables and with appropriate section headings, if applicable. Most research papers should be organized as follows: Introduction, Materials and Methods, Results, Discussion, and Conclusions.
- · Acknowledgments,
- Authorship confirmation/contribution statement (CRediT format is preferred)
- Author(s') disclosure (Conflict of Interest) statement(s), even when not applicable,
- · Funding statement, even when not applicable,
- · References,
- · Tables included in the text or as a separate document,
- Figure legends at the end of the main text or in a separate Word file,
- · Figures uploaded as individual high-resolution files,
- Supplemental files uploaded as individual files.

*Double-blinded journals require a separate title page with the title, all contributing authors' names and affiliations, a denotation of the corresponding author, author acknowledgements, disclosures, and related identifying information.

Your individual journal may require

- An Institutional Review Board (IRB) approval (or waiver) statement and statement of patient consent as a separate paragraph after the methods section,
- · Other relevant ethics attestations (see icmje.org for further guidance),
- · Data sharing statement,
- Specific abstract and content sections, depending on manuscript type,
- Word count limits, tables/figure limits, and reference format requirements.

Please note that paragaphs should be no longer than 15 lines once typeset.

Pre-Publication Policies

Funding

Upon manuscript submission, the submitting agent will have an opportunity to enter funding/grant information. If funding information is entered correctly, the publisher will deposit the funding acknowledgements from the article as part of the standard metadata to Funder Registry. The entered information should include funder names, funder IDs (if available), and associated grant numbers. Special care should be taken when entering this information to ensure total accuracy. Funding information must also be provided within the manuscript.

Government Funded Research / Funder Requirements

Mary Ann Liebert, Inc. publishers adheres to national and international funder requirements.

We comply fully with the open access requirements of <u>UKRI</u>, <u>Wellcome</u>, and <u>NIHR</u>. Where required by their funder, authors retain the right to distribute their author accepted manuscript (AAM), such as via an institutional and/or subject repository (e.g. EuropePMC), under a Creative Commons Attribution 4.0 International (CC BY 4.0) license for release no later than the date of first online publication.?

Other funders, such as the National Institutes of Health (NIH), Howard Hughes Medical Institute (HHMI), and the Bill & Melinda Gates Foundation, have specific requirements for depositing the accepted version and/or the article of record version of the author manuscript in a repository after an embargo period. Authors funded by these organizations should follow the self-archiving terms and conditions of these separate agreements based on the policies of the specific funding institutions. If you have questions, please contact us for more information.

Peer Review

After internal editorial screening for suitability, all manuscript submissions containing original research or that comprise scholarly review are subject to rigorous, independent, external peer review. Editorials, correspondence, news features, and/or Invited opinion or perspective contributions in other sections of the journal are subject to stringent editorial oversight; at need, external, independent review will be arranged to address specialized topics. Final decisions for publication are solely the responsibility of the Editor(s)-in-Chief.

Exclusivity

Manuscripts should be submitted with the understanding that they have neither been published, nor are under consideration for publication elsewhere, in the same form or substantially similar form. Conference abstracts are excluded. If work was presented at a conference, supply the name, date, and location of the meeting as a footnote on the title page of the submission.

Third-party Submissions and Integrity

If a third party is submitting the manuscript, the submitting agent designation must be used, with the identity of the submitting agent disclosed. We reserve the right to reject any manuscript that does not contain this disclosure. The authors are solely responsible for any manuscript submitted on their behalf.

Confidentiality

Editors and reviewers must maintain strict confidentiality of manuscripts during the peer-review process. Sharing a manuscript in whole or in part, outside the scope of what is necessary for assessment, is impermissible prior to an accepted manuscript's official publication date. Reviewers are not permitted to contact authors directly.

Sharing of Materials

Onaring or materials

Authors must honor any reasonable request for materials, methods, or data necessary to reproduce or validate the research findings during peer review unless it violates the privacy or confidentiality of human research subjects.

Conflicts of Interest by the Editorial Leadership

No member of the Editorial Leadership of a journal (Editor in Chief, Deputy/Associate/Guest Editors or Editorial Board members) is permitted to participate in the review or decision process for submissions where there is a potential or actual competing interest. This includes, but is not limited to research or review papers of their own authorship or co-authorship. In those cases, an independent member of the leadership will have full discretion to manage review and decision on the manuscript.

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Mary Ann Liebert, Inc., is committed to maintaining the integrity of the peer-review process by upholding the highest standards for all published articles. All manuscripts are analyzed and evaluated for plagiarism, peer review integrity, and publication integrity. Manuscript screening may be applied at any point in the process, from submission through post-publication. Plagiarized manuscripts or manuscripts with evidence of publication, image, or peer review misconduct will be rejected immediately. If publication misconduct is identified, we reserve the right to rescind acceptance prior to publication.

Authorship

Authorship is defined by the International Committee of Medical Journal Editors in Roles & Responsibilities.

Contributors who do not meet all criteria for authorship should not be listed as authors, but they should be acknowledged (with permission from the named parties) in the Acknowledgments section with a description of their contribution to the work.

