

# Academic-Industry Research and Publication: Learning From Recent Experience

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# **The duties and responsibilities of authors and editors**

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## **Mind set for research on human beings**

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That being able to do such research is a privilege, not a right, and having that privilege granted is, in and of itself, a form of public trust that is diminished or violated by any act that is insensitive or disrespectful of that trust

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## **Item 2 of the Nuremburg Warcode**

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The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

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## **Useful documents**

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Consolidated Standards of Reporting Trials (CONSORT)  
International Committee of Medical Journal Editors  
(ICMJE) “Vancouver Convention”  
Council of Science Editors (CSE) policy statement

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# **The publication principle in trials**

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Publish when the trial ends or is prematurely stopped in a peer-reviewed NLM-indexed journal and do so as forthrightly as possible; refrain from presentation in public forums until published

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# **Authorship requirements (Vancouver Convention)**

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Authorship credit should be based on:

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

Authors should meet conditions 1, 2, and 3.

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# Counting principles in trials

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1. A person to be counted as randomized the moment the treatment assignment is known to clinic personnel
  2. All persons randomized counted to the treatment group to which assigned and so counted regardless of course of treatment
  3. All events occurring from the moment of randomization forward are counted
  4. Events counted to the assigned treatment regardless of degree of treatment compliance at the time of the event
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## **Analysis rules in trials**

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- Primary analysis by treatment assignment, regardless of course of treatment
  - Patient considered to be randomized when assignment revealed to clinic
  - Followup timed from date of randomization
  - All deaths and morbid events counted regardless of when they occurred during the course of followup
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# Career enders

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- Fabrication or falsification of results
  - Plagiarism
  - Conduct of research on humans without IRB approval
  - Need to retract a publication because of a bonehead mistake
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# Tell tale signs of rule violations

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- Absence of specific statements regarding counting or analysis principles employed
  - Unexplained varying denominators
  - Telltale words in the abstract or methods, such as “evaluable” patients
  - Large differences in baseline comparability of the groups
  - Large departures from the expected assignment ratio
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# Data dredging

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**data dredging**  $\nu$  - Ad hoc data analyses aimed at finding statistically significant differences among the different groups or subgroups represented, especially such analyses leading to a presentation or publication heralding differences found as being real and important

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## **Essential supporting documents (provided to editors and readers on request or available online)**

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- Protocol and consent form
  - Study forms
  - Randomization protocol
  - Supplementary tables
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# Author do and don'ts

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## Do

- Analyze by the intention to treat principle
- Disclose facts relevant to understanding the results
- Be honest
- Let the data speak
- Describe the randomization process

## **Author do and don'ts**

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### **Don't**

- Switch the outcome measure
  - Data dredge
  - Spin the results
  - Obfuscate
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# **Authors' responsibilities to editors**

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- Disclosure of potential conflicts of interest; financial and scientific
  - Originality of results
  - Sole submission
  - Truthfulness
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## **Editors' duties**

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- Honest objective review
  - Reasonable turnaround
  - Assurance of accuracy
  - Assurance of necessary elements and content
  - Reasonableness when dealing with authors' revisions
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# Readers' expectation of authors

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That they have:

- Been honest and forthright
  - Revealed and disclosed all facts relevant to understanding the results (ie, have not withheld information that if made known to the serious reader would cause the reader to feel “diddled” or deceived)
  - Not “spun” or embellished their results
  - Not dredged results
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# The joint responsibilities of authors and editors to readers

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- An informative title and abstract
  - A reference list that is complete and accurate
  - Titles and legends of tables and figures in the King's English
  - Tables that “add up” or that include explanatory notes when they do not
  - A full credit list
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