

## Principles of Human Subjects Protection

There are three basic principles for the treatment of human subjects: autonomy, beneficence, and justice. These approximately correspond to the operational need for

- informed consent of subjects,
- reasonable ratios of benefits to risks, and
- equitable selection procedures and treatment.

Other concerns include:

- privacy/confidentiality concerns
- a plan for dealing with adverse effects
- the need to studies compare only treatments that are genuinely believed to be equally likely to have success
- Vulnerable populations must receive special attention to assure the appropriate application of these principles.

All human subjects research must be approved by the Institutional Review Board (IRB).

From [http://www.research.umn.edu/ethics/curriculum/human\\_subjects.html](http://www.research.umn.edu/ethics/curriculum/human_subjects.html).

**Case Study** At a residential treatment center for persons with mental retardation, lithium is frequently used to treat aggressive and self-injurious adolescents. However, this use of the drug has never been systematically tested on this population. Investigators propose a placebo-control experimental design but some staff members believe this is depriving patients of an established treatment.

Consider how the given principles might be applied in this case.

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## Animal Research

There are three guidelines for animal research:

- reduction in the numbers of animals used,
- refinement of techniques and procedures to reduce pain and distress, and
- replacement of conscious living higher animals with insentient material.

All animal research must be approved by the Institutional Animal Care and Use Committee (IACUC).

From “On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition”, by National Academy of Sciences.

**Case Study:** A researcher comes to you with two competing designs to test two pain relief medications in dogs. Dogs are given the medication and then poked with a electrical simulation. In one design, each dog gets both medications and is tested twice. In the other design, each dog only gets one medication and so is test only once. What principles come into play?

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## Openness and Confidentiality

Why should we protect confidential data? When is this appropriate?

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Why should we be open with data? When is this appropriate?

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In July 2004, the Census Bureau released correspondence and other materials indicating that the Office of Customs and Border Protection, which is part of the Department of Homeland Security, had made two requests for data about the Arab community in 2002 and 2003. The Census Bureau provided two extracts, which are data extracted from the public files, and data which are available on the Census Bureau's website in the American FactFinder. These extracts indicated the number of persons of Arab ancestry living in places of 10,000 people or more and by ZIP-code tabulation area (geographic areas closely associated with Postal Zip Codes).

How do these issues of openness and confidentiality come into play here?

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From "Ethics, Confidentiality, and Data Dissemination," Hermann Habermann, Deputy Director, US Census Bureau, <http://unstats.un.org/unsd/ethics.pdf>

Brainstorm some ideas for how to both release general information and maintain individual confidentiality.

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Name: \_\_\_\_\_

What principle for animal/human research was new or most interesting to you?  
Describe what you learned about it.

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