Instructions to the Authors

About the Journal

Neural Regeneration Research (NRR) is a peer-reviewed OA online journal with monthly print on demand compilation of issues published. Neural Regeneration Research aims to duly report the prospective, creative, and popular basic and clinical research in the international field of neuroregeneration. NRR focuses on rapidly publishing the articles pertaining to brain injury, spinal cord injury, peripheral nerve injury, neurodegenerative diseases and neuroimaging, which reflect the latest progress in neuroregeneration research, and aims to highlight the unique scientific characteristics of each article.

Scope of the journal

The journal will cover technical and clinical studies related to health, ethical and social issues in field of Nerve Regeneration Nervous System Physiological Phenomena. Articles with clinical interest and implications will be given preference.
To keep pace with the academic and technological innovation in the field, in 2014, we will focus on the following areas in relation to neural regeneration:

–Brain Injuries; Spinal Cord Injuries; Peripheral Nerve Injuries; Neural Degeneration; Neuroimaging.

–Treatment of CNS/PNS disorders including Stem Cells and Cell-Based therapy; Gene Therapy; Neuromodulation; Tissue Engineering; Biomaterials; Pharmacological treatment; Neural prostheses and other exciting topics in the field.

–Neuronal injury and regeneration from a cellular to molecular perspective, including Axonal regeneration, neuroplasticity, neural repair and replacement, neural circuit or network construction, neuromodulation or signaling repair, nerve transplantation, and neurosynaptogenesis.

The journal publishes report or interim summary supported by NIH and other National Funds, standards and survey on neuroscience industry, meta-analysis and academic discussion on innovative technologies, methods and development ; outstanding article will be granted for rapid publication.

The Editorial Process

A manuscript will be reviewed for possible publication with the understanding that it is being submitted to Neural Regeneration Research alone at that point in time and has not been published anywhere, simultaneously submitted, or already accepted for publication elsewhere. The journal expects that authors would authorize one of them to correspond with the Journal for all matters related to the manuscript. All manuscripts received are duly acknowledged. On submission, editors review all submitted manuscripts initially for suitability for formal review. Manuscripts with insufficient originality, serious scientific or technical flaws, or lack of a significant message are rejected before proceeding for formal peer-review. Manuscripts that are unlikely to be of interest to the Neural Regeneration Research readers are also liable to be rejected at this stage itself.

Manuscripts received from Editorial Board members will be screened by the Editor in Chief and sent to external peer reviewers. The editorial board members who are authors will be excluded from publication decisions.

Peer Review Process

Once the manuscript has passed quality control check, it is assigned to the strict double-blinded peer review process for a decision, either to accept, revise, or reject the article. Before manuscripts are sent for review, invited peer reviewers are confirmed regarding their availability, conflicts of interest with the manuscript, their agreements to have their names and comments published afterwords. A peer review report together with the reviewer’s name, if permitted, will be posted at the end of the article. Only 15–20% of submitted manuscripts are published in NRR. Most manuscripts will be evaluated by 3–5 external reviewers. Average time from the submission to the first editorial decision is 1 month. The review time could be shortened to 7 days for the paper with sophisticated review comments from other recognized journals in the field. According to these comments, the academic editors will make a decision as to accept, reject, request a revision or send to another peer review.

Manuscripts accepted for publication are copy edited for grammar, punctuation, print style, and format. Page proofs are sent to the corresponding author. The corresponding author is expected to return the corrected proofs within three working days. It may not be possible to incorporate corrections received after that period. The whole process of submission of the

manuscript to final decision and sending and receiving proofs is completed online. To achieve faster and greater dissemination of knowledge and information, the journal publishes articles online as ‘Ahead of Print’ immediately on acceptance.

Clinical trial registry

Neural Regeneration Research favors registration of clinical trials and is a signatory to the Statement on publishing clinical trials in Indian biomedical journals. Neural Regeneration Research would publish clinical trials that have been registered with a clinical trial registry that allows free online access to public. Registration in the following trial registers is acceptable: http://www.ctri.nic.in/; http://www.anzctr.org.au/; http://www.clinicaltrials.gov/; http://isrctn.org/; http://www.trialregister.nl/trialreg/index.asp; and http://www.umin.ac.jp/ctr. This is applicable to clinical trials that have begun enrollment of subjects in or after June 2008. Clinical trials that have commenced enrollment of subjects prior to June 2008 would be considered for publication in Neural Regeneration Research only if they have been registered retrospectively with clinical trial registry that allows unhindered online access to public without charging any fees.

Authorship Criteria

Authorship credit should be based only on substantial contributions to each of the three components mentioned below:

1. Concept and design of study or acquisition of data or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Each contributor should have participated sufficiently in the work to take public responsibility for appropriate portions of the content of the manuscript. The order of naming the contributors should be based on the relative contribution of the contributor towards the study and writing the manuscript. Once submitted the order cannot be changed without written consent of all the contributors. The journal prescribes a maximum number of authors for manuscripts depending upon the type of manuscript, its scope and number of institutions involved (vide infra). The authors should provide a justification, if the number of authors exceeds these limits.

Ethical responsibilities of authors

This journal is committed to upholding the integrity of the scientific record. The journal will follow the Committee on Publication Ethics (COPE) guidelines on how to deal with potential acts of misconduct.

Authors should refrain from misrepresenting research results which could damage the trust in the journal and ultimately the entire scientific endeavour. Maintaining integrity of the research and its presentation can be achieved by following the rules of good scientific practice, which includes:

- The manuscript has not been submitted to more than one journal for simultaneous consideration.
- The manuscript has not been published previously (partly or in full), unless the new work concerns an expansion of previous work (please provide transparency on the re-use of material to avoid the hint of text-recycling (“self-plagiarism”)).
- A single study is not split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. “salami-publishing”).
- No data have been fabricated or manipulated (including images) to support your conclusions.
- No data, text, or theories by others are presented as if they were the authors own (“plagiarism”). Proper acknowledgements to other works must be given (this includes material that is closely copied (near verbatim), summarized and/or paraphrased), quotation marks are used for verbatim copying of material, and permissions are secured for material that is copyrighted. Important note: the journal may use software to screen for plagiarism.
- Authors whose names appear on the submission have contributed sufficiently to the scientific work and therefore share collective responsibility and accountability for the results.

