



# Ethical Issues Related to Research and Publication in Biomedical Informatics

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Alan Meisel, JD  
Kenneth Goodman, PhD  
Reed Cushman, PhD  
And Many Others

# Ethical Issues Related to Research and Publication in Biomedical Informatics

*Ethical Principles: Dogmatic\* and Pragmatic*

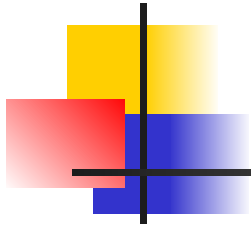


\* Dogmatic as in canine; actually guiding principles not dogma

# Is Ethics Relevant today?

Ann Intern Med July 4 2017

(Publishing about Ethics Viable)

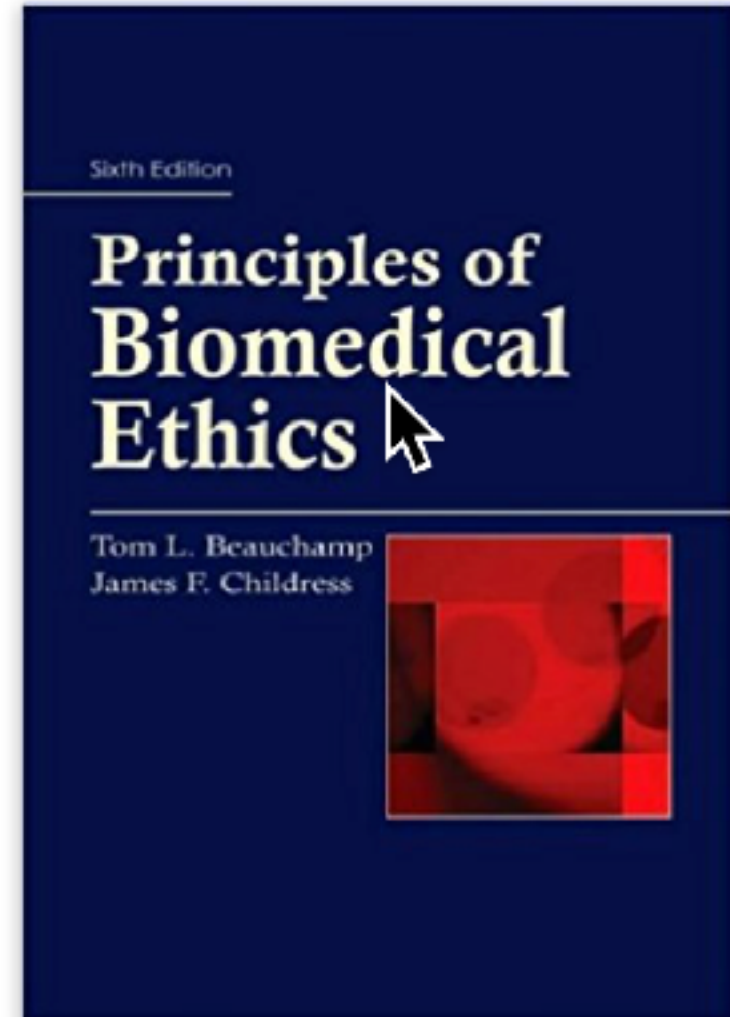


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- **CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts**
  - **Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors**
  - **Incidental Findings in Research Studies: One Student's Experience**

# Ethical Issues Regarding Informatics

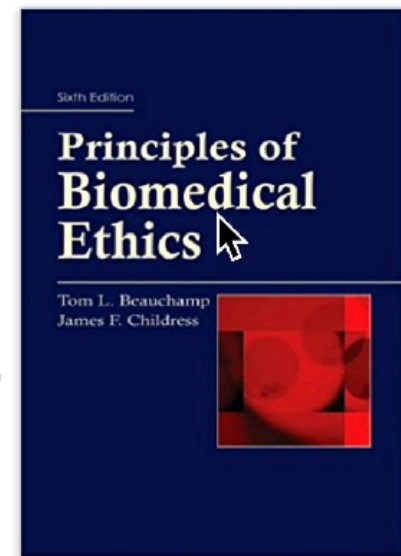
**Beauchamp and Childress**  
*Principles of Biomedical Ethics*

