Workshop

Scientific Integrity and Ethical Issues in Publishing
Publication Ethics

The deliberate and systematic consideration or moral problems arising in connection with the publication of scientific research.
Procedures to prevent or resolve moral dilemmas

- Ethical review
- Risk-benefit analysis
- Informed consent
- Peer review
- Uniform requirements for attributing authorship credits
- Professional ethics: Ethical Guidelines
Journal Ethical Policies

Author Declarations

- **Authorship Statement** – Declaration of substantive contribution signed by all authors
- **Conflict of Interest Statement** – Declaration of real and apparent Conflicts of Interest, in language comprehensible to average reader, signed by all authors
- **Redundant Publication Statement** – Declaration that the work has not been published previously in whole or in part
- **Human/animal subjects Statement** – Declaration that the study was reviewed by an Ethical Review Committee
- **Duplicate submissions** - Declaration that the work has not been published, or is not being considered for publication, by another journal
Integrity in Research Publishing

- Intellectual honesty in reporting research
- Accuracy in representing contributions of other scientists
- Collegiality in scientific interactions, including communications and sharing of information
- Transparency in conflicts of interest or potential conflicts of interest
- Protection of human subjects in the conduct of research
- Humane care of animals in the conduct of research
- Adherence to the mutual authorship responsibilities between investigators and their research teams.

Adapted from Institute of Medicine (2002)
Facilitators and Topics

- Kerstin Stenius
- Elise Langdon-Neuner
- Shirin Heidari
- Thomas Babor

- The seven deadly sins in scientific publishing
- I am an author – or am I not?
- How to correctly deal with study participants
- Guidelines for resolving ethical dilemmas
Publication Ethics

The 7 Deadly Sins in Scientific Publishing and How to Avoid Them

Kerstin Stenius
Why Ethical Issues are Important

- Ethical violations, especially less serious infractions, are prevalent
- Rates of detection are low, but when detected consequences are serious
- Ethical violations affect the quality and integrity of science
- Compliance review and journal requirements are increasing (e.g., human subjects committees, conflict of interest statements)
### Ethical Issues: Authors’ Seven Deadly Sins

<table>
<thead>
<tr>
<th>Sin</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Carelessness</td>
<td>Citation bias, understatement, negligence</td>
</tr>
<tr>
<td>2 Redundant publication</td>
<td>Same tables or literature review reported without noting prior source</td>
</tr>
<tr>
<td>3 Unfair authorship</td>
<td>Failure to include eligible authors, Honorary authors</td>
</tr>
<tr>
<td>4 Undeclared Conflict of Interest</td>
<td>Failure to cite funding source</td>
</tr>
<tr>
<td>5 Human/animal subjects violations</td>
<td>No approval from Review Board or Ethics Committee</td>
</tr>
<tr>
<td>6 Plagiarism</td>
<td>Reproducing others’ work or ideas without as one’s own</td>
</tr>
<tr>
<td>7 Other Fraud</td>
<td>Fabrication of falsification of data, Misappropriation of others ideas or plans given in confidence</td>
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</table>
1. Negligent Carelessness and Citation Bias

- A failure to adequately review the literature on a topic
- Citation of articles without having read the primary sources
- Selective citation of only those articles that support a particular point of view
- Selective citation to enhance one's reputation, epitomized by self-citation.
- Lack of candor or completeness in describing one's research methods
- Presentation of data that are based on faulty statistical analyses
Consequences of Negligent Carelessness and Citation Bias

<table>
<thead>
<tr>
<th>Sin</th>
<th>Examples</th>
<th>Punishments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Carelessness</td>
<td>Citation bias, understatement, negligence</td>
<td>Request for correction, letter to editor</td>
</tr>
</tbody>
</table>
Preventing Carelessness
and Citation Bias

- Read what you cite
- Cite critically
- Minimize self-citation
- Avoid other selection biases (e.g., language or cultural preferences)
2. Redundant Publication

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>2 Redundant publication</td>
<td>Same tables or literature review reported without noting prior source</td>
<td>Rejection of manuscript. Copyright infringement</td>
</tr>
</tbody>
</table>
### 3. Unfair Authorship

<table>
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<tr>
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<tr>
<td>3 <em>Unfair authorship</em></td>
<td>Failure to include eligible authors, Honorary authors</td>
<td>Angry colleagues, complaints to editor or employer</td>
</tr>
</tbody>
</table>
4. Undeclared Conflict of Interest