In addition:

- Changes of authorship or in the order of authors are not accepted after acceptance of a manuscript.
- Requests to add or delete authors at revision stage or after publication is a serious matter, and may be considered only after receipt of written approval from all authors and detailed explanation about the role/deletion of the new/deleted author. The decision on accepting the change rests with the Editor-in-Chief of the journal.
- Upon request authors should be prepared to send relevant documentation or data in order to verify the validity of the results. This could be in the form of raw data, samples, records, etc.

If there is a suspicion of misconduct, the journal will carry out an investigation following the COPE guidelines. If, after investigation, the allegation seems to raise valid concerns, the accused author will be contacted and given an opportunity to address the issue. If misconduct has been proven, this may result in the Editor-in-Chief’s implementation of the following measures, including, but not limited to:

- If the article is still under consideration, it may be rejected and returned to the author.
- If the article has already been published online, depending on the nature and severity of the infraction, either an erratum will be placed with the article or in severe cases complete retraction of the article will occur. The reason must be given in the published erratum or retraction note.
- The author's institution may be informed.

Contribution Details

Contributors should provide a description of contributions made by each of them towards the manuscript. Description should be divided in following categories, as applicable: concept, design, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. One or more author should take responsibility for the integrity of the work as a whole from inception to published article and should be designated as 'guarantor'.

Conflicts of Interest/ Competing Interests

All authors of must disclose any and all conflicts of interest they may have with publication of the manuscript or an institution or product that is mentioned in the manuscript and/or is important to the outcome of the study presented. Authors should also disclose conflict of interest with products that compete with those mentioned in their manuscript.

Submission of Manuscripts

Please submit your manuscript via our online manuscript handling site. First time users will have to register at this site. Registration is free but mandatory. Registered authors can keep track of their articles after logging into the site using their user name and password. Please note that your manuscript must be submitted as a text document (ie. Word). Manuscripts submitted as a PDF will be returned to authors, causing significant delays in the review process. Authors submitting manuscripts by email also can be accepted. If you experience any problems, please contact the editorial office by e-mail at editor [AT] nrren.org

The following information should be included and noticed when submitting an article to the journal:

1. Suggested and Excluded Reviewers: Please identify 2-4 reviewers who are well qualified to referee the work and do not have a conflict of interest. Manuscripts will be kept confidential by reviewers. Attached please see the reviewer nomination form. Also feel free to identify any reviewer or handling editor to be excluded for sound reasons. The recommended reviewers may or may not be sent for the review of the submitted manuscript.

2. What to expect after submission: The manuscript will be evaluated by the editorial staff and assigned editor on the basis of their merit. Please note that the manuscript will be returned to you if it is does not conform to the journal's guidelines with 7 working days. All articles are subjected to a double-blinded peer-review process. The time between receipt of a submitted manuscript and the initial decision regarding its publication averages between 4 and 6 weeks. The corresponding author is informed of the publication date of an accepted manuscript approximately 6 weeks before publication.

3. Similarity Check: All submitted manuscript will be screened twice using Crosscheck to verify originality, after submission and prior to publication. The manuscript would be screened more times if it does not pass the prior two screening procedures. The screening results will be provided to the authors, the dishonorable papers will be rejected by the journal.

4. Conditions for submission: Articles are accepted for exclusive publication in NRR. Previous presentation at a scientific meeting, and/or publication of the abstract in conjunction with the meeting,posted to preprint servers, does not preclude publication of the article; however, this information must be disclosed in a cover letter at the time of submission. Previously published articles, including those published in non-English-language journals, are not accepted. For dishonorable events including redundant/duplicate publication, suspected plagiarism, and undisclosed conflicts of interest, NRR will abide by the regulations suggested by COPE guidelines.

5. What to expect after acceptance: It will usually take 6 months from acceptance to publication, the authors are requested to keep in touch with the editorial office for revising and proofing process.

6. Authorship Issue: Everyone listed as an author should meet our criteria for authorship (https://www.nrronline.org/contributors.asp). No first authors or corresponding authors are allowed to be changed after submission. Following the COPE guidelines for changes in authorship, changing the author list after submission requires agreement from all authors. This includes additions, deletions, and changes in ordering. Requests must come from the corresponding author along with an explanation for the change. If the change is deemed to be appropriate, the corresponding author must receive and provide to NRR the consent to the change from all the authors, including any being added, deleted, or reordered. Authorship issues identified after

publication may result in a correction. In the case of an authorship dispute, the journal will not arbitrate. If the authors are unable to resolve the dispute themselves, we will raise the issue with the authors' institution(s) and abide by its guidelines.

7. Source of funding: All authors are required to declare the support they received to carry out their research during the initial submission. The journal does not accept the remove of funding source during the revising process without an appropriate explanation. Please notice that this conduct may trigger a manuscript rejection.

The submitted manuscripts that are not as per the "Instructions to Authors" would be returned to the authors for technical correction, before they undergo editorial/ peer-review. Generally, the manuscript should be submitted in the form of two separate files:

[1] **Title Page/First Page File/covering letter**:

This file should provide

1. Title: 20 word maximum.
2. Running Title: 40 character maximum.
3. Author names and affiliation: including department, city, province/state, country, postal code.
4. Corresponding authors: with complete address, including an email address, phone number, and fax number.
5. Authors Contribution:
6. Funding:
7. Acknowledgements: To note intellectual, technical or other assistance that does not warrant authorship.
8. Conflict of Interest:

[2] **Blinded Article file**: The main text of the article, beginning from Abstract till References (including tables) should be in this file. The file must not contain any mention of the authors' names or initials or the institution at which the study was done or acknowledgements. Page headers/running title can include the title but not the authors' names. Manuscripts not in compliance with the Journal's blinding policy will be returned to the corresponding author. Use rtf/doc files. Do not zip the files. **Limit the file size to 1 MB**. Do not incorporate images in the file. If file size is large, graphs can be submitted as images separately without incorporating them in the article file to reduce the size of the file. The pages should be numbered consecutively, beginning with the first page of the blinded article file.

[3] **Images**: Submit good quality color images. **Each image should be less than 2 MB in size**. Size of the image can be reduced by decreasing the actual height and width of the images (keep up to 1600 x 1200 pixels or 5-6 inches). Images can be submitted as jpeg files. Do not zip the files. Legends for the figures/images should be included at the end of the article file.