- a) Autonomy**
- b) Beneficence**
- c) Non-Maleficence**
- d) Justice / Fairness**



# Ethical Issues

## Dogmatic Principles



a) **Autonomy** - respect for individuals - patients' privacy, ability to make choices



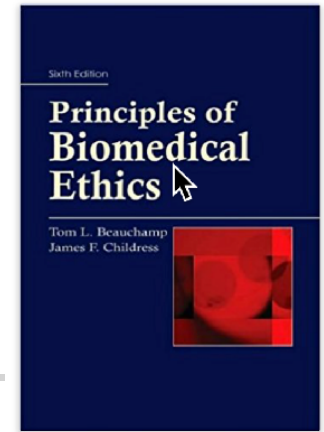
Prevent identification of subjects



Do not hinder subjects wanting to leave the study

# Ethical Issues

## Dogmatic Principles



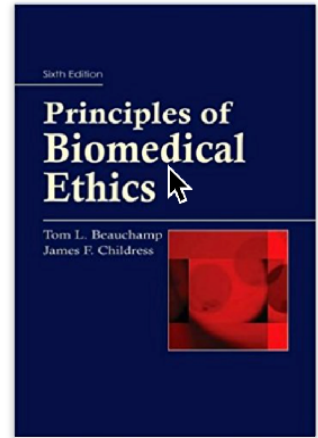
**b) Beneficence** - work should carry expectation of benefits to patients or society



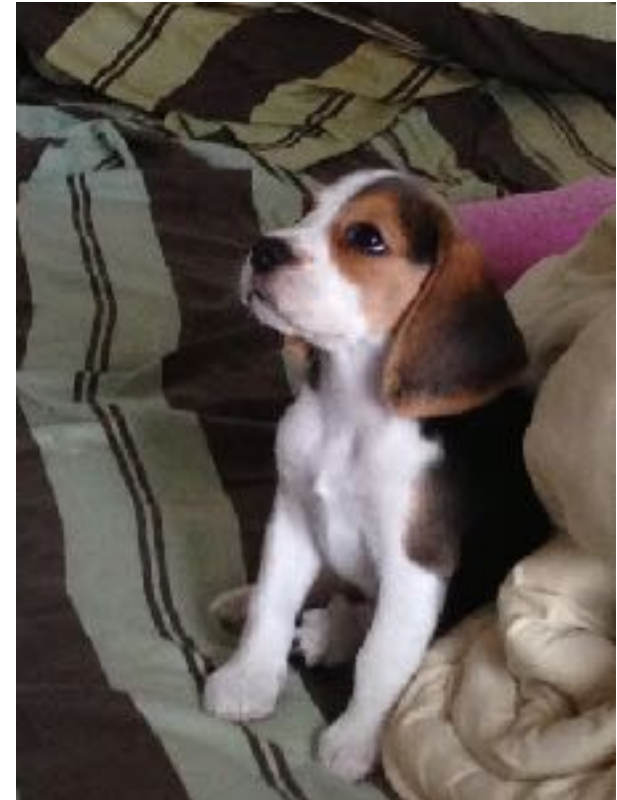
Subjects expectantly  
awaiting benefits from  
their participation in study

# Ethical Issues

## Dogmatic Principles

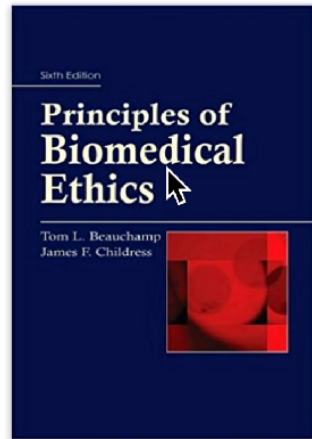


c) **Non-Maleficence** - avoid actions that might cause harm



# Ethical Issues

## Dogmatic Principles



### d) Justice - treat subjects fairly and equally



Even canine subjects understand unequal treatment —

if one gets a treat for a trick and the other does not, the latter is frustrated and feels wronged



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google.com

popsci.com

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**ANIMALS**

# DOGS AND WOLVES BOTH GET SAD WHEN YOU DON'T TREAT THEM FAIRLY

THEY'RE ALL SUCH GOOD BOYS!

