Responsible Conduct of Research

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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!

[Funding by the National Heart, Lung, and Blood Institute (NHLBI)
R25 HL161788]

We also thank the Keck School of Medicine of USC and the
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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…

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

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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.

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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The Declaration of Helsinki, 50 years later

JAMA (2013) Paul Nbedele, PhD.
Medical Research Council of Zimbabwe, Causeway, Harare, Zimbabwe

- Improved research oversight → underrepresentation of certain groups
- Research outcomes don't always generalize to underrepresented populations

  → Underrepresented groups become disadvantaged when they do not benefit from recent advances that others experience from the research outcomes

- Helsinki declaration 2013 **revision**: recommends increased access to clinical trials for underrepresented groups for them to benefit from the research
- Now excluded groups (minority, women, children) must be explicitly justified

Pregnant women as subjects

Should pregnant women be allowed to participate in clinical research regardless of the degree of risk to the fetus and offspring?

Ethical Issues Related to the Inclusion of Pregnant Women in Clinical Trials (I)

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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

link to case study

- 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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Los Angeles Times

SCIENCE

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

link to article

commentary

By AMINA KHAN, KAREN KAPLAN

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

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.

Reproducible Research

Reproducible Research

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

Steps to record

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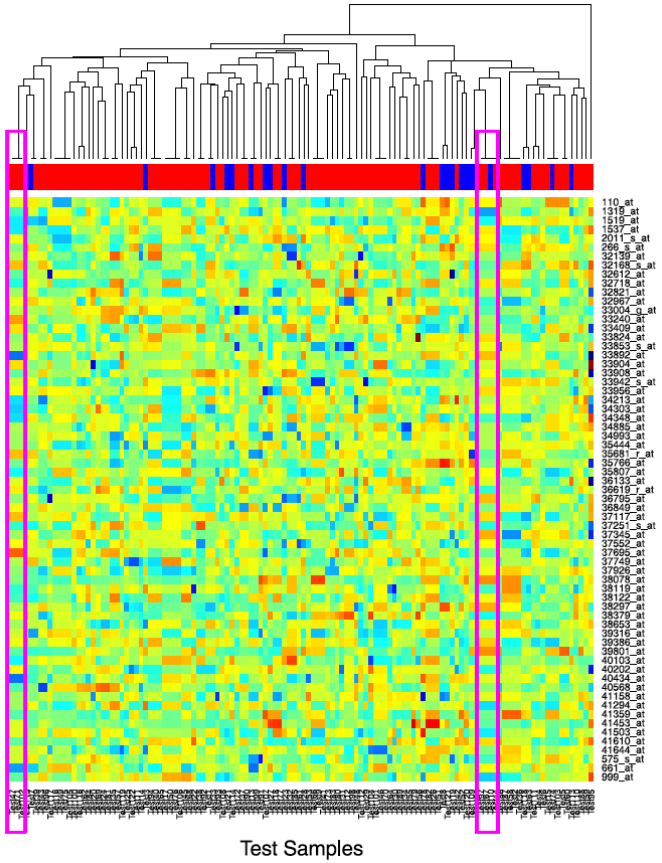
Forensic Bioinformatics



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The Annals of Applied Statistics
2009, Vol. 3, No. 4, 1309–1334

Making Data Analysis Reproducible

Software requirements:

1. Open-source
2. Easily shared
3. Organized (version control)

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Open-source environment and tools for statistical computing and graphics

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Software version control

GitHub

Open-source Software Development Platform

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Children's Health Study

Data use agreement

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