[4] **The contributors' / copyright transfer form** (template provided below) has to be submitted in original with the signatures of all the contributors within two weeks of submission via courier, fax or email as a scanned image. Print ready hard copies of the images (one set) or digital images should be sent to the journal office at the time of submitting revised manuscript. High resolution images (up to 5 MB each) can be sent by email.

Contributors' form / copyright transfer form can be submitted online from the authors' area on the submission site.

Preparation of Manuscripts

Manuscripts must be prepared in accordance with "Uniform requirements for Manuscripts submitted to Biomedical Journals" developed by the International Committee of Medical Journal Editors (October 2008). The uniform requirements and specific requirement of Neural Regeneration Research are summarized below. Before submitting a manuscript, contributors are requested to check for the latest instructions available. Instructions are also available from the website of the journal (https://www.nrronline.org) and from the manuscript submission site.

Neural Regeneration Research accepts manuscripts written in American English.

- **Redundant or duplicate publication**

We ask you to confirm that your paper is original, has not been published in its current form or a substantially similar form (in print or electronically, including on a web site), that it has not been accepted for publication elsewhere, and that it is not under consideration by another publication. The ICMJE has provided details of what is and what is not duplicate or redundant publication. If you are in doubt (particularly in the case of material that you have posted on a web site), we ask you to proceed with your submission but to include a copy of the relevant previously published work or work under consideration by other journals. Authors must draw attention to any published work that concerns the same patients or subjects as the present paper in a covering letter with their article.

- **Permissions to reproduce previously published material**

NRR requires you to send us copies of permission to reproduce material (such as illustrations) from the copyright holder. Articles cannot be published without these permissions.

- **Patient consent forms**

The protection of a patient's right to privacy is essential. Please collect and keep copies of patients' consent forms on which patients or other subjects of your experiments clearly grant permission for the publication of photographs or other material that might identify them. If the consent form for your research did not specifically include this, please obtain it or remove the identifying material.

A statement to the effect that such consent had been obtained must be included in the 'Methods' section of your paper. If necessary the individual journal Editor(s) may request a copy of any consent forms.

- **Ethics committee approval**

All articles dealing with original human or animal data must include a statement on ethics approval at the beginning of the Methods section. This paragraph must contain the following information: the name and address of the ethics committee responsible; the protocol number that was attributed by this ethics committee; the name of the Chairperson of the ethics committee (or the person who approved the protocol) and the date of approval by the ethics committee.

Copies of any (permissions)

It is the responsibility of authors/ contributors to obtain permissions for reproducing any copyrighted material. A copy of the permission obtained must accompany the manuscript. Copies of any and all published articles or other manuscripts in preparation or submitted elsewhere that are related to the manuscript must also accompany the manuscript.

Types of Manuscripts

Original articles:

These include randomized controlled trials, intervention studies, studies of screening and diagnostic test, outcome studies, cost effectiveness analyses, case-control series, and surveys with high response rate. The text of original articles amounting to up to 6000 words (excluding Abstract, references and Tables) should be divided into sections with the headings Abstract, Key-words, Introduction, Material and Methods, Results, Discussion, References, Tables and Figure legends.

Abstract: 400 words maximum, unstructured abstract.

Graphical abstract: The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership.

Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a resolution ≥ 300 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files.

*Please supplement a title for the Graphical Abstract and note it should not be the same as the title of the paper.

Key words: at least 10 key words, not repeat the title, to make your paper more searchable.

Introduction: 500 words maximum. The Introduction should briefly indicate the objectives of the study and provide enough background information to clarify why the study was undertaken and what hypotheses were tested. Please see examples at

http://lbcnimh.nih.gov/Bandettini/Publications/Kriegeskorte_etal_Neuron_inpress.pdf

Materials and Methods: The materials and methods section should be brief but sufficient to allow other investigators to repeat the research.

Reference should be made to published procedures wherever possible.

All companies from which materials were obtained should be listed.

Research Resource Identifiers (RRID): *NRR* is pleased to be a part of the Research Resource Identification Initiative, a project aimed at clearly identifying key research resources, aka materials, used in the course of scientific experiments. These include antibodies, cell lines, model organisms, and software tools. To help authors quickly find the correct identifiers for their materials there is a single web site (https://scicrunch.org/resources) where all resource types can be found and a '**cite this**' button next to each resource that contains proper citation text that should be included in the methods section of the manuscript. Several examples of properly formatted methods sections with RRIDs can be found below:

- **Antibodies:** "antibody against ERK1 (Abgent Cat# AP7251E, RRID:AB_2140114)."
- **Cell Lines:** "we used the following cell lines: RRID: CVCL_1H60,..."
- **Genetically modified organisms:** "Fgf9Eks/Fgf9+ mice (RRID:MGI_3840442)..."
- **Software tools**: "...terminals were mapped (Neurolucida, v10, RRID:SCR_001775)."

Statistical analysis: Authors must provide detailed information for each statistical test applied including: the type of test; specific p values (not > or <); degrees of freedom; population size; definition of population (e.g., number of individual measurements, number of animals, number of slices, number of times treatment was applied, etc.); and if performed, what correction was used to adjust for multiple pair wise comparisons.

Ethics: When reporting studies on human beings, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000 (available at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). For prospective studies involving human participants, authors are expected to mention about approval of (regional/ national/ institutional or independent Ethics Committee or Review Board, obtaining informed consent from adult research participants and obtaining assent for children aged over 7 years participating in the trial. The age beyond which assent would be required could vary as per regional and/ or national guidelines. Ensure confidentiality of subjects by desisting from mentioning participants' names, initials or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on the care and use of laboratory animals was followed.
Evidence for approval by a local Ethics Committee (for both human as well as animal studies) must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of anesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA and World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans for studies involving experimental animals and human beings, respectively). The journal will not consider any paper which is ethically unacceptable. A statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Study design:

Selection and Description of Participants: Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. *Technical information:* Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Reports of randomized clinical trials should present information on all major study elements, including the protocol, assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding), based on the CONSORT Statement (http://www.consort-statement.org).

