

Ethics and “Omics”

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Office of Research Integrity/DHHS
<http://ori.hhs.gov/education/products/clinicaltools/data.pdf>

What is Scientific Misconduct?

ORI Definition (42 CFR Parts 50 & 93):

- “Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” (also known as FFP)



UAB Definition:

- “...fabrication, falsification, plagiarism, or other practices which seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research



Nine Areas of Responsible Conduct



U.S. Department of Health & Human Services

» www.hhs.gov

Blog



Office of Research Integrity
U.S. Department of Health and Human Services

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RESPONSIBLE CONDUCT OF RESEARCH (RCR)

ORI supports several programs designed to promote education and training in the responsible conduct of research (RCR) that covers the following nine instructional areas:

- Data Acquisition, Management, Sharing and Ownership **a.k.a. “Data Management”**
- Conflict of Interest and Commitment
- Human Subjects
- Animal Welfare
- Research Misconduct
- Publication Practices and Responsible Authorship
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science

Reference: <http://ori.hhs.gov/education/>. Accessed 6/13/11

GENETICS

RN

High-proj

BY ERIKA CHECK

High-thr yielded the past that seem to rew genetics. But a fi being challengec warn of the stati data-intensive st

The latest case Humans and mo copies of most g But in some case the other copy i gene is describe 2010, a team le Christopher G University in Cal lished a study¹ in mouse genes — than previously

Now, research analysis led Dul estimate imprinti

Nature 4

COMPUTATIONAL SCIENCE

Materials To a Data-

Supercomputing power of crystalline materials search for the next best

When the Human Genom in 1990, the goal of seq lion letters of DNA in a 15 years seemed a dauntin advances in sequencing te researchers to finish th today, sequencing a sing almost pedestrian. Now, n ers are hoping that a sim ramp-up will help them task of their own: using c ulate the properties of a ety of solids to identify p breakthroughs for batteric many other applications.

Today's machines aren' late all types of materials. of researchers think steady nology has now made st powerful and available enc the task worth starting. " of computing is really m possible," says Gerbrand materials scientist at the chusetts Institute of Tecl in Cambridge. Richard l a computational material ist at Cornell University,

Science 335

SCIENCE PRACTICE

Networking Knowledge C

Stephen M. Fiore

In Reinventing Disc computing pioneer argues that the Internally change how we in standing of the universe and enthusiastic narrative ideas that could, indeed, r lutionize knowledge crea Nielsen offers a set of fasc ing examples to illustrate rapidly emerging method innovation produce impo discoveries. He goes furth suggest that these will ch our concepts of how sci gets done and what it mea be a scientist. However, t are substantial systemic

Science 336:36.

NEWS&ANALYSIS

U.S. SCIENCE POLICY

Agencies Rally to Tackle Big Data

John Holdren, the president's science adviser, wasn't exaggerating when he said last week that "big data is indeed a big deal." About 1.2 zettabytes (10²¹) of electronic data are generated each year by everything from under-ground physics experiments and telescopes to retail transactions and Twitter posts.

Holdren was kicking off a federal effort to improve the nation's ability to manage, understand, and act upon that data deluge. Its goal is to increase fundamental understanding of the technologies needed to manipulate and mine massive amounts of information; apply that knowledge to other scientific fields; address national goals in health, energy, defense, and education; and train more researchers to work with those technologies. The impetus for the initiative, to be managed by the Office of Science and Technology Policy (OSTP) that Holdren directs, comes from a December 2010 report by a presidential task force that, Holdren said, concluded the nation was "underinvesting" in the field.

Computer scientists welcome the spotlight that the White House is shining on big-data research. "The announcements demonstrate a recognition by a broad range of federal agencies—Defense, Energy, NIH, and many more—that further advances in "big data" management and analysis are critical to achieving their missions," says Edward Lazowska of the University of Washington, Seattle, who co-chaired the 2010 report on the nation's digital future. "The White House [OSTP] deserves enormous credit for herding the cats to create a top national initia

Science 336:22. April 6, 2012

a decade within DOE's Advanced Scientific Computing Research program. The Defense Department says it plans to spend \$60 million this year on new awards for research on big data, but officials couldn't say if that amount is more than what it has spent in previous years.

