INSTRUCTIONS FOR AUTHORS

1. CATEGORIES OF ARTICLES

The Rinsho Hyoka accepts submissions of manuscripts categorized as originals, reviews, opinions, commentaries, short communications, materials. Manuscripts should not have been published or submitted to any other journal for publication.

2. REVIEW AND ACCEPTANCE OF SUBMISSIONS

All manuscripts are peer reviewed by a group of experts before being accepted for publication. Authors/contributors of such manuscripts may be asked to modify or amend the submitted manuscript during the review process.

3. MANUSCRIPT PREPARATION

1) Articles or contributions may be submitted either in the Japanese or the English language.

2) The Title Page must contain the following：
   a) Title (In Japanese and English. If the study design is randomized controlled trial (RCT), this should be specifically stated in the title).
   b) Key words (Provide five (5) key words written in English. In the case of RCT, provide the name of the test drug and controll drug used in the study, and RCT).
   c) Author's name (In Japanese and English)
   d) Affiliation of authors (In Japanese and English)

3) Provide a separate page for the abstract written in English, within 250 words. In the case of originals, a "structured abstract" has to be used. The structured abstract of an original article, in principle, should contain proper items such as Objective, Design, Methods, Results, Discussion and Conclusion.

4) Manuscripts of original articles should, in principle, follow the following format or order： Introduction (or Background), Objective, Methods, Results, Discussion, Conclusion, Conflicts of Interest, Acknowledgement (if necessary), and References, in this order. In the case of RCT, the format of reporting should follow the CONSORT statement (see the material 1, 2).

5) Include a brief title for each figure, table, photograph and other illustrations used in the article. Their titles should be written in English. Figures, tables, and pictures should be clear and large enough to remain legible after they have been reduced to fit in a boxed portion on the journal page.

6) The first time that an abbreviation appears, it should be in parentheses following the words or term for which it stands. Units of measurements should, in principle, follow the International System of Units (SI).

7) Persons' names appearing in the articles should, in principle, be written in the original language. The names of drugs should be expressed in generic terms (small letters in English). At the first appearance of the generic name, it should be followed by the trade/brand names following by the registered trademark® (Example：haloperidol (Serenace®)；etidronate disodium (Didronel®)).

8) The reference listings should be numbered consecutively as they are quoted. References cited in tables and figures must also be numbered in the reference list. The style of references should follow the Vancouver Style.

Style of Journal References：

Example 1：Sato T, Yoshimura I. Expectations for an international harmonized guideline. *Drug Information Journal*. 1998；32(1)：135-9.

Example 2：Tsubaki H, Fujita T, Satoh Y. [Historical remarks on the patient oriented clinical evaluation in Japan and its statistical aspects]. *Tokei Suri (Proceedings of the Institute of Statistical Mathematics)*. 1998；46(1)：97-115. Japanese.

Style of Book References：

Example 1：Meinert C, Tonascia S. *Clinical trials: Design, conduct, and analysis*. New York：Oxford University Press；1986.

Example 2：Nagoh N. [Evidence and clinical practice]. In：Tsutani K, Shimizu N, editors. *Iyakuhin Tekiogai Shiyo no Ebidensu (Evidence of Off-Label Use of Drug)*. Tokyo：Digital Press；1999. p. 33-52. Japanese.

Style of Website References：

Example 1：Rinsho Hyoka (Clinical Evaluation) [cited 2016 Jun 10]. Available from：http://cont.o.oo7.jp/

Example 2：Tufts Center for the Study of Drug Development. Investigative site landscape remains highly fragmented as the number of active investigators worldwide reaches an all-time high；2013 Mar 12 [cited 2014 Mar 10]. Available from：http://csdd.tufts.edu/news/complete_story/ir_pr_mar_apr_2013

9) In the case when the manuscript includes materials or quotations taken from published sources, beyond the definition of quotations of copyright law, a written statement or certificate allowing publication in Rinsho Hyoka must be attached to the manuscript.

10) Financial associations or support for a study or conflicts of interest related to the study must be disclosed in the form of a written statement in the manuscript or submitted in separate letter by the authors to the editors. In the case of clinical trials, the name of the sponsoring company, the controllers and the statistical analysis institution must be stated. The authors may also undertake to provide data or cooperate with the editors in obtaining materials or data to ensure the reliability of the manuscript. For the research covered by ethical guideline, adherence to it should be declared in proper way. In case there are no conflicts of interest to be disclosed, it should be mentioned in the manuscript or in a separate letter by the authors to the editors.

11) If the author has a plan to share with others the data underlying the results presented in the article, it should be described in the article and/or in a letter to the editor.

12) Authors should submit the manuscript by e-mail or by another type of electronic media.

