

# **Responsible Conduct of Research: Data Acquisition, Ownership, Management, & Sharing**

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RESEARCH

University of South Alabama

# Social Contract of Scientists

*The institution of science involves an implicit social contract between scientists so that each can depend on the trustworthiness of the rest...the entire cognitive system of science is rooted in the moral integrity of aggregates of individual scientists.*

The Common Sense of Science  
Jacob Bronowski

# Ownership and Sharing of Data from Federally Funded Research

- The “Bayh-Dole Act” (The Patent and Trademark Amendment PL96-517) of 1980 governs the ownership and transfer of technology developed under federally supported grants and encourages the commercialization of new technologies.
- Section 36 of the Office of Management and Budget (OMB) Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (Revised November 19, 1993, as further amended September 30, 1999) regulates the use, ownership, and sharing of data and other intellectual property developed under federal grants, including the rights of the public to gain access to research information under the Freedom of Information Act.

# Principles of Data Acquisition

- Data acquisition is the process of obtaining and recording primary experimental information.
- Proper data acquisition and recordkeeping is an essential feature of experimental science and technology. It provides the foundation information on which subsequent data analysis and generalizations are based. Without good data collection and recordkeeping, all subsequent use of the data is tainted by questionable authenticity and accountability. Proper recordkeeping is of vital importance for patentable inventions.

# Data Handling and Recordkeeping

## **Preliminary Experimentation:**

- Develop experimental skills
- Confirm existing concepts
- Provide direct exposure to process or phenomenon
- Help develop an experimental plan or rationale

Data developed from such preliminary experimentation is primarily to help you; the responsibility is primarily to yourself, i.e. don't fool yourself! (Self-deception)

# Data Handling and Recordkeeping

**FORMAL DATA** — documented observations used as basis for public disclosure of conclusions which may have important consequences!

- Further understand or insight about specific question
- Call for change in lifestyle or therapeutic approach!

Grave moral responsibility to have reliable data which support your conclusions

# Data Handling and Recordkeeping

## **Systematic and Designed Observation:**

**Purely observational** — requires no direct intervention

- Prospective study design
- Retrospective analysis of existing information

**Experimentation** — involves some intervention to observe process or phenomenon to

- Allow for more precise measurement
- Gain access to information
- Test responses to a perturbation
- Determine limits, etc.

# Data Handling and Recordkeeping

**EXPERIMENTATION** — the process of performing a deliberate controlled intervention in order to obtain detailed or more complete information

- To confirm or verify conclusions made by others
- To provide new insights leading to new conclusions, further developments to hypothesis, advancement of concepts!

# Data Handling and Recordkeeping

## PRINCIPLES OF OBJECTIVITY:

- Impartial, objective, not biased
- Not motivated by personal gain
- Rigorous test of hypothesis
- Avoid becoming personally attached to a hypothesis or concept
- Willingness to modify concepts or position
- Accept responsibility for validity of report

# Data Handling and Recordkeeping

## **PERSONAL GAIN and HUMAN NATURE:**

- Desire to please one's supervisors or mentors
- Desire for promotion and advancement
- Desire for personal recognition (*Be right!*)
- Improve chances for grant funding
- Facilitate acceptance of data and publication

# What Do Scientists Recognize as Data?

- **Quantitative:** Recorded numbers, graphs, and charts of numerical raw experimental results, and instrument output including photographs and digital images from which quantitative data can be derived.
- **Qualitative:** Notes of any type, some types of instrument output, photos, movies, and digital images.
- **Original samples** in unanalyzed form: e.g., biological specimens.
- **Research tools:** Protocols, computer software.

# Another Way of Classifying Data

- **Raw data:** Information obtained directly from experiments surveys, etc. Includes information in lab notebooks and instrument output; may include information in computers.
- **Processed data:** Graphs, equations, tables, descriptions, summaries, and conclusions derived from raw data but not yet released to the public.
- **Published data:** Information distributed to people beyond those involved in data acquisition and project administration. Theses and dissertations are published when they become available to the public in a library.

# Principles of Data Acquisition

## *Laboratory Notebooks*

- Primary records are those set down contemporaneously in laboratory notebooks (datebooks). Suitable notebooks are bound and have sequentially numbered pages. A basic principle: Notebooks should be kept in a way that will enable someone else to repeat each experiment and obtain the same result.
- For further information: [1] Kanare, H.M., *Writing the Laboratory Notebook*, American Chemical Society, Washington, D.C., 1985. 145 pp. [2] Anon, University of Minnesota.

