

Ethics and “Omics”

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

Slide 1

JAE1

needs to acknowledge data storage in the cloud and the risks thereof.

Jeffrey A Engler, 4/30/2014

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



Slide adapted from a slide by Dr. Charles Prince and Mr. Joe Roberson, 2009

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-throughput genomics yielded the past that seem to rewrite genetics. But a field being challenged warn of the static data-intensive st

The latest case Humans and millions of copies of most genes. But in some cases the other copy of a gene is described. In 2010, a team led by Christopher Gerbrandt University in California published a study¹ in mouse genes — more than previously.

Now, research analysis led by Dulce estimate imprint

COMPUTATIONAL SCIENCE

Materials To a Data-

Supercomputing power of crystalline materials search for the next best

When the Human Genome in 1990, the goal of sequencing a billion letters of DNA in a 15 years seemed a daunting task. Advances in sequencing technology today, sequencing a single almost pedestrian. Now, researchers are hoping that a similar ramp-up will help them tackle their own: using supercomputing to calculate the properties of a variety of solids to identify potential breakthroughs for batteries and many other applications.

Today's machines aren't late all types of materials. Researchers think steady technology has now made supercomputing powerful and available enough to start the task worth starting. "The power of computing is really more possible," says Gerbrandt, a materials scientist at the Massachusetts Institute of Technology in Cambridge. Richard Nielsen, a computational materials scientist at Cornell University,

Science 335

Nature 4

SCIENCE PRACTICE

Networking Knowledge C

Stephen M. Fiore

In *Reinventing Discovery*, computing pioneer argues that the Internet will change how we understand the universe and enthusiastic narrative ideas that could, indeed, revolutionize knowledge creation. Nielsen offers a set of fascinating examples to illustrate rapidly emerging methods of innovation produce important discoveries. He goes further to suggest that these will change our concepts of how science gets done and what it means to be a scientist. However, there 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 (10^{21}) of electronic data are generated each year by everything from underground 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 initiative."

Science 336:22. April 6, 2012



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A very public case of data falsification and fabrication

DECEPTION AT DUKE: FRAUD IN CANCER CARE?

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

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

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

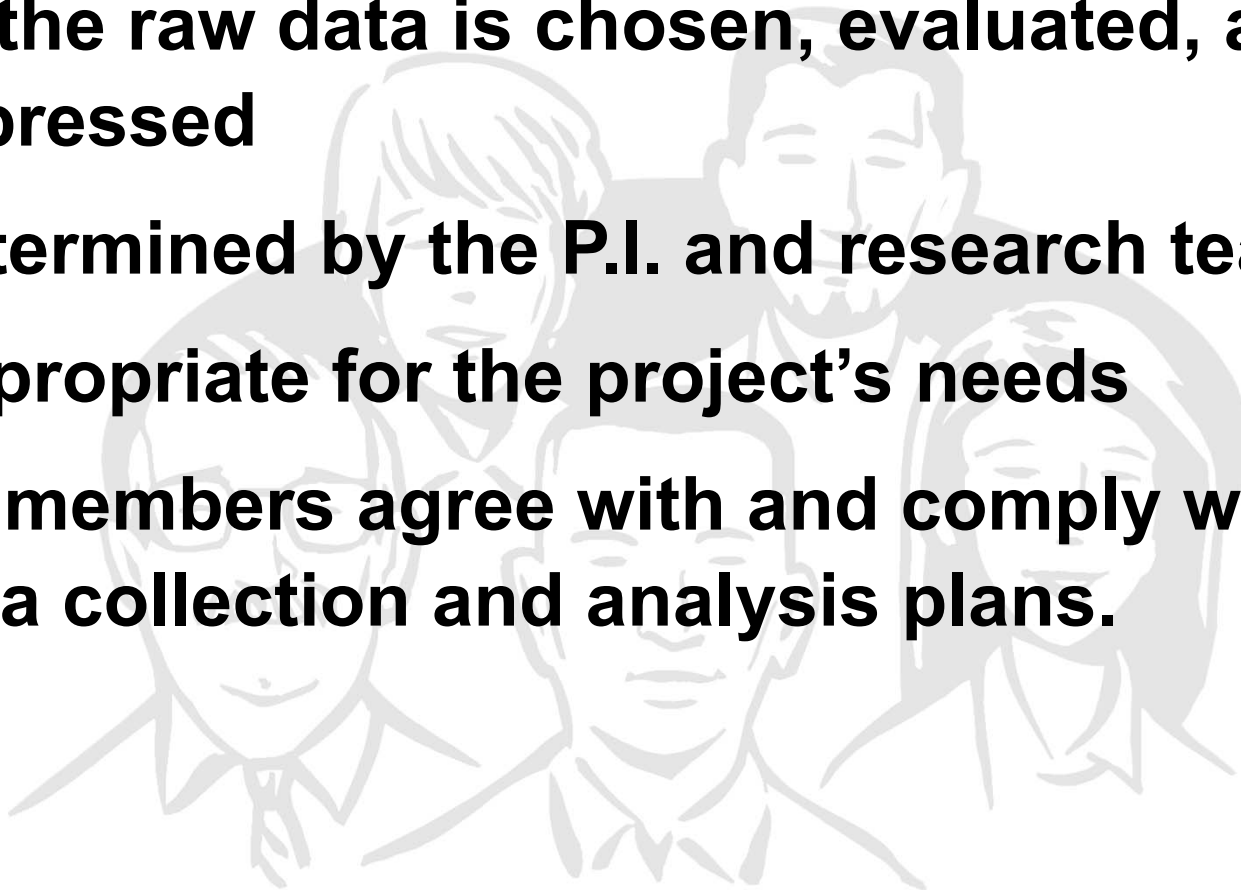
How secure is storing data in the “cloud”?