ORCID IDs

All submitting authors are required to complete their submissions using an ORCID identifier.

Corresponding Authors

One author should be designated as the corresponding author who will be responsible for communication between the authors and the journal editorial office and publisher. This individual will be responsible for ensuring all authors submit copyright forms, coordinating and responding to page proofs, and managing any other necessary contact during the peer review and production processes.

The submission system permits only one author to be identified as the corresponding author of record. However, we recognize that some submissions call for more than one corresponding author to be noted. In such cases, select one author to be the main point of contact for all communications regarding the peer review process of the paper, and on the title page of the manuscript, designate additional co-corresponding authors by including an asterisk after the authors' names in the byline. Include an accompanying footnote on the title page that reads, "*Co-corresponding authors." Please ensure that the title page carries the full affiliation details and email address of any author who should be noted as a corresponding author. If the paper is accepted for publication, the full contact information for all designated co-authors will be listed at the end of the article as per usual journal style.

Authorship Confirmation/Contribution Statement

An authorship contribution statement must be included with the manuscript. We strongly recommend that the authorship contribution statement follow the CRediT Taxonomy guidelines. (https://credit.niso.org/)

• Conceptualization (Ideas; formulation or evolution of overarching research goals and aims.)

- Data curation (Management activities to annotate (produce metadata), scrub data and maintain research
 data (including software code, where it is necessary for interpreting the data itself) for initial use and later
 re-use.)
- Formal analysis (Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data.)
- Funding acquisition (Acquisition of the financial support for the project leading to this publication.)
- Investigation (Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.)
- Methodology (Development or design of methodology; creation of models.)
- Project administration (Management and coordination responsibility for the research activity planning and execution.)
- Resources (Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.)
- Software (Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.)
- Supervision (Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team.)
- Validation (Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.)
- Visualization (Preparation, creation and/or presentation of the published work, specifically visualization/data presentation.)
- Writing original draft (Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).)
- Writing review & editing (Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or postpublication stages.)>

Example

Author 1: review and editing (equal). **Author 2**: Conceptualization (lead); writing – original draft (lead); formal analysis (lead); writing – review and editing (equal). **Author 3**: Software (lead); writing – review and editing (equal). **Author 4**: Methodology (lead); writing – review and editing (equal). **Author 5**: Conceptualization (supporting); Writing – original draft (supporting); Writing – review and editing (equal).

Changes in Authorship

Changes in authorship after submission, revision, or acceptance of a paper are generally not permitted, but the editorial leadership recognizes that in rare circumstances, it may be required. The policy for such cases is as follows:

- A request to alter authorship must be made in writing from the corresponding author to the Editor-in-Chief, with a detailed explanation for the request, the nature of the changes, and the names and affiliations of all authors.
- Written approval of all authors named on the manuscript, as well as any individual(s) being added to or removed from the author list must be provided. The Publisher can provide a form for this, if needed.
- Upon receipt of the request and all written approvals of all involved parties, the Editor-in-Chief will consider the request, render a decision, and notify the corresponding author.
- · Post-publication changes or alterations to conference abstracts are prohibited.

 If authors are added or removed upon revision submission, without accompanying documentation of the request, the manuscript will be unsubmitted.

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Mary Ann Liebert, Inc. supports the implementation of name changes for reasons including (but not limited to) gender identity, changes to marital status, religious conversion, etc.

Please contact the <u>Director of Production and Editorial</u> to confidentially update your record. Identification or documentation is not required, apart from confirmation that the change is on behalf of yourself (requests cannot be made for other individuals).

Updates will be made to the online versions of the article, but without a formal correction notice and without coauthors being notified.

We recommend authors update ScholarOne and ORCID records with any name changes.

Author Disclosure Statements

Upon submission, authors are required to fully disclose any interests, funding or employment that may inappropriately influence or affect the integrity of the submission. Authors should disclose

- Competing Interests. A competing interest exists when an individual (or the individual's institution) has
 financial or personal relationships that may inappropriately influence his actions. These competing
 interests may be potential or actual, financial or other.
- Personal Financial Interests. Stocks or shares in a company that may gain or lose financially from
 publication of the article; consulting fees or other remuneration from an organization that may gain or lose
 financially from publication of the article; patents or patent applications that are owned by or licensed to
 companies/institutions that may gain or lose value from publication of the article.
- Funding. Research support by organizations that may gain or lose financially from publication of the article.
 This support includes salary, equipment, supplies, honoraria, reimbursement or prepayment for attending symposia, and other expenses.
- *Employment*. Recent (within the past 5 years), current, or anticipated employment by an organization that may gain or lose financially from publication of the article.
- Other Competing Interests. Any personal relationship which may inappropriately affect the integrity of the
 research reported (by an author) or the objectivity of the review of the manuscript (by a reviewer or Editor),
 for example, competition between investigators, previous disagreements between investigators, or bias in
 professional judgment.