A conflict of interest is a situation or relationship in which professional, personal, or financial considerations could be seen by a fair-minded person as potentially in conflict with independence of judgement (FARM 1997). A conflict may be personal, commercial, political, academic or financial

- Personal conflicts include “pet” theories, validation of one’s own ideas, achieving publishable results, and gaining recognition for a discovery

- “Financial” interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies, and company support for staff (COPE 2001)

- Conflict of interest is not in itself wrongdoing (FARM 1997)
Conflict of Interest

The potential for conflict of interest in the addiction field is enhanced by relationships or funding connected with industry, for-profit health care systems, “social aspect organizations” and governments.

There are two levels of conflict of interest:

• A **real** conflict of interest means that the author, or the administrative unit with which the author has an employment relationship, has a financial or other interest that unduly influence the author’s position with respect to the subject matter being considered.

• An **apparent** conflict of interest exists when an interest would not necessarily influence the author but could result in the author’s objectivity being questioned by others.
Conflict of Interest:
ISAJE Guidelines

• Each author should declare to the editor any interests that could constitute a real, potential or apparent conflict of interest with respect to his/her involvement in the publication, between

  (1) commercial entities and the participant personally
  (2) commercial entities and the administrative unit with which the participant has an employment relationship.

• Sources of funding for the study, review, or other item should be declared in the final publication
## Consequences of Undeclared Conflicts of Interest

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<tr>
<td>4  Undeclared conflict of interest</td>
<td>Failure to declare support from pharmaceutical industry</td>
<td>Notification in the journal, possibly retraction of the article, mistrust among colleagues</td>
</tr>
</tbody>
</table>
5. Violations of human and animal subjects policies

Ethical review a necessary requirement for all scientific research on human subjects in many, but not all, countries.
6. Plagiarism

- Plagiarism ranges from the unreferenced use of others’ published and unpublished ideas to submission under “new” authorship of a complete paper, sometimes in a different language. It may occur at any stage of planning, research, writing, or publication; it applies to print and electronic versions.

- All sources should be disclosed through appropriate citation or quotation conventions, and if a large amount of other people’s written or illustrative material is to be used, permission must be sought (COPE 2001).
Self-Plagiarism:

- Author is not allowed to re-use previously published material when rights have been assigned to the publisher (as they are in most cases).
- Many journals are not interested in reproducing previously published material because it consumes valuable space.
- Use without permission is a violation of copyright.

**How to avoid self-plagiarism**

- Short quotes from a previously published article should be set off in quotation marks and original version cited.
- Permission must be requested when large sections are reproduced.
- Methods and literature reviews should be paraphrased.

Consequences of Plagiarism

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<td>Retraction of manuscript &amp; notification of employer</td>
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7. Other Scientific Misconduct

- “Trimming”: altering one’s data
- “Cooking”: selective reporting of one’s data
- “Forging”: making up the data

Charles Babbage (1830)
## Consequences of Scientific Misconduct

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Biomedical Authorship

Elise Langdon-Neuner
http://www.emwa.org/, click journal, then free sample copy of TWS
Who is an author?

*The person who writes a document?*

Authorship in biomedicine is more complicated

**Overall:**

- An author must have substantially contributed intellectually to the study
- + be able to take responsibility for it or parts of it
ICMJE Guidelines (www.icmje.org)

Used to determine which contributions = authorship

A substantive intellectual contribution

- Conceived or designed study or
- Acquired data or
- Analysed or interpreted data

And

- Drafted the article or revised it for intellectual content and
- Approved final version to be published
ICMJE exclude from authorship

Someone who *just*

- is the departmental chair
- acquired funding
- provided general supervision
- collected data
- provided purely technical support
- provided writing assistance

- Acknowledgement
What are guest and ghost authors?

- A guest author: is an author but shouldn’t be
- A ghost author: is not an author but should be
Who are guest authors?

Named authors who do not meet authorship criteria

Why?

Departmental heads
- pressure to publish/convention
- boost acceptance chances

Other guests
- mutual support to pad out biographies
- condition for providing samples/patients
Who are ghost authors?