Even small investments are welcome. The U.S. Geological Survey points to a tiny (annual budget of \$650,000) synthesis and analysis center in Fort Collins, Colorado, that brings groups of scientists together for a week to crunch large data sets. The National Institutes of Health (NIH) is counting a

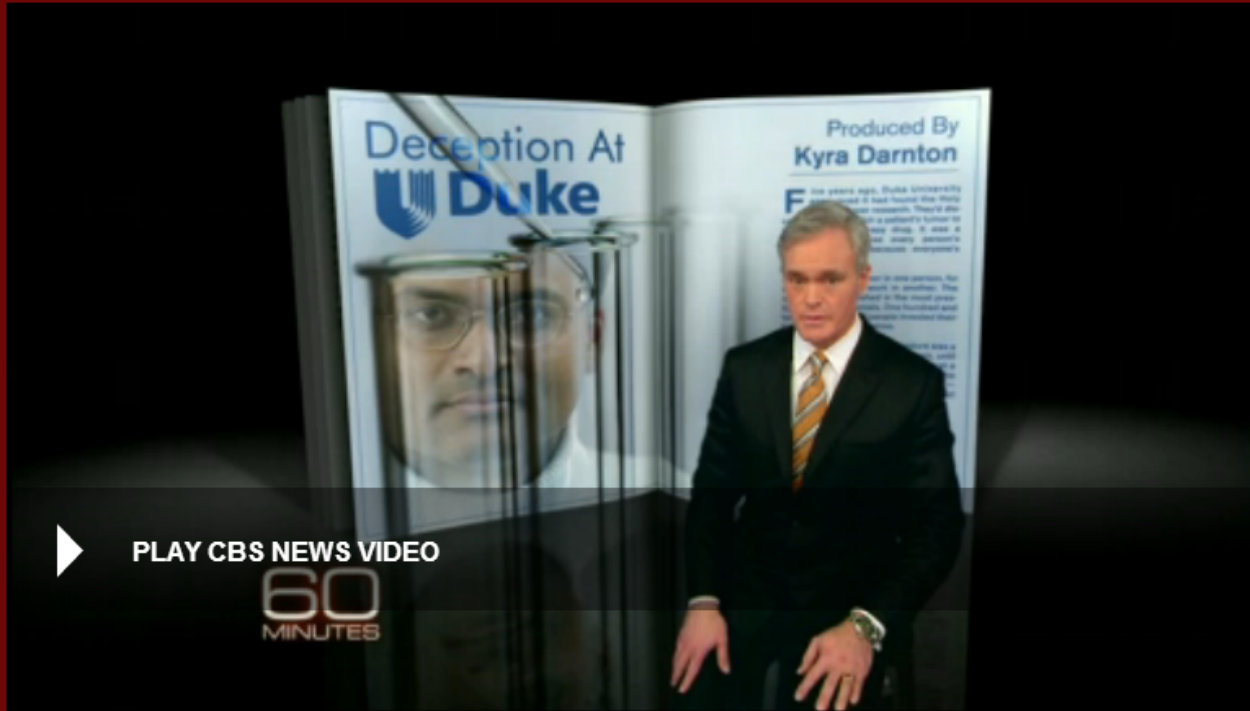


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60 MINUTES

EPISODES ▾ OVERTIME ▾ TOPICS ▾



PLAY CBS NEWS VIDEO

60
MINUTES

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AUTO ON SHARE CC

A very public case of data falsification and fabrication

<http://www.cbsnews.com/news/deception-at-duke-fraud-in-cancer-care/>. Accessed 5/14/2014.

DECEPTION AT DUKE: FRAUD IN CANCER CARE?

Were some cancer patients at Duke University given experimental treatments based on fabricated data? Scott Pelley reports.

What is Data?

True or False?

In research, only the information and observations that are made as part of the inquiry are considered data.



What is Data?

T/F?: In research, only the information and observations that are made as part of the inquiry are considered data

False!