Reporting Guidelines for Specific Study Designs

Guideline	Type of Study	Source
STROBE	Observational studies including cohort, case-control, and cross-sectional studies	https://www.strobe-statement.org/index.php?id=available-checklists
CONSORT	Randomized controlled trials	http://www.consort-statement.org
SQUIRE	Quality improvement projects	http://squire-statement.org/index.cfm?fuseaction=Page.ViewPage&PageID=471
PRISMA	Systematic reviews and meta-analyses	http://prisma-statement.org/PRISMAStatement/Checklist.aspx
STARD	Studies of diagnostic accuracy	https://pubs.rsna.org/doi/full/10.1148/radiol.2015151516
CARE	Case Reports	https://www.care-statement.org/checklist
	Clinical	

AGREE	Practice Guidelines	https://www.agreetrust.org/wp-content/uploads/2016/02/AGREE-Reporting-Checklist-2016.pdf

The reporting guidelines for other type of studies can be found at https://www.equator-network.org/reporting-guidelines/.

Results: This section should present clearly but succinctly the experimental findings.

Numerical data should be analyzed using appropriate statistical tests.

Only results essential to establish the main points of the work should be included.

Discussion: 1500 words maximum. Include summary of key findings, Strengths and limitations of the study, interpretation and implications in the context of the totality of evidence, Controversies raised by this study, and Future research directions. Extensive discussion of the literature is discouraged.

References: Please download it from EndNote.

Figures and Tables: Figures should be either Photoshop or Illustrator files (in tiff, jpeg, pdf formats) at high-resolution.

Keep the original document for the picture made by Microsoft Office, such as Word, PowerPoint, Excel.

Data Audibility

NRR encourages to submit original experimental data as supplementary files, including original data, images, or tables. Such open access of data will increase study transparency, accelerate the scientific research pace, and establish a credible system of scientific research.

The author(s) can also upload the original experimental data on Figshare (https://figshare.com/) prior to or after publication in case the files are too large to submit to the manuscript system.

Invited Review: an overview of a single theme or topic for Neural Regeneration Research

Mostly solicited by the editors, but authors are also encouraged to submit potential topics for consideration.

It is expected that these articles would be written by individuals who have done substantial work on the subject or are considered experts in the field. A short summary of the work done by the contributor(s) in the field of review should accompany the manuscript.

Procedures for Submission

Authors considering submission of reviews must submit a 1-page outline of the article to the Editor-In-Chief for approval.

Once the review topic is approved for consideration, it is expected that the completed reviews will be submitted within approximately 2 months.

All reviews will be sent to peer review process.

All submission and publication fees with Invited Reviews are waived, including color figures, once the paper is accepted.

General Structure□4000-6000 words□8-10 printed pages

Abstract: 400 words maximum, unstructured abstract.

Key words: at least 10 key words, not repeat the title, to make your paper more searchable.

Introduction

Data Sources: Describe all information sources (e.g., databases with dates of coverage) in the search and date last searched. Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a table or flow diagram.

• Use concise headings and provide clear links between each section.

• End with a brief summary of your article, a strong take-home message and include a clear indication of future research.

Text

Conclusion

Author contribution:

Conflict of interest:

References: • Please concentrate on the seminal references of the past 2-4 years (most references should be no more than five years old); • Review articles can be cited if necessary to refer to older data, however we strongly encourage authors to cite the relevant primary literature when discussing specific findings; • The limit of 50-100 references should not be exceeded. Please download it from EndNote.

Perspectives:

an overview of a single theme or advanced topic for Neural Regeneration Research, including your opinion on particular views on a topic, the implications and applications of new technologies, the summary of your recent achievements and their applications.

Only solicited by the editor.

1500-2000 words□1-2 printed pages

Procedures for Submission

Once a perspective topic is approved for consideration, it is expected that the completed paper will be submitted within approximately 2 months so that publication remains timely.

All submissions will be submitted to the Editor-In-Chief, who will oversee your submission much as a Senior Editor does.

The word length of perspective may not exceed 1-2 printed pages (ca. 2000 words) and should not contain more than two images.

All perspective/research highlights articles will be sent to peer review process.

All the invited perspective/research highlights articles will be sent to peer review process: Publication fees with perspective/editorial articles will be waived, including color figures, once the paper is accepted after peer review.

Template

(Word Limit: 2000 including)

Text, excluding references and figures—1500-2000 words

TITLE PAGE—

The following information should appear: title of article; first name and last name of author(s); affiliations, grant support, and presentation in part or whole at any meeting.

AUTHORS AND INSTITUTIONAL AFFILIATIONS:

Authors:

--No more than 2 authors.

-- Authors must indicate exactly how they want their names to appear.

Institutional Affiliations:

--Include author’s department, institution, city with postal code, and state/country.

MAIN BODY—

an overview of a single theme or advanced topic for Neural Regeneration Research, including your opinion on particular views on a topic, the implications and applications of new technologies, the summary of your recent achievements and their applications.

No abstract and tables, should not contain more than two images;

REFERENCES—

Provide only the references that give essential background materials, no more than 10 references. Please download from Endnote.

(*Please note that this is a strict limit. Manuscripts that are significantly more than this length will lead to unnecessary delays in the processing of your article*.)

--All the invited perspective/editorial articles will be sent to peer review process: Publication fees with perspective/editorial articles will be waived, including color figures, once the paper is accepted.

--Published NRR articles have the opportunity to release news press on EurekAlert! (www.eurekalert.org/) and EurekAlert!Chinese (bilingual website, chinese.eurekalert.org/): EurekAlert will provide highest possible global visibility for your research; To write a science news with 600-800 words for your article, please follow the structure of sample release as attached.

--Submission deadline: It is expected that the completed paper will be submitted within approximately 2 months so that publication remains timely.

References Style of Neural Regeneration Research

References should be cited in the text as follows: "The procedure used has been described elsewhere (Green, 1978),"or "Our observations are in agreement with those of Brown and Black (1979) and of White et al. (1980),"or with multiple references, in chronological order: "Earlier reports (Brown and Black, 1979, 1981; White et al., 1980; Smith, 1982, 1984).... "

In the list of references, papers should be given in alphabetical order according to the surname of the first author. In two-author papers with the same first author, the order is alphabetical by the second author's name. In three-or-more-author papers with the same first author, the order is chronological. Do not number or bullet the references. If the author list for a paper in the references exceeds 20, the paper should be cited as Author A et al. The following illustrate the format to be used:

Examples of Reference
Journal Article

1. Hamill OP, Marty A, Neher E, Sakmann B, Sigworth F (1981) Improved patch-clamp techniques for high-resolution current recordings from cells and cell free membrane patches. Pflugers Arch 391:85-100.
2. Hodgkin AL, Huxley AF (1952a) The components of membrane conductance in the giant axon of Loligo. J Physiol (Lond) 116:473-496.
3. Hodgkin AL, Huxley AF (1952b) The dual effect of membrane potential on sodium conductance in the giant axon of Loligo. J Physiol (Lond) 116:497-506.