Affiliations

Authors should identify as their institution(s) the facility where the work was performed and executed. Changes in an author's affiliation after the work was completed, but prior to the submission or publication of the manuscript should be noted using a superscript asterisk in the author listing and a footnote on the title page indicating "Current Address" and listing the new affiliation. Corrections to affiliations or contact information due to relocation after publication is not permitted.

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Mary Ann Liebert, publishers, Inc. understands that emerging computing methodologies and tools are critical parts of advancing research. The policies below will be reviewed and updated as technologies, best practices and ethical considerations in AI evolve.

Transparency and Disclosure

Liebert Journals require authors to disclose any use of Al systems in their research and manuscript preparation.

Authors are required to provide descriptions of an AI system's use in their Materials and Methods section. Include the name and version of the software, the date of the original use, and all relevant prompts, queries or cues that initiated the AI's response. Potential biases and limitations of the outcomes of AI use should be discussed by the authors when presenting their results.

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Al systems are not authors and should not be used or named as authors on a manuscript.

Authorship of a scholarly work requires responsibility for the conduct of the research and the content of the written work created as a result of that research. The contributions of each author should be stated in the paper, noting their specific roles in the research and writing. An AI system used to generate any part of the content must be stated in the Methods section, as above. The listed authors are expected to review a final text and accept responsibility for its accuracy.

Peer Review

All scholarly works considered for publication undergo thorough and rigorous peer review. Manuscripts with Algenerated content are no exception.

Reviewers will evaluate the rigor, methodology, and significance of the research, considering the involvement of Al systems. Reviewers should consider the appropriateness of the use of Al tools when they assess the work, along with the authors' discussion of their use. If any Al tools were used by the Reviewer in the process of preparing their comments, this must be acknowledged to the Editor as part of your report.

Intellectual Property and Copyright

Ownership and copyright of any work can only be awarded to human authors or human-operated institutions, ensuring compliance with intellectual property laws.

How to report concerns

Authors and readers who wish to identify concerns with a manuscript either before or after publication should contact the journal's editorial office.

Ethics

Institutional Review Board Approvals/Waivers

When reporting research involving human data, authors must document the procedures followed in securing approvals from the responsible institutional and national review committee(s), along with confirmation that the research was

completed in accordance with the Declaration of Helsinki as revised in 2013.

An institution without an Institutional Review Board must arrange for an outside/external IRB to be responsible for initial and continuing review of studies conducted at the non-IRB institution. Such arrangements must be documented in writing in the manuscript.

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. Approval by a responsible review committee does not preclude editors from forming their own judgment whether the conduct of the research was appropriate. Please see https://www.icmje.org/icmje-recommendations.pdf for additional information.

The publisher requires a statement from authors in the Materials and Methods section to confirm that the appropriate ethical approval has been received, that appropriate processes have been followed, and the name of the committee.

Informed consent by patients/participants should always be secured. A statement confirming that informed patient/participant consent was obtained is required in the Materials and Methods section. The statement of IRB review is accepted as covering the review of consent documentation.

If the study is judged exempt from review, a statement from the committee is required in the Materials and Methods section, including, if applicable, documentation of institutionally approved waiver of informed consent.

Ethics of Experimentation

See the following resources for studies involving human fetuses, fetal tissue, embryos, and embryonic cells:

- NIH Grants Policy Statement
- · National Conference of State Legislatures Embryonic and Fetal Research Laws

Ethical Treatment of Animals

All peer-reviewed submissions containing animal experiments must comply with local and national regulatory principles and contain a statement in the **Materials and Methods** section of the main text stating whether national and institutional guidelines for the care and use of laboratory animals were followed.

Human Subjects: Patient Consent and Release

If applicable, it is incumbent upon the author(s) to obtain permission to reproduce any identifiable images of patients. Any identifying information should not be published in descriptions or photographs unless the information is essential for scientific purposes and the patient (or patients' parent/guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be submitted. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity cannot be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are de-identified, the manuscript should contain assurances/statements that such changes do not distort scientific meaning.

In keeping with patients' rights of privacy, the Journal does not require the submission of patient consent forms, but instead requires the author(s) to retain and archive all patient consent documentation. Upon submission of a

manuscript for review, the authors must make a statement in the cover letter to the Editor/Journal which attests that

they have received and archived written patient consent in addition to providing the requisite statement in the manuscript.

Data Sharing

We recommend, but do not require, the sharing and archiving of data and any other artifacts that define and support the results stated in a manuscript in a suitable public repository (in accordance with valid privacy, legal, and ethical guidelines). We recommend that a data availability statement be included in the manuscript in the Methods section or as a separate section at the end of the main text file. Describe the location of the data, details on how it can be accessed and any licensing information. If the data is not publicly available or accessible, that information should also be provided.

Datasets should be cited in the reference list.

Important: Please check with your funding agencies to ensure that are you following their data sharing polices. If your funding agency has additional requirements exceeding our policy, you must follow the requirements of your funder.

Update: New NIH policies for data management and sharing are in effect as of January 25, 2023. If your research has NIH funding, please refer to the guidelines for new requirements.

Preprint Servers

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