# Data Handling and Recordkeeping

**CLEAR DOCUMENTATION** is essential for scientific credibility!

- Written evidence of experimental plan (i.e. thesis proposal, grant application)
- Detailed records of specific experiments conducted (i.e. number of dates, raw data, strip recordings, computer printouts, assays, blots, prints, etc.)
- Results from individual experiments that led to conclusions
- Results are not “once in a lifetime” but can be reproduced by you and by others

# Electronic Laboratory Notebooks



Electronic data notebooks should be in some way to assure that the data were actually recorded on a specific date and not changed at some later date. If you collect your data electronically, you must be able to demonstrate that they are valid and have not been changed.

# **Principles of Data Ownership:**

## ***Who Owns Research Done at USA?***

Raw data (includes laboratory notebooks) and processed data are generally owned by USA.

University ownership is subject to conditions established by granting agencies or contracts with sponsors.

Management of research data, according to these conditions, is implicitly delegated to the Principal Investigator and the Administrator of the unit in which he/she works.

# Principles of Data Management

## *Access Restrictions*

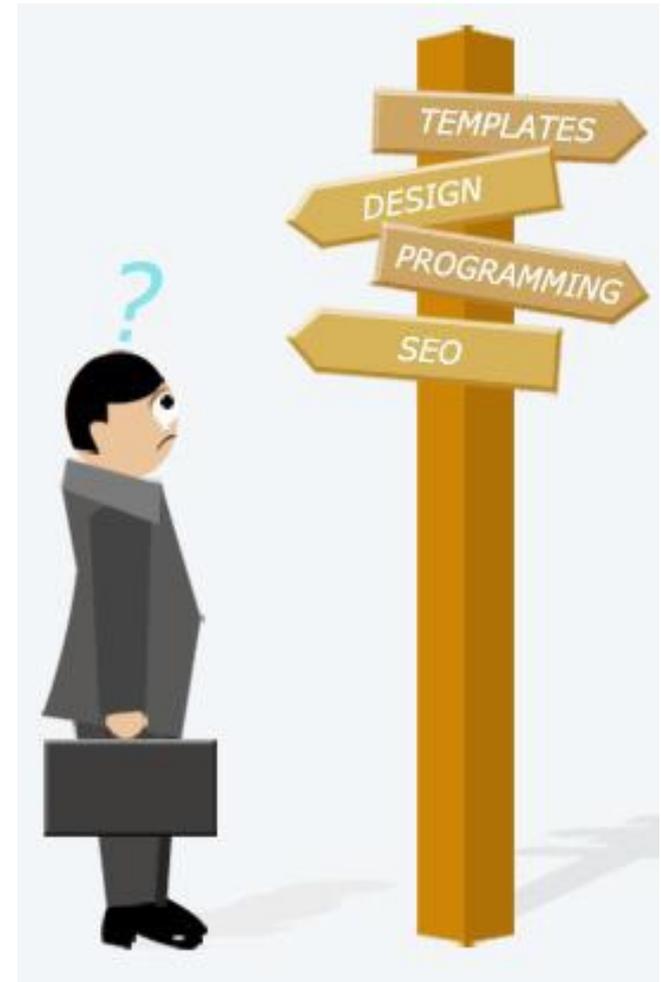
**Access to raw data and processed data may be restricted for the following reasons:**

- Temporary restrictions to allow investigators to complete experimental protocols and to repeat experiments as judged necessary to assure valid results
- Temporary restrictions to preserve intellectual property or copyright claims
- Temporary restrictions due to requirements of granting agencies or contracts with other sponsors
- Permanent restrictions to ensure privacy of human subjects

# Decisions to Release Data and Publish

In practice, the PI usually decides whether and how to release data. Considerations include:

- Is the PI confident that the data are accurate and reliable?
- Are data significant enough to publish?
- Should negative results be published?
- Have obligations to granting agencies and project sponsors been satisfied?



# Principles of Data Management

## *Data Retention and Storage*

**There is no universal standard for how long raw and processed research data should be retained.**

- Some federal agencies, such as NIH, require that data be retained for three years after completion of the project.
- In general, three years should be considered a minimum in academia. Some experts recommend retention of raw and processed data for five years. Many companies, however, have retention cycles.
- When patent or other legal issues are involved, advice of an attorney should be sought before any records are destroyed.

Proper data retention and storage is the responsibility of the PI and the Administrator of the unit in which he/she works.

# Data Handling and Recordkeeping

## SCIENTIFIC ERRORS:

- **Design Level** — experimental design favors desired results
- **Experimental Level** — undesirable or negative results are discarded or disregarded
- **Analysis Level** — statistical treatment is not appropriate or grouping is forced
- **Interpretation Level** — personal bias leads to interpretation not consistent with data
- **Fraud** — deliberate error with intent to deceive

# Data Handling and Recordkeeping

## TYPES OF ERRORS OR BIAS

- **Sampling Error**— due to chance variation in sample selection, usually because of very small sample size
- **Selection Bias** — distortion resulting from manner in which subjects were selected
- **Information Bias** — distortion due to measurement error or misclassification of subjects
- **Confounding Error** — influence of uncontrolled other variables that are linked with studied independent and dependent variables

# Data Handling and Recordkeeping

## FRAUD

There are many different reasons why erroneous data may result or incorrect interpretations may be made. Mistakes of this nature can be costly and may have serious consequences...but they are **NOT FRAUD**.