Book

1. Hille B (1984) Ionic channels of excitable membranes. Sunderland, MA: Sinauer.

Chapter in a book

1. Stent GS (1981) Strength and weakness of the genetic approach to the development of the nervous system. In: Studies in developmental neurobiology: essays in honor of Viktor Hamburger (Cowan WM, ed), pp288-321. New York: Oxford UP.

Abbreviations of journal titles should follow those listed in the Index Medicus.

Tables

- Tables should be self-explanatory and should not duplicate textual material.
- Tables with more than 10 columns and 25 rows are not acceptable.

- Number tables, in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading.
- Explain in footnotes all non-standard abbreviations that are used in each table.
- Obtain permission for all fully borrowed, adapted, and modified tables and provide a credit line in the footnote.
- For footnotes use the following symbols, in this sequence: *, †, ‡, §, ||,¶ , **, ††, ‡‡
- Tables with their legends should be provided at the end of the text after the references. The tables along with their number should be cited at the relevant place in the text

Illustrations (Figures)

You should provide primitive figure files that can be re-drawn easily. The curves or straight lines should be clear. Units cannot be omitted. Combine related curves in a single figure when possible. A composite of curves will save space and convey more information. Standard symbols (e.g. ○ ,● ,× ,□ ,■ ,□ ,▲) should be used when there are multiple curves.

Photographs, Images and Legends

- The photographs supplied should be at least 85 mm in height and 126 mm in width, and at a resolution of 300 dpi.
- Images submitted should be those which uniquely display the data. Figures are not limited, but must be thoroughly justified. Micrographs should be provided with a scale bar, if appropriate, instead of magnification. Figures should be at 300 dpi resolution (for a figure at least 50 mm in height and 86 mm in width).
- Please provide only one legend for each photograph or figure that contains all the pertinent information.

    1. Figures or photographs should be grouped according to their themes. For example, Figure 1 Pathological changes of xxxx tissue before and after treatment. A: , B: , C: , D: , E: , F: …..
    2. Explain the symbols, arrows, numbers, or letters in the illustrations.
    3. Identify the method of staining and magnification of the photomicrographs (e.g. HE stain, ×900). For those including methodology, the legend should be 100-300 words.
    4. Letters in photographs or figures should be lower case and the first should be capitalized. An interval should be inserted between numbers and units.
    5. Photographs or figures that are obtained at different times or places must not be grouped into one, unless these photographs or figures are arranged in time order. Photographs or figures in the same group should be separated by blanks.
- Authors should list the tools that they used to obtain and edit image files. Images must be edited equally and contrast must be reasonable. Authors should not over-emphasize the difference between experiment and control data, or over-emphasize a certain part of the photograph by ignoring other parts.

Protection of Patients' Rights to Privacy

Identifying information should not be published in written descriptions, photographs, sonograms, CT scans, etc., and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian, wherever applicable) gives written informed consent for publication. Authors should remove patients' names from figures unless they have obtained written informed consent from the patients. When informed consent has been obtained, it should be indicated in the article and copy of the consent should be attached with the covering letter.

Sending a revised manuscript

The revised version of the manuscript should be submitted online in a manner similar to that used for submission of the manuscript for the first time. However, there is no need to submit the “First Page” or “Covering Letter” file while submitting a revised version. When submitting a revised manuscript, contributors are requested to include, the ‘referees’ remarks along with point to point clarification at the beginning in the revised file itself. In addition, they are expected to mark the changes as underlined or colored text in the article.

Reprints and proofs

Journal provides no free printed reprints. Authors can purchase reprints, payment for which should be done at the time of submitting the proofs.

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The journal publishes articles on its website immediately on acceptance and follows a ‘continuous publication’ schedule. Articles are compiled for ‘print on demand’ semiannual issues.

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Neural Regeneration Research charges $1500 per article. When a paper is accepted for publication, the authors will be issued an invoice for payment of the open-access service fee. The open-access service fee is used to pay for online open access, development and maintenance of the editing and reviewing system, and data processing for exposure on Google Scholar, iPhone, iPad and Android smartphones, as well as for PubMed indexing and CrossRef presentation.

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Covering letter

- Signed by all contributors
- Previous publication / presentations mentioned
- Source of funding mentioned
- Conflicts of interest disclosed

Authors

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- Author for correspondence, with e-mail address provided
- Number of contributors restricted as per the instructions
- Identity not revealed in paper except title page (e.g. name of the institute in Methods, citing previous study as 'our study', names on figure labels, name of institute in photographs, etc.)

Presentation and format

- Double spacing
- Margins 2.5 cm from all four sides
- Title page contains all the desired information information (vide supra)
- Running title provided (not more than 50 characters)
- Abstract page contains the full title of the manuscript
- Abstract provided (not more than 150 words for case reports and no more than 300 words for original articles)
- Unstructured abstract provided for an original article
- Key words provided (at least 10)
- Graphical abstract provided
- Research highlights provided
- Introduction

- Headings in title case (not ALL CAPITALS, not underlined)
- References cited in superscript in the text without brackets
- References according to the journal’s instructions.

Language and grammar

- Uniformly American English
- Write the full term for each abbreviation at its first use in the title, abstract, keywords and text separately unless it is a standard unit of measure. Numerals from 1 to 10 spelt out
- Numerals at the beginning of the sentence spelt out
- Check the manuscript for spelling, grammar and punctuation errors
- If a brand name is cited, supply the manufacturer's name and address (city and state/country).
- Species names should be in italics

Tables and figures

- No repetition of data in tables and graphs and in text
- Actual numbers from which graphs drawn, provided
- Figures necessary and of good quality (colour or black&white)
- Table and figure numbers in Arabic letters (not Roman)
- Labels pasted on back of the photographs (no names written)
- Figure legends provided
- Patients' privacy maintained (if not permission taken)
- Credit note for borrowed figures/tables provided
- Write the full term for each abbreviation used in the table as a footnote

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Ethical

Guidelines

1.Ethical Guidelines for Peer Reviewers

Peer review in all its forms plays an important role in ensuring the integrity of the scholarly record. The process depends to a large extent on trust, and requires that everyone involved behaves responsibly and ethically. Peer reviewers play a central and critical part in the peer-review process, but too often come to the role without any guidance and may be unaware of their ethical obligations.