Data also includes anything related to understanding the data generated by the project

- Samples collected, survey instruments, cell lines, informed consent documents, procedures, products generated, online content.**

Key Concepts of Data Management

- **Data Ownership**
 - Who owns it?
- **Data Collection**
 - Systemic and reliable
- **Data Storage**
 - What should be retained?
- **Data Protection**
 - Safe storage
 - Prevent tampering
- **Data Retention**
 - How long to keep original data?
- **Data Analysis**
 - Rubric for analysis and interpretation
- **Data Sharing**
 - Dissemination plan
- **Data Reporting**
 - Publication and authorship

Adapted from Steneck, N.H. (2007), Introduction to the responsible conduct of research. <http://ori.dhhs.gov/documents/rcrintro.pdf>. Accessed 6/11/11.

Who “Owns” Your Data?

- **The Principal Investigator?**
- **All members of the research team?**
- **The research subjects?**
- **Your home institution?**
- **The sponsor?**
 - **Grants (“assistance funding”)**
 - **Contracts (“procurement funding”)**



Data Collection

What is the role of Data Collection in completing successful research?

1. Ensuring the validity of data is key
2. Ensuring reliability is key
3. Ensuring both validity reliability is key
4. It doesn't matter.



Data Collection – Upholds the Integrity of the Project

- **Details the rationale for the project and its design**
- **Yields reliable and valid results**
- **Allow accurate analysis and assessment**
- **Allows others to replicate the process and evaluate the results**
- **Provides justification to sponsors for costs and expenditures.**



Planning for Data Collection

A well thought out plan will help assure that all members of the project team collect data consistently.

Questions that should be addressed:

- **Purpose of the research project**
- **Rationale for methodologies chosen**
- **Implementation of methodologies**
- **What worked and failed to work**
- **How data will be collected or analyzed**
- **How to report unexpected findings or errors**
- **Implications of the research and future directions.**

Data Storage and Retention

- **What data to retain?**
 - **Everything necessary to reconstruct the findings.**
- **How long to retain it?**
 - **3 years beyond the end of funding for the project.**
 - **Longer if there are patents to be filed.**
 - **Can establish precedence of the work**

Data Protection

In the following list, which is the most effective way to protect project data?

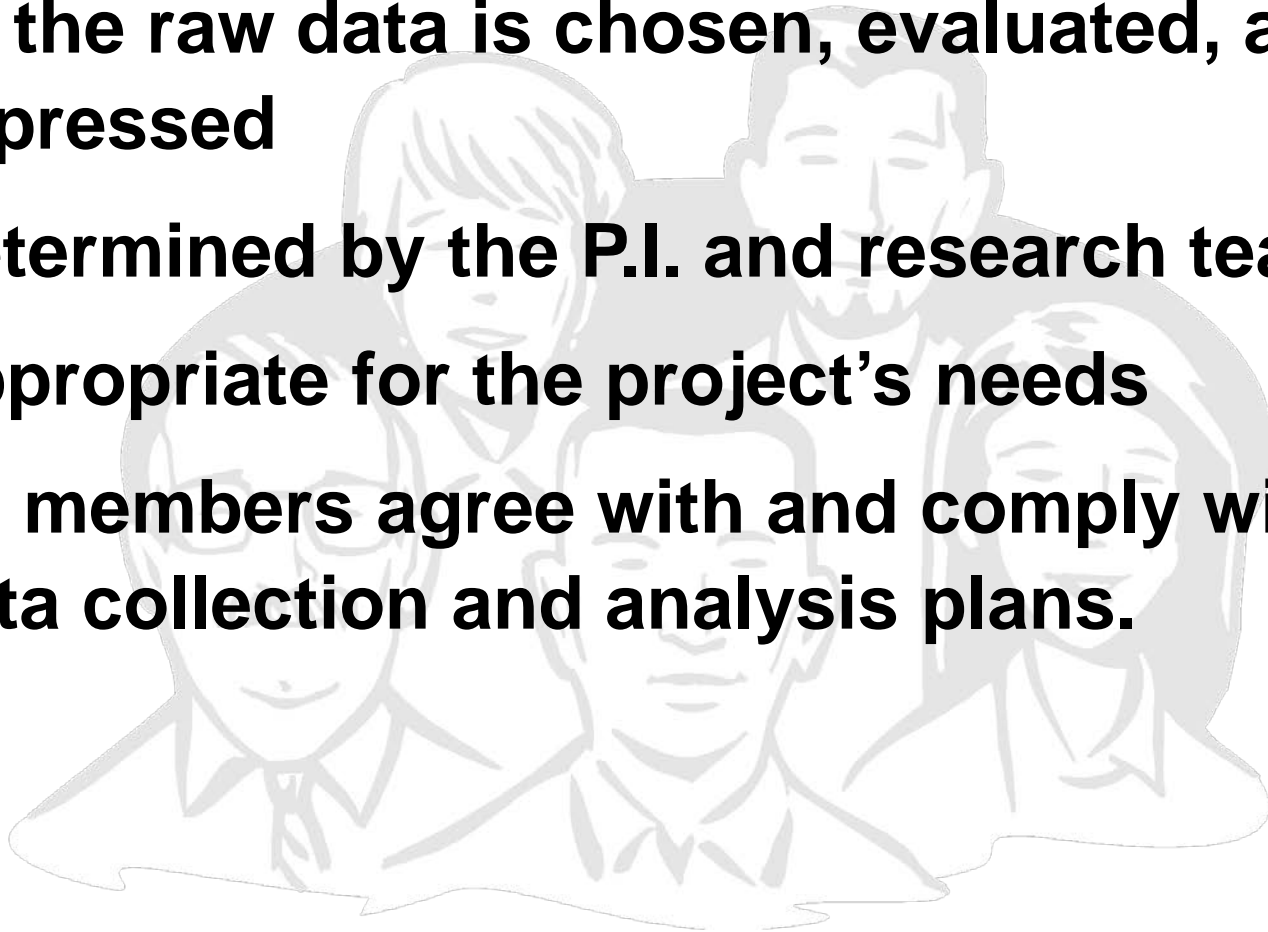
1. Strip identifiers from human subjects data
2. Limit who has access
3. Destroy written data after copying it to an electronic database