### **Fraud involves the deliberate intent to deceive**

- Saying you ran experiments that you did not
- Saying you ran more experiments than you actually did
- Changing the data to fit your bias
- Intentional misinterpretation of data

# Human Subjects

Special data-management practices are necessary for research projects involving human subjects. The most common types of projects involving human subjects are:

- Medical research that may involve personal medical information, including DNA information about individuals
- Psychological testing and interviews
- Opinion surveys, including questionnaires and interviews

Each discipline has well-established protocols for protecting the types of information it handles. Knowledge of these protocols is essential for investigators in a particular discipline. In general, all records should be kept confidential, and written records should be carefully secured. Failure to adhere to these protocols could result in serious harm or embarrassment to not only the subjects but also to the investigators. In extreme cases, it could subject the investigators and USA to legal action.

# Industrial Contracts

Industrial sponsors of academic research often want to have raw processed data secured at the University. They have legitimate reasons for wanting security, since premature distribution of the information could help competitors and could jeopardize patent rights.

## Industrial Contracts (continued)

While legitimate, the sponsors' desire for information security does not harmonize well with normal practice in many university laboratories. Universities generally operate in an open way, including:

- information flowing informally and in seminars among investigators working on different projects
- shared work spaces, instruments, computers, and networks
- absence of strict practices for securing raw and processed data within laboratories (except where human subjects are involved)
- relatively open reporting to USA Administration

## Industrial Contracts (continued)

These differences are best addressed when the initial agreement is formulated between the sponsor and the USA Office of Research Administration. Compromises may be necessary from both sides. Once an agreement is reached, all University personnel involved in a project should be made aware of the contract provisions. The Principal Investigator and Administration should make a good-faith effort to carry out the agreed practices.

# Principles of Data Sharing Overview



- Academic tradition requires publication of all significant research results. Free exchange of ideas and information within the institution is also traditional, for example, in student seminars on research in progress.
- It is a challenge for investigators to harmonize these traditions of openness with the requirements for protecting ownership rights to intellectual property, described previously. A degree of compromise is inevitable.

# Principles of Data Sharing

## *Government Funding*

The academic tradition of openness is supported by federal funding agencies, but with qualifications. An example is the NSF policy statement on *Sharing of Findings, Data, and Other Research Products*

[http://www.nsf.gov/pubs/gpg/nsf04\\_23/6.jsp](http://www.nsf.gov/pubs/gpg/nsf04_23/6.jsp)

# Principles of Data Sharing

## *Government Funding (continued)*

- “NSF expects significant findings from the research and education activities it supports to be promptly submitted for publication, with authorship that accurately reflects the contributions of those involved. It expects investigators to share with other researchers, at no more than incremental cost and within a reasonable time, the data, samples, physical collections, and other supporting materials created or gathered in the course of the work. It also encourages awardees to share software and inventions or otherwise act to make the innovations they embody widely useful and usable.”
- “Adjustments and, where essential, exceptions may be allowed to safeguard the rights of individuals and subjects, the validity of results, or the integrity of collections or to accommodate legitimate interests of investigators.”

# Principles of Data Sharing

## *Authorship and Inventorship*

Determining authorship and inventorship are often sensitive issues, and they have led to many heated controversies. The NSF says that papers should be published with “authorship that accurately reflects the contributions of those involved.”

—A good guideline, but who decides?



# Trainees and Research Data

- Trainees cannot take original copies of data when they leave the Institution without written permission of the Chair or Dean
- Trainees may be allowed to take duplicate copies of data with permission from the Principal Investigator
  - Should be arranged in advance
  - Helpful if agreement is in writing

# Disputes about Data Ownership

- Should be settled at the lowest possible level (primary parties involved with data)
- Next level of arbitration is Chair and/or Dean
- If necessary, Vice President for Research can be asked to review the issues and render a recommendation for resolution

# Freedom of Information Act (FOIA)

- If you receive a FOIA request, notify the University Research Compliance Office. Do not respond until advised to do so.
- Federally funded projects are subject to the FOIA under OMB Circular A-110, Section 36. Although it may be necessary to provide some data to the requestor, other data may be exempt from disclosure.
- The rules are complex and change from time to time, and it is impractical for everyone to become an expert in these rules. Therefore, all USA personnel who receive an FOIA request should promptly notify the Research Compliance Office and defer any action until advise from that office is received.