Basic principles to which peer reviewers should adhere

Peer reviewers should:

- only agree to review manuscripts for which they have the subject expertise required to carry out a proper assessment and which they can assess in a timely manner
- respect the confidentiality of peer review and not reveal any details of a manuscript or its review, during or after the peer-review process, beyond those that are released by the journal
- not use information obtained during the peer-review process for their own or any other person's or organization's advantage, or to disadvantage or discredit others
- declare all potential conflicting interests, seeking advice from the journal if they are unsure whether something constitutes a relevant interest
- not allow their reviews to be influenced by the origins of a manuscript, by the nationality, religious or political beliefs, gender or other characteristics of the authors, or by commercial considerations
- be objective and constructive in their reviews, refraining from being hostile or inflammatory and from making libellous or derogatory personal comments
- acknowledge that peer review is largely a reciprocal endeavour and undertake to carry out their fair share of reviewing and in a timely manner
- provide journals with personal and professional information that is accurate and a true representation of their expertise
- recognize that impersonation of another individual during the review process is considered serious misconduct

2.Guidelines for retracting articles

Journal editors should consider retracting a publication if:

- they have clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error) (accident or misconduct)
- the findings have previously been published elsewhere without proper crossreferencing, permission or justification (i.e. cases of redundant publication)
- it constitutes plagiarism
- it reports unethical research

Journal editors should consider issuing an expression of concern if:

- they receive inconclusive evidence of research or publication misconduct by the authors
- there is evidence that the findings are unreliable but the authors' institution will not investigate the case
- they believe that an investigation into alleged misconduct related to the publication either has not been, or would not be, fair and impartial or conclusive
- an investigation is underway but a judgement will not be available for a considerable time

Journal editors should consider issuing a correction if:

- a small portion of an otherwise reliable publication proves to be misleading (especially because of honest error)
- the author / contributor list is incorrect (i.e. a deserving author has been omitted or somebody who does not meet authorship criteria has been included)

Retractions are not usually appropriate if:

- a change of authorship is required but there is no reason to doubt the validity of the findings

Notices of retraction should:

- be linked to the retracted article wherever possible (i.e. in all electronic versions)
- clearly identify the retracted article (e.g. by including the title and authors in the retraction heading)
- be clearly identified as a retraction (i.e. distinct from other types of correction or comment)
- be published promptly to minimize harmful effects from misleading publications
- be freely available to all readers (i.e. not behind access barriers or available only to subscribers)
- state who is retracting the article
- state the reason(s) for retraction (to distinguish misconduct from honest error)
- avoid statements that are potentially defamatory or libelous

3.Cooperation between research institutions and journals on research integrity cases

Institutions and journals both have important duties relating to research and publication misconduct. Institutions are responsible for the conduct of their researchers and for encouraging a healthy research environment. Journals are responsible for the conduct of their editors, for safeguarding the research record, and for ensuring the reliability of everything they publish. It is therefore important for institutions and journals to communicate and collaborate effectively on cases relating to research integrity. To achieve this, we make the following recommendations.

Institutions should:

- have a research integrity officer (or office) and publish their contact details prominently;
- inform journals about cases of proven misconduct that affect the reliability or attribution of work that they have published;
- respond to journals if they request information about issues, such as disputed authorship, misleading reporting, competing interests, or other factors, including honest errors, that could affect the reliability of published work;
- initiate inquiries into allegations of research misconduct or unacceptable publication practice raised by journals;
- have policies supporting responsible research conduct and systems in place for investigating suspected research misconduct.

Journals should:

- publish the contact details of their editor-in-chief who should act as the point of contact for questions relating to research and publication integrity;
- inform institutions if they suspect misconduct by their researchers, and provide evidence to support these concerns;
- cooperate with investigations and respond to institutions' questions about misconduct allegations;
- be prepared to issue retractions or corrections (according to the COPE guidelines on retractions) when provided with findings of misconduct arising from investigations;
- have policies for responding to institutions and other organizations that investigate cases of research misconduct.

4.A Short Guide to Ethical Editing for New Editors

Becoming an editor of a journal is an exciting but daunting task especially if you are working alone without day to day contact with editorial colleagues. This short guide aims to summarize key issues.

1. **Initial assessment of journal when you take over**

   Journals vary in the ways they prevent or handle ethical issues depending on the size of the journal staff, the resources available and the discipline they cover. We therefore recommend using the audit in conjunction with the publisher and journal manager. It may take a considerable time to alter practice.
2. **Relations with the outgoing editor**

   Ideally there should be a handover period with the new and old editor working together. The duration should be agreed with the publisher. This should allow the outgoing editor to complete submissions they started dealing with. New editors should not overturn the previous editor's acceptance decisions unless serious problems are identified such as

plagiarism or data fabrication.

3. **Relations with the other editors/ editorial board**

   In some journals, the editor-in-chief will be expected to work with a team of co-editors. When a new editor is appointed, it is a good opportunity to review and confirm the roles and responsibilities of all editors and editorial staff so that everybody is clear about who does what.
   Most journals also have an editorial board, although their levels of activity and involvement vary. New editors should contact board members and discuss their expectations of them (eg if they are expected to review a certain number of manuscripts each year). Based on the response you may wish to appoint new editors. Ask existing editors to step down and restructure the editorial board. Some journals have a policy of appointing editors for a fixed time period and you will need to consult the publisher.

4. **Relations with authors**

   The instructions to authors will need reviewing to ensure they are up to date with current guidelines. They should clearly state what is expected of authors and what the editor will do in cases of suspected misconduct such as plagiarism or data fabrication. You should consider consulting with colleagues, the publisher or a language editor to ensure journal instructions are not ambiguous. In the submission system you may wish to provide a check list of what is expected from authors to maintain standards of manuscripts.
   Editors are responsible for everything they publish and should therefore take all reasonable steps to ensure the quality of this material, recognising that journals and sections within journals will have different aims and standards.
   Editors' decisions to accept or reject a paper for publication should be based only on the paper's importance, originality, and clarity, and the study's relevance to the remit of the journal.