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

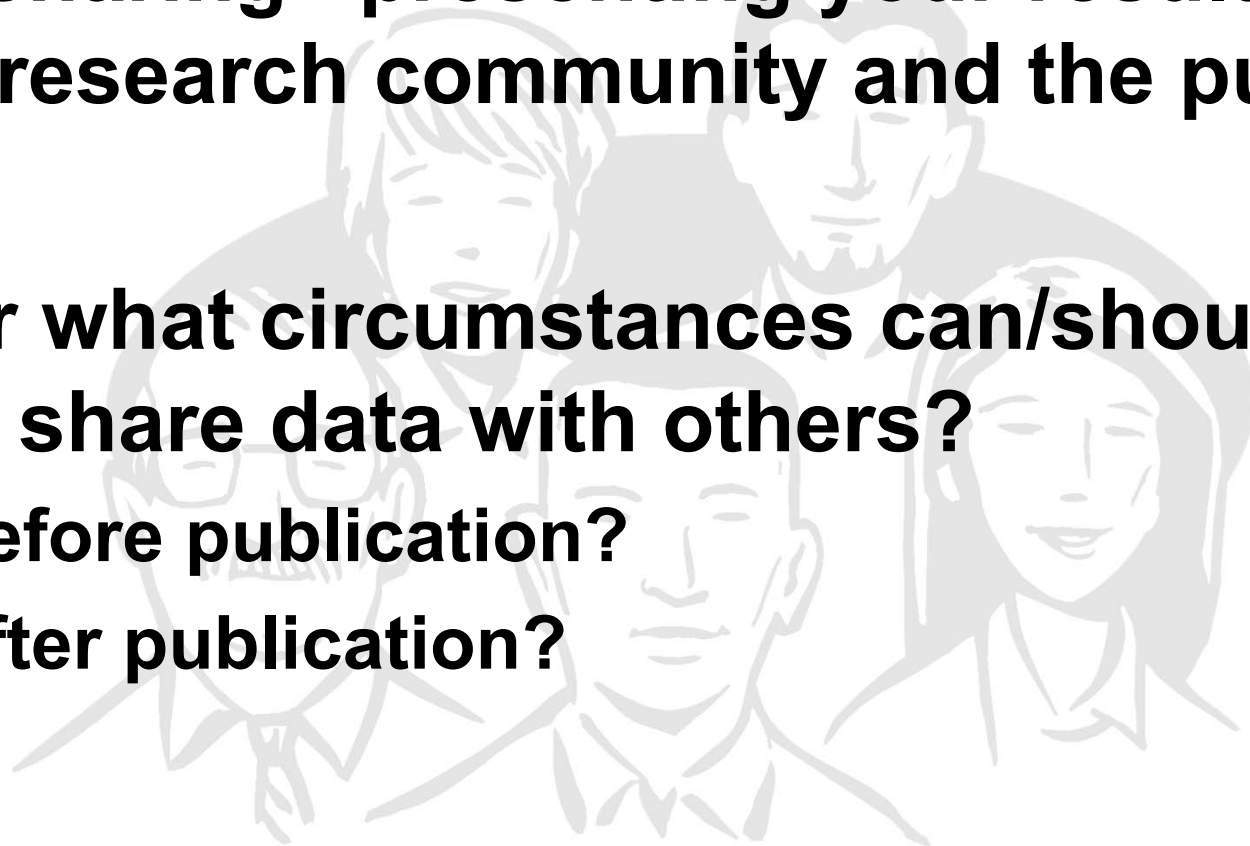
**Communicating expectations to the research team
is critical!**

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 shows the ORI website interface. At the top, there is a blue header with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is the ORI logo and the text 'THE OFFICE OF RESEARCH INTEGRITY'. A navigation menu includes links for Home, News & Events, Research Misconduct, RCR Resources, Programs, Policies & Regulations, and Assurance Program. A search bar is located in the top right corner. The main content area is titled 'General Resources' and includes a breadcrumb trail: Home >> RCR Resources >> General Resources. The page was 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 side, there is a 'Popular Content' section with tabs for 'Today' and 'Most Popular'. The 'Most Popular' tab is selected, showing a list of popular content 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

Below the popular content section, there are two buttons: '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>