People **not listed** on the paper **who do meet** authorship criteria

**Why?**

To avoid a dilution of credit

*e.g.* junior faculty member

To hide a potential pharma company influence

*e.g.* sponsor employee, medical writer, statistician
What’s wrong with guest/ghost authorship?

**Guest authorship is**
- Unfair—junior authors do not receive the credit they deserve
- Dangerous—department head can be held responsible for a junior’s unethical behaviour

**Ghost authorship**
- Leaves readers unaware of possible bias
- Avoids accountability for the work
Who decides authorship and when?

ICMJE:

- The group should jointly decide about contributors/authors before submitting the manuscript for publication.
- The corresponding author should be prepared to explain the presence and order of these individuals.
Who checks authorship?

Office of Research Integrity (ORI)
- excludes authorship issues from its official purview
- considers authors’ institutions are responsible for authorship

Journals
- also consider authors’ institutions are responsible for determining authorship
How to prevent authorship problems

- Develop institutional policies that are fair and establish transparency
- Distribute and discuss an outline before finalising the paper
How to prevent authorship problems

- Decide on authorship at the beginning of each study
- Compile an inventory of contributions to be revisited in the middle and end of the study
- Circulate manuscript for approval before submission
Who is a contributor?

Someone who added usefully to the work

ICMJE:
- editors should have a contributorship policy
- + identify who is responsible for the integrity of the work (guarantor)

In reality contributors usually=
= listed authors
Contributor statements

- Some journals require authors to sign contributor statements and
  - provide checklist or
  - ask authors to state contribution in their own words

- Some journals will ask questions if suspicious
Reporting ethics in scientific publications

Shirin Heidari
Reporting ethics in scientific publications

Author: ‘Who checks this anyway?’

Whose responsibility?

Editor: ‘Checking this will take too much time’

Peer-reviewer: ‘The editor will have checked this’
# Guidelines on the ethics of biomedical research with human subject

Table 1. Selected Guidelines on the Ethics of Biomedical Research With Human Subjects*

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Source</th>
<th>Year and Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fundamental</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuremberg Code\textsuperscript{35}</td>
<td>Nuremberg Military Tribunal decision in <em>United States v Brandt</em></td>
<td>1947</td>
</tr>
<tr>
<td>Belmont Report\textsuperscript{37}</td>
<td>National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research</td>
<td>1979</td>
</tr>
<tr>
<td>International Ethical Guidelines for Biomedical Research Involving Human Subjects\textsuperscript{38}</td>
<td>Council for International Organizations of Medical Sciences in collaboration with World Health Organization</td>
<td>Proposed in 1982; revised, 1993</td>
</tr>
</tbody>
</table>

*From Emanuel et al. *JAMA.* 2000; 283: 2701-2711*
“Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research.” Helsinki Declaration

- Authors: accountable for completeness and accuracy.
- Editors: reject research not in accordance with ethical principles.
- Peer-reviewers: expert judgement related to field and region

Protect life, health, dignity, integrity, right to self-determination, privacy, confidentiality of research participants.
7 ethical requirements

1. Social and Scientific value
2. Scientific validity
3. Fair subject selection
4. Favorable risk – benefit ratio
5. Independent review
6. Informed consent
7. Respect for potential and enrolled subject
Ethical reporting starts at the ‘beginning’

what you do not have... you cannot report

- **Design phase:** Obtain ethical clearance.
  - ‘Institutional review boards’ or ‘committees on human subjects’ review and approve ethics/safety of research proposal. Helsinki Declaration.

- **Implementation phase:** Obtain participant’s consent.
  - Written informed consent legally protects the author and the journal/publisher.

- **Dissemination phase:** Report ethical clearance and patient consent in publication and protect confidentiality.

Adopted from Framework for Operations and Implementation Research in Health and Disease Control Programs
Ethical review

- Exists to protect the rights, safety, dignity and well-being of research participants;
- **AND**
- To facilitate and promote ethical research that is of potential benefit to participants, science and society.

**Elements of a review:**
- Scientific design and conduct of study
- Recruitment, care and protection of research participants
- Protection of confidentiality
- Informed consent process
- Community considerations

**In theory:** all research that involves human subjects requires ethical approval
- National guidelines differ
- Review boards can also grant waivers

WHO guidelines (elements)
National Research Ethics Service (UK)
Participant’s consent

- Any research that studies humans may pose a risk (e.g. side-effects) and always inflicts a cost (e.g. time). More ‘invasive’ studies carry a greater risk

- ‘The voluntary consent of the human subject is absolutely essential’
  First principle of the Nuremberg Code.