*By Sara Chodosh*  
June 08, 2017



11:00 75% AT&T

google.com

bbc.co.uk

**BBC NEWS**

# Dogs and wolves share sense of fair play

**Matt McGrath**  
Environment correspondent

09 June 2017 | [Science & Environment](#)



Dogs and wolves displayed a strong sense of inequity when their partners got better treats

The sense of fair play is an important human trait

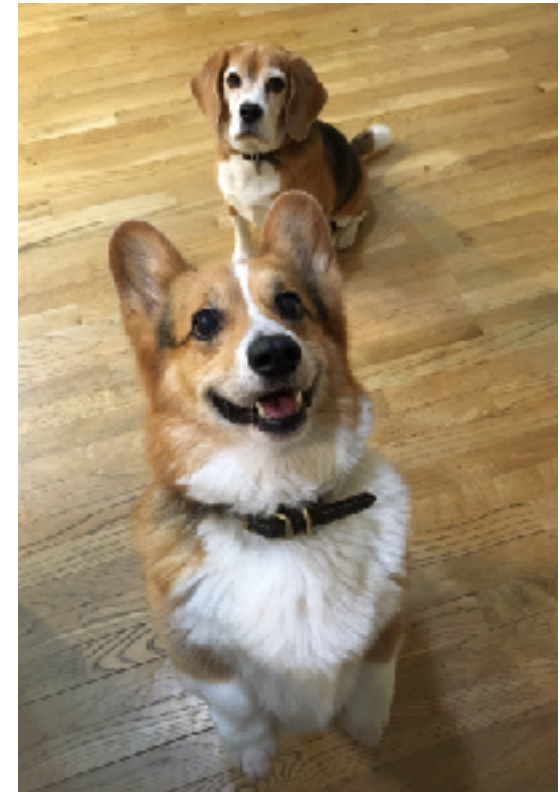
# Name the Ethical Issues

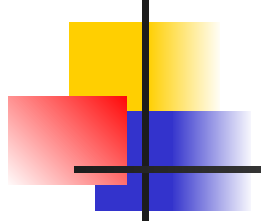
## Dogmatic Principles

Sixth Edition

Principles of  
Biomedical  
Ethics

Tom L. Beauchamp  
James F. Childress





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# **Ethical Issues Regarding Informatics Research**

# Years of Ethics Charges, but Star Cancer Researcher Gets a Pass

By JAMES GLANZ and AGUSTIN ARMENDARIZ

Last Updated: 04:00 CT



**New York Times**

**March 8, 2017**

# Ethical Issues Regarding Informatics Research



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**You are working in the lab of a distinguished Professor at your institution**

**One of his graduate students confidentially tells you:**

***“The data from recent experiments published in prominent journals may have been falsified.”***

# Ethical Issues Regarding Informatics Research



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*“The data from recent experiments published in prominent journals may have been falsified.”*

Issues/Concerns?      What do you do?

- 1) **What possible scenarios might be true?  
What might be “fake news”?**

# Ethical Issues Regarding Informatics Research



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*“The data from recent experiments published in prominent journals may have been falsified.”*

Issues/Concerns?

What do you do?

**2) Which persons/entities could be harmed by what happens next? How?**

**Grad Student**

**Other Lab Members**

**Department Chair**

**Grant Sponsor(s)**

**Professor**

**Faculty Colleagues**

**Dean / School / Institution**

**Journals / Editors**

# Ethical Issues Regarding Informatics Research



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*“The data from recent experiments published in prominent journals may have been falsified.”*

Issues/Concerns?