Data Analysis

How the raw data is chosen, evaluated, and expressed

- **Determined by the P.I. and research team**
- **Appropriate for the project's needs**
- **All members agree with and comply with the data collection and analysis plans.**



Data Analysis

Questions that the P.I. should consider:

- What are the accepted standards of the field?
- What data should be included?
- Include or exclude outliers?
- Dealing with missing or incomplete data
- Responsible conduct: procedures to identify falsified or fabricated data

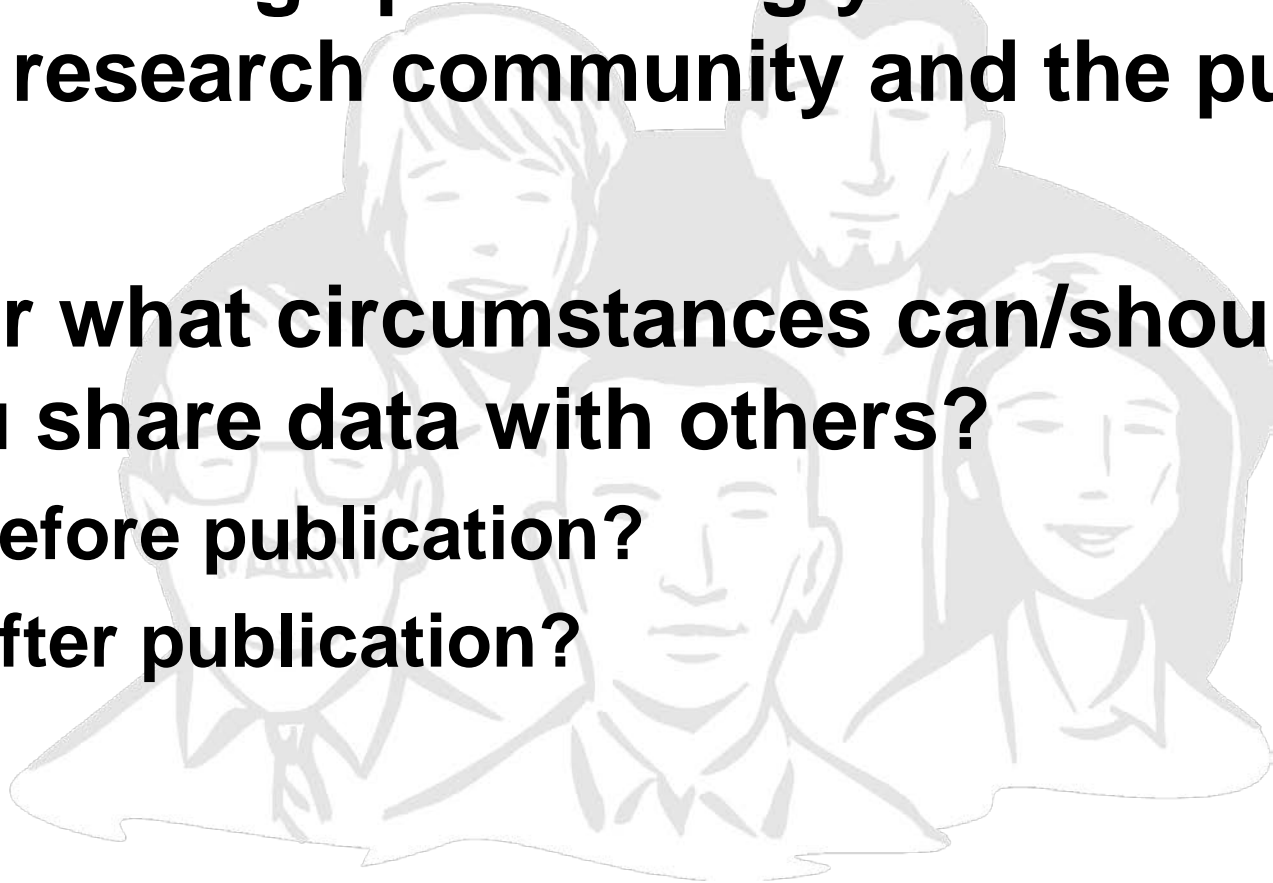
**Communicating expectations to the research team
is critical!**

