Responsible Conduct of Research

Kim Siegmund

Responsible Conduct of Research

- The National Institutes of Health funds our research

- They require all grant recipients to receive training in the responsible conduct of research

- That includes LA's BeST@USC!

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Goals

- Develop, foster, and maintain a culture of integrity in science;

- discourage and prevent unethical conduct;

- empower researchers to hold themselves and others accountable to high ethical standards;

- increase knowledge of, and sensitivity to, ethical issues surrounding the conduct of research by researchers with diverse backgrounds;

- improve the ability to make responsible choices when faced with ethical dilemmas involving research…

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https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

Core Areas

Data acquisition, Management, Sharing and Ownership

Mentor/Trainee Responsibilities, Collaborative Science, Conflicts of Interest

Publication Practices, Authorship, Peer Review

Human Subjects Research

The "Common Rule", a federal policy protecting human subjects defines:

- **Research** is a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge

- A **human subject** is a living individual **about whom** an investigator (whether professional or student) conducting research obtains:

  (1) Data through intervention or interaction with the individual; or
  (2) identifiable private information

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Most cited ethical lapses

- **Nazi Doctor Experiments** during WWII

- **Tuskegee Syphilis Study** by the U.S. Public Health Service in 1930 on black men in Alabama

Public outrage eventually ended the study and led to the Belmont report (1978) and subsequent federal human rights protections.

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Human Subject Protections

Nuremberg Code: "the voluntary consent of the human subject is absolutely essential"

Declaration of Helsinki: "Risks should not exceed benefits"

Belmont Report
1. Respect for persons
2. Beneficence
3. Justice

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Social Responsibility

New scientific knowledge can stimulate public interest, and public concern

Scientists who make discoveries must accept responsibility to help society use the discovery appropriately.

Is it ever ethical to censor scientific research?

Case Study on Parkinson's Disease

- Study of 1,000 patients and 1,000 controls

- Having a history of head trauma (p=0.005), high blood pressure (p= 0.01), or exposure to agricultural pesticides (p=0.04) is related to 25-60% higher risk of PD.

- Surprisingly, current cigarette smokers were at 40% lower risk of PD as compared to non-smokers (p=0.02).

- And non-smokers exposed to second-hand smoke had 12% lower PD risk as compared to non-smokers without exposure to second-hand smoke, but this association was not formally statistically significant (p=0.07).

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SCIENCE

FDA approves much-debated Alzheimer's drug panned by experts

link to article

By AMINA KHAN, KAREN KAPLAN

JUNE 7, 2021 **UPDATED** 8:07 PM PT

commentary

WASHINGTON — In a decision based as much on hope as on science, the Food and Drug Administration on Monday approved a drug designed to treat Alzheimer's disease despite scant evidence that it improved the symptoms of patients who tested it.

The lack of a clear clinical benefit after two late-stage clinical trials prompted an FDA advisory panel to urge that the drug, called aducanumab, be rejected. The agency acknowledged the uncertainties about the medication but said its approval was justified by the seriousness of the disease and the dearth of options for treating it.

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Reproducible Research

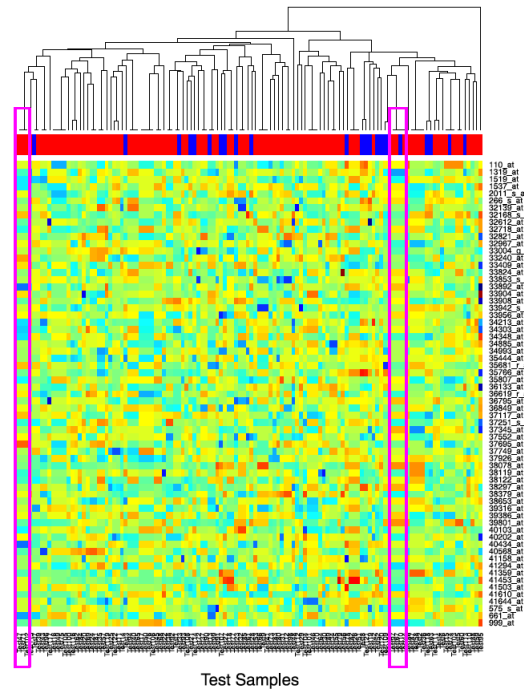| | Reproducible Research | Given the same data, the analysis can be reproduced to give identical results |

| | Steps to record | 1. Data manipulation
2. Analysis decisions |

Forensic Bioinformatics

Test Samples

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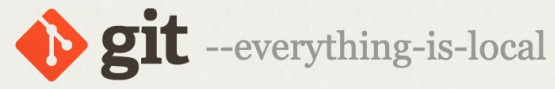# Making Data Analysis Reproducible

Software requirements:

1. Open-source

2. Easily shared

3. Organized (version control)

Open-source environment and tools for statistical computing and graphics

GitHub

Software version control

Open-source Software
Development Platform

Create GitHub account

Clone class repository:

https://github.com/USCbiostats/LAsBEST

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