What do you do?

**3) Which persons/entities have the power / authority to determine facts of situation in a fair manner?**

**Grad Student**

**Other Lab Members**

**Department Chair**

**Grant Sponsor(s)**

**Professor**

**Faculty Colleagues**

**Dean / School / Institution**

**Journals / Editors**



# Ethical Issues Regarding Informatics Research



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*“The data from recent experiments published in prominent journals may have been falsified.”*

Issues/Concerns?

What do you do?

**4) Which persons/entities have the power / authority to rectify the situation once facts are known?**

**Grad Student**

**Other Lab Members**

**Department Chair**

**Grant Sponsor(s)**

**Professor**

**Faculty Colleagues**

**Dean / School / Institution**

**Journals / Editors**

# Ethical Issues

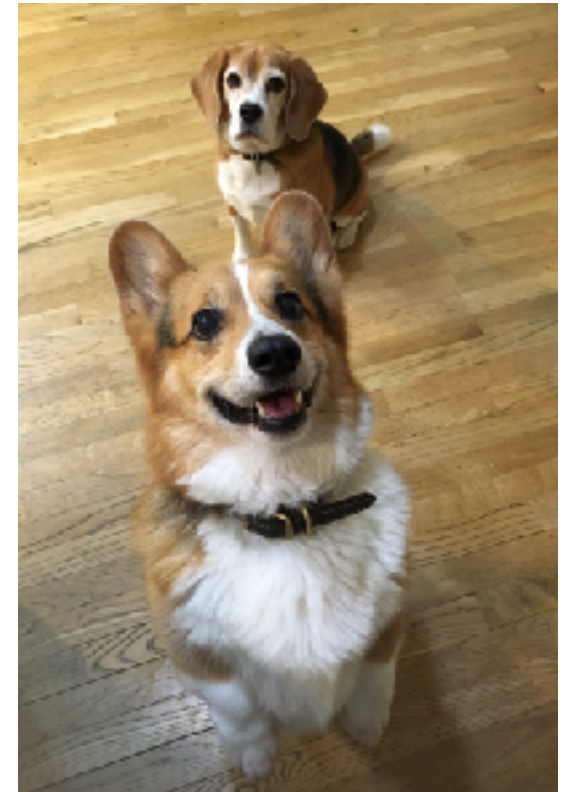
## Dogmatic Principles

Which Principles Apply & How?

Sixth Edition

Principles of  
Biomedical  
Ethics

Tom L. Beauchamp  
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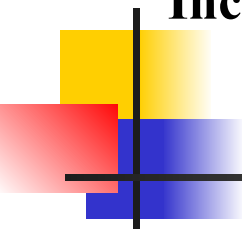


# **Ethical Issues Regarding Informatics Research**

**Incidental Findings in Research Studies: One Student's Experience**

*Ann Intern Med July 4 2017*

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**During my freshman year of college, I took part in a research study that explored differences in brain structure between children with and without cleft lip and cleft palate.**

**The study included neurocognitive, behavioral, and genetic testing; a neurologic examination; and a brain MRI.**

**I participated one afternoon in January 2011 during my winter break, because I needed something to do and it was a way to make a little money before heading back to school.**

**Once the study was over, I deposited my check and more or less forgot about the study and what it could mean for me later.**

# **Ethical Issues Regarding Informatics Research**

**Incidental Findings in Research Studies: One Student's Experience**

*Ann Intern Med July 4 2017*

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**During his freshman year of medical school, he developed neurological symptoms and had a second MRI study.**

**The MRI study revealed a malignant brain tumor. After undergoing surgery, radiation, and chemotherapy, the student sought to obtain a copy of his MRI from 4 years previously.**

**The earlier MRI showed evidence of the same tumor, but the student had signed a permission for the study that acknowledged that the MRIs would be evaluated anonymously and study participants would not be able to know the results.**

**Earlier treatment would have helped him. He is now lobbying for improved disclosure standards for participants in research studies.**