Data Sharing and Reporting

Data sharing –presenting your results to the research community and the public

Under what circumstances can/should you share data with others?

- Before publication?**
- After publication?**



Who is Responsible for Data Management?

The Principal Investigator has overall responsibility to develop and oversee the data management plan.

All Members of the Research Team:

- Project director
- Students
- Postdoctoral fellows
- Clinical fellows
- Research staff
- Hospital staff
- Statisticians
- Consultants
- IT support
- Librarians

For More Information

The screenshot displays the ORI website interface. At the top, the U.S. Department of Health & Human Services logo and the URL www.hhs.gov are visible. The ORI logo, 'THE OFFICE OF RESEARCH INTEGRITY', is prominently featured. A navigation menu includes links for Home, News & Events, Research Misconduct, RCR Resources, Programs, Policies & Regulations, and Assurance Program. A search bar and 'Contact Us | About ORI' link are also present. The main content area is titled 'General Resources' and includes a breadcrumb trail: Home >> RCR Resources >> General Resources. Below this, it states 'Page last updated on Mon, 2011-08-22 12:53.' A sidebar on the left lists file formats: Web Module, PDF, Zip, Books, and Related. The main content area lists several resources:

- Laboratory Management Video Vignettes** by the University of California, Davis. Laboratory Management Video Vignettes by the University of California, Davis
- CITI Responsible Conduct of Research Program** by the Collaborative Institutional Training Initiative, University of Miami. CITI Responsible Conduct of Research Program
- A Guide to Research for Undergraduates** by Northeastern University. A Guide to Research for Undergraduates
- Open Seminar in Research Ethics** by the Land Grant University Research Ethics Education Project. Open Seminar in Research Ethics

On the right, a 'Popular Content' section offers filters for 'Today' and 'Most Popular'. It lists several items:

- Speaker Highlight: Marlene Belfort
- ORI Conference Coming in March
- General Resources
- Research Misconduct
- Data Management
- Mentorship
- Human Subject Research
- New ORI Website Launched
- Animal Resources

At the bottom right, there are buttons for 'Misconduct Case Summaries' and 'Newsletter'.

Reference: <http://ori.hhs.gov/general-resources-0>. Accessed 3/7/12

Thank you!



Office of Research Integrity/DHHS
<http://ori.hhs.gov/education/products/clinicaltools/data.pdf>