- **Important to note:** Consent legally protects authors/ journals/ publishers, but ‘fails to protect the participant from future personal negative consequences of being the subject of a report.’

- The need for an informed decision by the participant varies:
  - have sufficient knowledge –including potential risks and harms- and comprehension of the study. *Voluntary, knowing and competent?*
  - Consent to participate in research is not the same as consent to publication i.e. sharing of individual data.
  - *To consider: minors/disability, language, education level, time for questions, withdrawal clause, publication information.*

Adopted from Informed Consent for Case Reports Levine&Stagno J Psychoter Pract Res 2001
+ Framework for Operations and Implementation Research in Health and Disease Control Programs
+ Nuremberg Code + Declaration of Helsinki.
2001 Declaration of Commitment on HIV/AIDS included: Enforce legislation, regulations and other measures to ensure rights of people living with HIV, including privacy and confidentiality.
Participant’s anonymity

Every precaution must be taken to protect privacy, ensure confidentiality, minimize impact. (Helsinki Declaration)

- How to do this...
  - First step is ‘Consent’.
  - Identifying information should not be published unless essential for scientific purposes. Non-essential details of participants should be omitted.
  - Informed consent in case of identifiable participants requires the manuscript to be shared prior to publication.
  - But...participant’s data should never be falsified to obtain anonymity. Alterations need to be stated on submission and verified not to distort scientific meaning.

Adopted from BMJ 1995 311:1272 Protection of patients’ rights to privacy
+ Council of Science Editors: 3.1.1 Mistreatment of Research Subjects.
Editorial review

The editor’s dilemma:

Journal requirements vs local regulations

Criteria for review:

- Scientifically valid and clearly presented
- Confounding factors/biases have been excluded or considered
- Ethical harms have been minimised
- Benefits outweigh the harms
- Local regulations have been followed
- Peer-reviewer expert advice

Adapted from guidance for editors from COPE
Reporting correctly

- **Clinical trial registration**: any research study that prospectively assigns human subjects to health related interventions (e.g. drugs) to evaluate health outcomes. Register with a publicly accessible registry, trial registration number - last line of the abstract.

- **Ethical clearance**: Approval or approved waiver stated with details of granting body in methods section.

- **Patient consent**: To be stated in methods section, how informed, verbal/written consent was obtained, also information on compensation.

- **Conflict of interest**: Disclosure of any potential conflicts of interest, also part of seeking ethical clearance. Personal gains that compromise integrity.

Adapted from JIAS instructions to authors. Helsinki Declaration.
PUBLICATION ETHICS:

Guidelines for Resolving Ethical Dilemmas in the Real World

Thomas Babor
Scientific issues embrace three ethical realms

- The individual, co-workers, and research participants
- The institution
- Professional field, science and society
Publication Ethics Draws from Many Sources

- Ethical principles
- Ethics codes
- Scientific values
- Professional guidelines
- Procedures to implement ethical principles and professional guidelines
“Can you tell me Socrates, is virtue something that can be taught? Or does it come by practice? Or is it neither teaching nor practice that gives it to a man, but natural aptitude or something else?”
Ethical Traditions
Applicable to Publication Ethics

• Ethics of virtue and character ("being good" owing to traits of integrity, honesty and compassion)

• Ethics of individual acts and rights ("doing good" by applying principles such as fairness and justice)
## General Ethical Principles

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for persons</td>
<td>Autonomy and self-determination, Meaningful informed and voluntary consent</td>
</tr>
<tr>
<td>Beneficence</td>
<td>Maximizing benefits by promoting the well-being of subjects and society</td>
</tr>
<tr>
<td>Non-maleficence</td>
<td>Minimizing harm</td>
</tr>
<tr>
<td>Justice</td>
<td>Persons bearing burden of research should receive appropriate benefits: subjects should not be placed at risk merely because of their compromised position</td>
</tr>
<tr>
<td>Autonomy</td>
<td>Respect people’s choices</td>
</tr>
<tr>
<td>Stewardship</td>
<td>Use resources efficiently and justly</td>
</tr>
<tr>
<td>Fairness</td>
<td>Avoid discrimination and exploitation</td>
</tr>
</tbody>
</table>