# Ethical Issues Regarding Informatics Research

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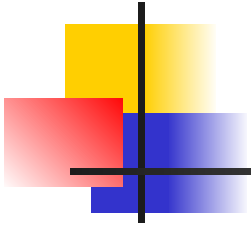


**You serve on your institution's research oversight committee.**

**The institution has developed a biobank that helps researchers store and analyze patients' DNA samples.**

**The biobank has information on 500,000 local patients.**

# Ethical Issues Regarding Informatics Research



**A leading researcher at your institution uses the biobank.**

**She discovers that a certain set of genetic markers, when present, predicts with 95% certainty premature death before age 35 years.**

**200 patients in the biobank have the markers; 90 are < 30 yrs old. The others died before age 35.**

**Issues/Concerns? Ethical principles?**

# Ethical Issues Regarding Informatics Research

## Pragmatic Issues



<http://albany.bivfsites.com/wp-content/uploads/sites/25/2014/01/dna.png>

*A leading researcher at your institution, using the biobank, discovers that a certain set of genetic markers, when present, predicts a 95% certainty of premature death.*

**Which ethical principles are relevant?**

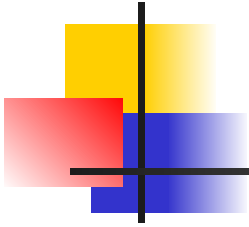
- a) **Autonomy** - respect patients: privacy, ability to make choices
- b) **Beneficence** - work should benefit patients and/or society
- c) **Non-Maleficence** - avoid actions that might cause harm
- d) **Justice** - treat subjects fairly and equally

**What would you recommend?**

**What are implications of “de-identified” vs “identifiable”?**

**What are implications of “opt-in” vs “opt-out” enrollment?**

# Ethical Issues Regarding Informatics Research



<http://blogtimenow.com/wordpress/copy-duplicate-wordpress-post-page>

**You have just completed a term on an NIH Study Section reviewing grant proposals.**

**Now, three months later, you join a new Study Section for a different NIH component institution.**

**One of the grant proposals assigned for your review is from the same university and investigators as a proposal you recently reviewed at the former Study Section.**



# Ethical Issues Regarding Informatics Research



<http://blogtimenow.com/wordpress/copy-duplicate-wordpress-post-page>

**The proposal in question has the same unchanged content as the previous proposal, as best as you can remember.**

**The previous review assigned a mediocre scientific merit score.**

**The current review session occurs 3 months after your last grant review meeting.**

**You know that grant proposals are not reviewed until 4-5 months after submission to NIH.**

**What are your options? Ethical principles?**

# **Ethical Issues Regarding Informatics Research Pragmatic Issues**

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**“The same proposal under review was reviewed elsewhere already.”**

- 1) Which persons/entities could be harmed by what happens next?**
- 2) Which persons/entities have the power and authority to determine the facts of the situation in a fair manner?**
- 3) Which persons/entities have the power and authority to rectify the situation once the facts are known?**
- 4) How can your actions in reporting the incident protect all persons and entities involved to the extent possible?**



# Ethical Issues Regarding Informatics Research Pragmatics

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**Per Code of Federal Regulations (CFR) and NIH, Institutional Review Boards (IRBs) must oversee human subjects research**

**If you are thinking of potentially publishing** any clinical data or other human subject data analysis (e.g., Quality Control/Safety) **obtain IRB approval** early, not post-study

Institution-provided **Ethics in Research Training** is available online through programs such as **Collaborative Institutional Training Initiative (CITI)** developed by the University of Miami et al.

The CITI program: an international online resource for education in human subjects protection and the responsible conduct of research. Acad Med. 2007 Sep;82(9):861-4.