4. REMUNERATION AND PUBLICATION FEE

1) The Rinsho Hyoka shall, in principle, pay for manuscripts of original reports of negative trials, reports on adverse drug reactions (ADR) and adverse event (AE).

2) For submitted articles, the authors should pay for the publication.

3) Request for publication of extra illustrations must be paid for by the authors.

Manuscript Submission

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1) Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardner MJ. More informative abstracts revisited. *Ann Intern Med*. 1990；113(1)：69-76.
2) Aoki M. [Usefulness of structured abstracts]. *Igaku Toshokan (Journal of the Japan Medical Library Association)*. 1995；42(3)：317-24. Japanese.
3) Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010；340：c332. doi: 10.1136/bmj.c332. [Tsutani K, Motoo Y, Nakayama T, translators. [CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomized trials]. *Jpn Pharmacol Ther*. 2010；38(11)：939-49. Japanese.]
4) International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *Ann Intern Med*. 1997；126：36-47.
5) Yoshida K, Yamazaki Y. [Uniform requirements for manuscripts submitted to biomedical journals, Fifth edition]. *Igaku no Ayumi (Journal of Clinical and experimental medicine)*. 1998；186(11)：812-4. Japanese.
6) Yoshida K, Yamazaki Y. [Uniform requirements for manuscripts submitted to biomedical journals, Fifth edition]. *Igaku no Ayumi (Journal of Clinical and experimental medicine)*. 1998；186(12)：872-9. Japanese.

Instruction for authors

4/1974	the first edition
10/1981	the second edition
4/1984	the third edition
9/1999	the forth edition
6/2011	the fifth edition
6/2016	the sixth edition
2/2019	the seventh edition

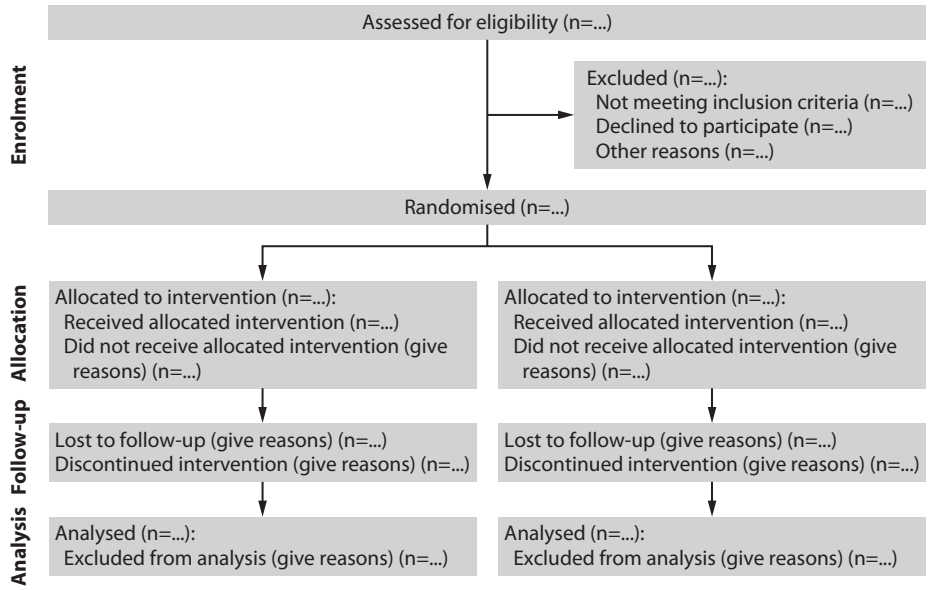
Material 1　CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[a,b])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[c])	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration[d] for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials,[e] non-inferiority and equivalence trials,[f] non-pharmacological treatments,[g] herbal interventions,[h] and pragmatic trials.[i] Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010；340：c332. doi: 10.1136/bmj.c332. [Tsutani K, Motoo Y, Nakayama T, translators. [CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials]. *Jpn Pharmacol Ther*. 2010；38(11)：939-49. Japanese.]

Material 2 Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)



Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010；340：c332. doi: 10.1136/bmj.c332. [Tsutani K, Motoo Y, Nakayama T, translators. [CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials]. *Jpn Pharmacol Ther*. 2010；38(11)：939-49. Japanese.]

References for material 1, 2

a) Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet*. 2008；371：281-3.
b) Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: Explanation and elaboration. *PLoS Med*. 2008；5：e20.
c) Ioannidis JP, Evans SJ, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med*. 2004；141：781-8.
d) Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010；340：c869.
e) Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004；328：702-8.
f) Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006；295：1152-60.
g) Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med*. 2008；148：295-309.
h) Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C. Reporting randomized, controlled trials of herbal interventions: An elaborated CONSORT statement. *Ann Intern Med*. 2006；144：364-7.
i) Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ*. 2008；337：a2390.