5. **Transparency**

   Editors should work with the journal publisher/editorial office to agree processes for handling submissions that are the most efficient and appropriate for the journal. Electronic submission systems can be designed to ensure authors provide all required information (eg authorship declarations, funding information), but this should be balanced against the need to avoid over-complex submission systems which may be off putting. It may be helpful to require all elements are complete before a manuscript will be sent for peer review (since chasing details at a later stage can delay publication and upset schedules).
   Journals should adopt and promote an authorship policy that is appropriate to the field of research. Editors should adopt systems to encourage appropriate authorship and discourage guest and ghost authors. For studies in humans, regulations regarding what type of study requires ethical approval vary worldwide. In some countries all studies require ethical approval but in others not. This may lead to submission to journals of manuscripts relating to such studies that do not satisfy the journal's normal requirement for independent ethical approval, and rejection of the manuscript because of misunderstanding of local regulations.

6. **The submission system**

   Electronic submissions usually include standard communications to authors, reviewers and other editors. If these are specific to your journal (rather than used throughout the publisher) you should review them to ensure that they reflect current practices, are consistent with the Instructions to Authors, and are clear. Getting standard letters reviewed by other editors, editorial staff or a language editor may also help improve them and ensure they are clear.

7. **Relationship with reviewers**

   Editors should provide guidance to reviewers on everything that is expected of them. This guidance should be regularly updated.

8. **The peer-review process**

   Editors should adopt a peer-review process that is appropriate for their journal / field of work and resources / systems available. You should think about the number of reviewers used, whether review is anonymous or signed, whether author names and affiliations are masked, and whether reviewers complete checklists / forms. Editors should have systems to ensure that material submitted to their journal remains confidential while under review.
   They should also ensure that peer review is undertaken in a timely fashion so that authors do not experience undue delays. This will usually involve monitoring the process regularly and trying to increase efficiency and prevent delays.

9. **Can editors publish in their own journal?**

   Editors should not be denied the ability to publish in their own journal, but they must not exploit their position. The journal must have a procedure for handling submissions from the editor or members of the editorial board that ensures that peer review is handled independently of the author/editor.

5.How to handle authorship disputes: a guide for new researchers

How to reduce the incidence of authorship problems

- Encourage a culture of ethical authorship
- Start discussing authorship when you plan your research
- Decide authorship before you start each article

Key concepts in authorship

- Acknowledgements
- Appeals
- Contributorship
- Corresponding author
- First and last authors
- Ghost authors
- Gift authors
- Group authorship
- Guarantor
- Instructions to authors
- Number of authors
- Order of authors

Flowchart

http://publicationethics.org/files/u2/All_flowcharts.pdf

(The above excerpt from COPE)

Clinical trial

Clinical Trial

What is a clinical trial?

For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

What is trial registration?

WHO regards trial registration as the publication of an internationally-agreed set of information about the design, conduct and administration of clinical trials. These details are published on a publicly-accessible website managed by a registry conforming to WHO standards.

Trial Registration

Why is Trial Registration Important?

The registration of all interventional trials is considered to be a scientific, ethical and moral responsibility because:

- There is a need to ensure that decisions about health care are informed by all of the available evidence
- It is difficult to make informed decisions if publication bias and selective reporting are present
- The Declaration of Helsinki states that "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject".
- Improving awareness of similar or identical trials will make it possible for researchers and funding agencies to avoid unnecessary duplication
- Describing clinical trials in progress can make it easier to identify gaps in clinical trials research
- Making researchers and potential participants aware of recruiting trials may facilitate recruitment
- Enabling researchers and health care practitioners to identify trials in which they may have an interest could result in more effective collaboration among researchers. The type of collaboration may include prospective meta-analysis
- Registries checking data as part of the registration process may lead to improvements in the quality of clinical trials by making it possible to identify potential problems (such as problematic randomization methods) early in the research process

Organizations with Policies

The organizations listed below have policies on clinical trial registration.

Codes of Research Practice

- Guidelines for the Conduct of Research in the Intramural Research Program at NIH
- NHMRC, Australian Code for the Responsible Conduct of Research
- UK Research Integrity Office, Code of Practice for Research (3.7.13)

Funders

- Canadian Institutes of Health Research (CIHR)
- National Institute of Allergy and Infectious Diseases
- National Institutes of Health (NIH), United States of America
- Wellcome Trust

Ethics Committees

- Mc Master University
- National Research Ethics Service, UK (2 links below)
    - Project Contributes to Transparency & Safety in UK Clinical Trials
    - Project to improve public reporting of clinical trials underway
- The Royal Children's Hospital Melbourne

Legal Requirement

- Drugs Controller General, India
- European Commission
- Food and Drug Administration (FDA) Amendment Act 2007
- Ministerio de Salud, Argentina
- Ministry of Health, Israel: Guidelines for Clinical Trials In Human Subjects
- Agência Nacional de Vigilância Sanitária (ANVISA), Brazil
- Department of Health, South Africa (2 links below)
    - National Health Act of 2004
    - South African Good Clinical Practice Guidelines – 2006
      National Research Ethics Oversight Agencies
- National Statement on Ethical Conduct in Human Research (2007), Australia
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), Canada

Professional Organizations

- American Medical Assocation
- European Medical Research Councils / European Science Foundation
- FairDrugs.org: Call for Ethical Clinical Trials in Developing Countries
- National Health and Medical Research Council: Australian Code for the Responsible Conduct of Research
- Pan American Health Organization
- Red Latinoamericana de Ética y Medicamentos (RELEM): The Buenos Aires Declaration on the Ethics of Clinical Trials
- The Association for Research in Vision and Ophthalmology
- The Society for Clinical Trials
- World Medical Association: Declaration of Helsinki

Publishers

- British Medical Journal (BMJ)
- Council of Science Editors (CSE)
- Pan American Journal of Public Health

- International Committee of Medical Journal Editors (ICMJE)
- SciELO (Scientific Electronic Library Online)
- Statement on Publishing Clinical Trials in Indian Biomedical Journals. Indian J Med Res 127, February 2008, pp 104-105
- Joint Statement of Establishing Chinese Clinical Trial Registration and Publication System. Chinese Clinical Trial Registration and Publication Collaboration
- World Association of Medical Journal Editors (WAME)

Universities

- Boston University Medical Campus
- Imperial College London
- University of Oxford

(The above excerpt from WHO)

Frequently Asked Questions:

Questions about Clinical Trials Registration:

Will the ICMJE consider clinical trial results posted at ClinicalTrials.gov in compliance with the Food and Drug Administration Amendments Act of 2007 to be prior publication?