*(Belmont Report 1979)*
A Procedure for Ethical Analysis and Decision-making
(White & Popovits, 2001)

- Borrows from major traditions, guidelines and principles
- Designed to stimulate critical thinking about ethical complexity, rather than provide definitive answers
Ethical analysis requires asking three questions

1. Whose interests are involved and who is likely to be harmed?
2. What principles apply to this situation and what course of action is suggested by these principles?
3. What laws, standards, policies, practice guidelines, historical practices should guide us in this situation?
# Checklist for Analysis of Critical Incidents

1. Whose interests are involved; who can be harmed?

<table>
<thead>
<tr>
<th>interests and vulnerabilities</th>
<th>significant</th>
<th>moderate</th>
<th>minimal / none</th>
</tr>
</thead>
<tbody>
<tr>
<td>yourself</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>co-workers</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>institution</td>
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<tr>
<td>professional field</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>science / society</td>
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</tbody>
</table>

Which interests, if any, are in conflict?
Application of Universal Values

- Autonomy (freedom over one's own destiny)
- Beneficence (do good; help others)
- Nonmaleficence (don't hurt anyone)
- Justice (be fair; distribute by merit)
- Obedience (obey legal and ethically permissible directives)
- Conscientious refusal (disobey illegal or unethical directives)
- Gratitude (pass good along to others)
- Competence (be knowledgeable and skilled)
- Stewardship (use resources wisely)
- Honesty and candor (tell the truth)
- Fidelity (keep your promises)
- Loyalty (don't abandon)
- Diligence (work hard)
- Discretion (respect confidence and privacy)
- Self-improvement (be the best that you can be)
- Restitution (make amends to persons injured)
- Self-interest (protect yourself)
- Other culture-specific values
Ethical Analysis Exercise

- Read the case
- Use checklist to answer the discussion questions
- Compare your answers to an ethicist’s analysis of the case
How did we do?

- Please take a minute to fill out our evaluation form.
- Many thanks for your participation.
Have a guess...

- Average number of authors per paper?
Have a guess...

- **Average number of authors per paper?**
  3.6 authors/paper

- **Record number of authors for scientific publication?**
Have a guess…

- **Average number of authors per paper?**
  
  3.6 authors/paper

- **Record number of authors for scientific publication?**
  
  
  2512 authors (18 of the pages of the paper is a list of authors…)

Courtesy of Linus Svenssson
Participant’s consent

- Also required for identifiable human material or data (collection, analysis, storage, re-use)

- Evidence: most commonly a signature testifying informed, written consent,
  - non-written consent must be formally documented and witnessed

- Impossible or impractical cases – still require approval of research ethics committee.
## Validating your research

<table>
<thead>
<tr>
<th>Construct</th>
<th>Specify therapeutic elements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active ingredient</td>
</tr>
<tr>
<td>Internal</td>
<td>Detail population and measurements</td>
</tr>
<tr>
<td></td>
<td>Parameters</td>
</tr>
<tr>
<td>Statistics</td>
<td>Analyse statistical power</td>
</tr>
<tr>
<td></td>
<td>Sample size, which numbers?</td>
</tr>
<tr>
<td>External</td>
<td>Discuss in context</td>
</tr>
<tr>
<td></td>
<td>Generalizability</td>
</tr>
</tbody>
</table>

Adapted from AIDS Education and Prevention 16(4)341-52, 2004, Flores et al
What Laws, Standard, Policies, Practice Guidelines, Historical Practices should guide us in this situation?

- Copyright laws
- Review Board/Ethics Committee standards
- Professional policy documents
Limitations are ok, but they need to be acknowledged.

- **Bias: The study population**
  - **Researcher: selection bias**
    - Control or reference group
    - Comparable and representative study groups
  - **Subjects: participation bias + reporting bias**
    - People who participate in a study may be more stable, healthy, at lower risk.
    - HIV sexual risk behaviours, social stigma and illegal drug use can influence reporting
  - To include: selection criteria, refusal rate, lost to follow-up
What laws, standards, policies, practice guidelines, historical practices should guide us in this situation?

- Copyright laws
- IRB standards
- Professional policy documents
Towards a moral compass

- Patients/participants
  - Do no harm
  - Benefit the participant
- The scientific community
  - Transparency
  - Honesty
  - Accuracy