# Ethical Issues Regarding Informatics Research



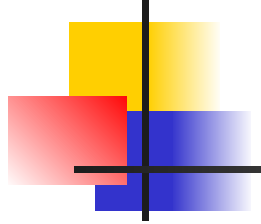
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- a) **Autonomy** - respect patients' privacy, ability to make choices
- b) **Beneficence** - work should benefit patients and society
- c) **Non-Maleficence** - avoid actions that might cause harm
- d) **Justice** - treat subjects fairly and equally

**IRB approval is only first step – monitoring during study imperative to make sure that above principles followed throughout**

**What might go wrong during a clinical informatics trial related to:**

- a) **Recruitment/enrollment**
- b) **Magnitude of effects during trial**
- c) **Magnitude of side effects during trial**



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# **Ethical Issues Regarding Publication in Informatics**

# Ethical Issues Regarding Informatics Publication

Principles: Editors of Informatics Journals Editorial

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- 1. Do not generate concurrent duplicate submissions to different journals**
- 2. Avoid serial *unaltered* submissions to journals (“journal shopping”)**
- 3. Avoid serial minimally altered republication without attribution/permission**
- 4. Avoid self-plagiarism of materials whose copyright you do not hold**
- 5. Avoid non-disclosure of conflicts of interest**

# **Ethical Issues Regarding Informatics Publications**

**Data Sharing Statements for Clinical Trials: A Requirement of ICMJE**

**Ann Intern Med July 4 2017**

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**The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk.**

**1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.**

# **Ethical Issues Regarding Informatics Publications**

**Data Sharing Statements for Clinical Trials: A Requirement of ICMJE**

**Ann Intern Med July 4 2017**

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**2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration.**

**The ICMJE's policy regarding trial registration is explained at [www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).**

**If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.**



# **Ethical Issues Regarding Informatics Publications**

**Data Sharing Statements for Clinical Trials: A Requirement of ICMJE**

**Ann Intern Med July 4 2017**

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## **Data sharing statements must indicate the following:**

**whether individual de-identified participant data (including data dictionaries) will be shared;**

**what data in particular will be shared;**

**whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.);**

**when the data will become available and for how long;**

**by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).**

# Ethical Issues Regarding Informatics Publication

## Principles: Committee on Publication Ethics (COPE)

COPE 20TH ANNIVERSARY

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- Code of Conduct**  
Through the Code of Conduct, COPE aims to define best practice in the ethics of scholarly publishing and to assist editors, editorial board members, owners of journals and publishers to achieve this.  
[View Code](#)
- Flowcharts**  
Flowcharts are designed to help editors follow COPE's Code of Conduct and implement its advice when faced with cases of suspected misconduct.  
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- Guidelines**  
Access COPE's official guidance, including the Retraction Guidelines.  
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- eLearning**  
COPE's eLearning course is designed to give editors a deeper understanding about publication ethics and practical guidance about how to detect, prevent and handle misconduct.  
[View eLearning](#)

# **Ethical Issues Regarding Informatics Publication**



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**A research team locally derives a dataset of hospital patient parameters useful for predicting hospital length of stay for patients with certain conditions.**

**They publish their results in a major journal.**

**A year later, members of the team learn to their surprise that a former junior member of the team who is now at another institution has published a secondary analysis using the dataset from the first article.**

**Issues/Concerns? Ethical principles? Best practices?**



# **Ethical Issues Regarding Informatics Publication Pragmatics**

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**Research teams, at the outset of their work, should:**

- a) review and comply with COPE principles**
- b) decide who will own / access / protect data**
- c) decide how / when / why to destroy data**
- d) decide who has what publication rights regarding data,  
for how long**
- e) on project initiation, determine who will author paper(s),  
order of authors**
- f) as early as possible, and before project completion, decide who  
manages commercialization rights, if any, and percentage  
contribution of each IP author**

# Ethical Issues: Summary

From Goodman KW et al. Chapter 10 in Shortliffe EH, Cimino JJ (eds).  
*Biomedical Informatics 4th Edition*. Springer: London, 2014. p 329

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**“Students and practitioners of the health sciences, including informatics, share an important obligation to explore the moral underpinnings and ethical challenges related to their research and practice.”**

# Ethical Issues

## Dogmatic Principles

Sixth Edition

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