It is important to note that the ICMJE clinical trial registration policy requires prospective registration of all interventional clinical studies, but does not require results reporting for registered trials. While the ICMJE recognizes the potential problems associated with posting preliminary research results that have not yet undergone an independent peer-review process, it acknowledges that the Food and Drug Administration Amendments Act of 2007 (FDAAA; U.S. Public Law 110-85, Title VIII), mandates the posting of summary results data for certain trials in ClinicalTrials.gov. Thus, the ICMJE will not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication. However, editors of journals that follow the ICMJE recommendations may consider posting of more detailed descriptions of trial results beyond those included in ClinicalTrials.gov to be prior publication. The ICMJE anticipates that the climate for reporting results for registered trials will change dramatically over coming years and the ICMJE may need to amend these recommendations as additional agencies institute other mandates related to results reporting.

Does the ICMJE require registration of clinical trials of devices? What if I register my device trial in ClinicalTrials.gov and it is covered by the delayed posting (“lock box”) provision of Food and Drug Administration Amendments Act of 2007 (FDAAA), meaning that the registered information is not publicly accessible immediately following registration?

The ICMJE does require public, prospective registration of clinical trials of all interventions, including devices. Two options are available to investigators who are conducting trials covered by the FDAAA lock box provision and seeking consideration for publication in ICMJE journals:
If you wish for the information to be made available to the public in accordance with the ICMJE clinical trials registration policy, do not answer the optional question, “Delayed Posting? (Y/N),” during the registration process that results in the placement of device trial registration in the lock box.
Alternatively, you may wish to register the trial in another acceptable registry, in addition to ClinicalTrials.gov. Although the ICMJE believes that dual registration should be avoided in most situations, it is, however, another mechanism around the ClinicalTrials.gov device trial lock box problem. Note that each registration should cross-reference the unique registration identification number (e.g., NCT number for ClinicalTrials.gov) issued by the other registry to ensure recognition that both registrations present information about a single device trial.)

Do trials that began before July 1, 2005 need to be enrolled before September 13, 2005 in order to be eligible for consideration at an ICMJE journal?

Trials that began before July 1, 2005:
Investigators should register trials that began enrolling patients any time before July 1, 2005 as soon as possible if they wish to submit them to a journal that follows the ICMJE policy. While the ICMJE hoped that all such trials would be registered by September 13, 2005, the committee understands that the policy statement was not entirely clear. Thus, ICMJE journals will consider trials that began before July 1, 2005 that were not registered prior to September 13, 2005. However, beginning on September 13, 2005, ICMJE journals will consider such trials only if they were adequately registered before journal submission. The ICMJE journals will accept "retrospective registration" of trials that began before July 1, 2005 (retrospective meaning registration occurs after patient enrollment begins).
Trials that began after July 1, 2005:
ICMJE journals will consider trials beginning on or after July 1, 2005 only if registration occurred before the first patient was enrolled (“prospective registration”).

What is the ICMJE definition of an “ongoing” trial?

The ICMJE considers trials that began enrollment before July 1, 2005 to be “ongoing” if the investigators were still collecting, cleaning, or analyzing data as of July 1, 2005. Ongoing trials

require registration before submission to a journal.

What is the ICMJE definition of a clinical trial?

The most recent editorial on trails registration at www.icmje.org discusses the evolution of the ICMJE definition of clinical trials. In June 2007 the ICMJE adopted the WHO's definition of clinical trial: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after 1 July 2008. Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal. The ICMJE secretariat office is unable to review specific studies to determine whether registration is necessary. If researchers or others have questions about the need to register a specific study, they should err on the side of registration or consult the editorial office of the journal they wish to publish the study in.

What is the relationship between the ICMJE trials registration policy and the ongoing WHO trials registry effort?

In September 2005, the ICMJE implemented a policy that requires registration of clinically directive trials. The WHO is also working towards the implementation of an international trials registration process. Although several editors of ICMJE journals are independently involved as advisors to the WHO process, the two efforts are separate. The ICMJE welcomes the WHO initiative and is following its progress closely. When the final WHO policy is available, the ICMJE will determine whether to revise the ICMJE requirements to correspond to the WHO requirements. At present, the ICMJE expects investigators who wish to publish in ICMJE journals to adhere to the current ICMJE trials registry policy as documented on this web site (see May 2005 editorial and Frequently Asked Questions for details of the current ICMJE policy including the definition of applicable trials, acceptable registries, timing of registration, and required data items).

Which trials registries are acceptable to the ICMJE?

The ICMJE accepts registration in the following registries:

www.anzctr.org.au
www.clinicaltrials.gov www.ISRCTN.org
www.umin.ac.jp/ctr/index/htm
www.trialregister.nl https://eudract.ema.europa.eu/ new registration after June 20, 2011
In addition to the above registries, starting in June 2007 the ICMJE will also accept registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (see http://www.who.int/ictrp/network/primary/en/index.html Because it is critical that trial registries are independent of for-profit interests, the ICMJE policy requires registration in a WHO primary registry rather than solely in an associate registry, since for-profit entities manage some associate registries. Trial registration with missing or uninformative fields for the minimum data elements is inadequate even if the registration is in an acceptable registry.

What should trial registries that wish to be ICMJE-acceptable registries do?

The ICMJE is no longer the entity that reviews registries for acceptability. Registries should consult the WHO International Clinical Trials Registry Platform. Registries that the WHO designates as primary registries will be acceptable to the ICMJE.

Where can I get information about how to register a trial?

Please refer to the registry that you choose to register in for instructions about the registration process for that specific registry.

I'm having trouble registering my trial in ClinicalTrials.gov or believe that my trial is not eligible for registration in that registry... What now?

Send an email to with your question or explaining the problems you are encountering.

Are clinical trials registries in languages other than English acceptable to meet the ICMJE's trials registration policy?

The ICMJE is cooperating with the WHO effort and will adopt WHO policy with respect to registry language. However, until the WHO has a mechanism in place to solve the problems of searching across registries in different languages, the ICMJE feels that the minimal data items need to be registered in English as well as in the native language of the registry.

Do I need to register a trial if the subjects were health care providers and not patients?

Some trials assign health care providers, rather than patients, to intervention and comparison/control groups. If the purpose of the trial is to examine the effect of the provider intervention on

the health outcomes of the providers' patients, then investigators should register the trial. If the purpose is to examine the effect only on the providers (for example, provider knowledge or attitudes), then registration is not necessary.

(The above excerpt from ICMJE)