Dear Safety Pharmacology Members,

The Journal of Pharmacological & Toxicological Methods is the leading international journal devoted exclusively to experimental procedures used by pharmacologists and toxicologists and publishes focused issues that are devoted to a single research topic. Once again the forthcoming focused issue centers on “Methods in Safety Pharmacology”. You are invited to contribute to this, the 5th special issue of the journal on this topic, especially if you have presented at the Safety Pharmacology Society meeting. For this special issue you are asked to write a manuscript that may be an "Appraisal of state-of-the-art" or “Historical review” or simply describe a particular model, method, technique or apparatus used in the conduct of Safety Pharmacology studies. This focused issue will be devoted to manuscripts that describe methods of fundamental importance to Safety Pharmacology and will also contain the SPS meeting abstracts. The manuscripts should describe methods that are utilized, optimized and validated according to international ICH ethics and scientific quality standards that reflect proper study design, conduct of experiments, data recording methods and data reporting practices. Thus, it will be a primary resource aid to individuals in academia and industry that are interested in understanding Safety Pharmacology methods and will provide a comprehensive overview of the most advanced procedures in Safety Pharmacology studies today.

On behalf of the Journal and the Safety Pharmacology Society, I am inviting expert researchers who actively conduct studies of this nature, and especially those who presented at the latest SPS meeting, to submit manuscripts for inclusion in this focused issue of the Journal of Pharmacological & Toxicological Methods. As the Guest Editor for this exciting annual focused issue I would very much welcome the opportunity to work with you on this project.

This issue will be of greater significant value to readers than previous issues because of the expanded topics that comprised the last Safety Pharmacology Society meeting. Each manuscript will be subjected to the normal peer review process and should conform to the "Instructions to Authors" details as outlined in the attached documentation. The deadline for submission of manuscripts will be December 31, 2007.

Should you have any further questions please do not hesitate to contact me. I thank you in advance and look forward to hearing from you regarding this endeavor.

Yours sincerely,

Michael K. Pugsley, Ph.D., F.B.PharmacolS., Associate Editor,

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An Invitation to Submit a Manuscript to a Focused Issue of the Journal of Pharmacological & Toxicological Methods on “Methods in Safety Pharmacology”

General instructions for Authors

Publication Policy.

The Journal of Pharmacological and Toxicological Methods is an international journal, publishing papers concerning all aspects of the methodology of pharmacology and toxicology (including safety pharmacology):

1. "Original articles": description and characterization of a new or modified disease model, method, technique, apparatus or approach to analysis of data. This may include interspecies comparisons that contrast drug actions from a model relevance perspective;

2. "Brief communications" detailing simple modifications of an existing model, method, technique, apparatus or approach to analysis of data;

3. "How To" articles that provide step-by-step guidance on the execution of a specific technique;

4. "Appraisal of state-of-the-art" or "Historical review" of particular models, methods, techniques or apparatus;

5. "Methods in drug discovery" - perhaps the most important category. Here, by showing how a method was used to select a drug that was eventually found to be clinically effective, the author establishes validation of the method.

Papers focused on the actions of drugs are beyond the scope of the journal. Manuscripts will be evaluated by a member of the board of editors of the Journal, and a panel of international reviewers. An editorial decision will normally be made within 4 weeks of receipt of the manuscript, and publication will normally take place within 3 months of final acceptance.

Preparation of Manuscripts.

"How to", "appraisal of state of the art", "historical review" and "methods in drug discovery" articles have special instructions available on request (Michael.Pugsley@frx.com), from the journal web page, or from the extended Instructions printed in the first issue of each volume. The following format should be used for "original articles" and "brief communications", with the manuscript typed double-spaced throughout, and its sections numbered according to the format 1., 2. 2.1. 2.1.1, 2.2. etc.

1. Title page: This should include the title (no more than 120 characters), a short title for the running head, name(s) of author(s), place(s) where the work was undertaken, name address phone fax and email of corresponding author and (if appropriate) the current address of co-authors.

2. Abstract: This must not exceed 300 words and should be subdivided into four subsections headed: Introduction, Methods, Results, Discussion.

3. Key terms: Up to 10, in alphabetical order. This should include the species studied, and the word "methods".

4. After the abstract the text should be numbered in sections from 1. Introduction, with subsections (e.g., 2.1. Statement on use and care of animals) as appropriate.

5. In the text, the referencing style should be author names and year, not numbers (e.g., Zamora 2002 for a single author; Knight & Iwelumo 2004 for two authors, and Ward et al., 1979 for 3 or more authors).

6. Introduction: This must outline the reason for the study and justify the approach taken.

7. Methods: This must begin with a statement of ethical approval by a domestic regulatory authority, or (if human subjects are used) the Declaration of Helsinki (Brit Med J 1964; ii:177). Methods should be sufficiently detailed to permit the reader to replicate the study. Published methods should be described in brief with
An Invitation to Submit a Manuscript to a Focused Issue of the *Journal of Pharmacological & Toxicological Methods* on “Methods in Safety Pharmacology”

appropriate citation. Full details of the experimental material should be given (including type and source of materials).

8. Results: This section should be concise and must not contain repetition of the methods. Data in the text must not replicate data in tables or figures. SI units must be used.

9. Discussion: The potential value of the data to pharmacological or toxicological research methods must be clearly explained, with appropriate reference to existing methods and their limitations. This section must not contain paragraphs dealing with topics that are beyond the scope of the study.

10. Statements on conflict of Interest and Source of Funding. A conflict of interest exists when an author or the author's institution has a financial or other relationship with other people or organizations that may inappropriately influence the author's actions. All submissions to *Journal of Pharmacological and Toxicological Methods* must include disclosure of all relationships that could be viewed as presenting a potential conflict of interest. *Journal of Pharmacological and Toxicological Methods* may use such information as a basis for editorial decisions and may publish such disclosures if they are believed to be important to readers in judging the article.

At the end of the text, under a subheading "Conflict of Interest Statement," all authors must disclose any financial, personal, or their relationships with other people or organizations within 3 years of beginning the work submitted that could inappropriately influence the work submitted. Examples of conflicts include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants. If there are no conflicts of interest, authors should state that there are none. Investigators should disclose potential conflicts to participants in clinical trials and other studies and should state in the manuscript whether they have done so. *Journal of Pharmacological and Toxicological Methods* may decide not to publish on the basis of a declared conflict, such as the financial interest of an author in a company (or its competitors) that makes a product discussed in the paper.

All sources of funding should be declared as an acknowledgment at the end of the text. Authors must also describe the role of the study sponsor(s), if any, in a study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If the study sponsor(s) had no such involvement, the authors should so state.

References in the following style:


11. Figures (color is permissible, web pre-publication color is free but paper color printing will incur a page charge - information requests may be made to the Associate Editor regarding current color printing charges).

**Submitting a manuscript and a cover letter**

Send the manuscript as an email attachment to Michael.Pugsley@frx.com using Microsoft Word (text and figures) and PowerPoint (figures). Make sure that a cover letter, signed by all the authors, is also submitted by this means (as a PDF) or posted to MK Pugsley Ph.D., Department of Pharmacology, Forest Research Institute, Harborside Financial Center, Plaza V, Jersey City, NJ, 07311. This cover letter must be signed by all the authors and declare that "the manuscript contents are original and have not already been published or accepted for publication, either in whole or part. No part of the manuscript is under consideration for publication elsewhere and will not be submitted elsewhere if accepted by *J Pharm Tox Methods*."