

# SCIENTIFIC RECORD KEEPING

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#### What does "Data Management" involve?

- 1) Physical record keeping
  - lab notebook
  - instrument printouts
  - images
  - computer analysis
  - e-mail
  - lab meeting discussion
  - probes and cells
- 2) Analysis of primary data
  - data selection
  - statistical analysis
  - calculations
  - normalization

- 3) Presentation of results
  - graphs
  - tables
  - pictures
  - Figures
- 4) Publication
  - posters
  - seminars
  - manuscripts
  - funding requests













#### Why is data management important?

- Mandated by funding agency
- Maintain focus on experimental objective
- Document observations
- Troubleshooting
- Organization of thoughts
- May analyze data differently in the future
- Communication with mentor



## TYPES OF LAB NOTEBOOKS

General notebook: Experiment description, data, interpretation, conclusions

Procedure or reagent notebook

Computerized records

Summary of findings, figures for papers



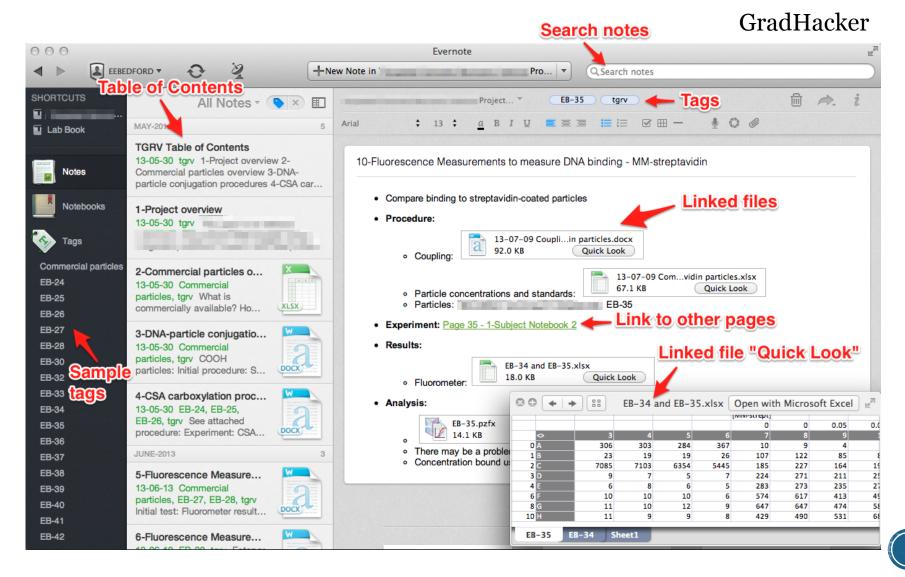
#### LABORATORY NOTEBOOKS

- Bound with serially numbered pages
- Date all records
- Use permanent ink
- Prepare table of contents
- Include the exact data, e.g., photographs, readings, negatives, autoradiograms, printouts, etc.





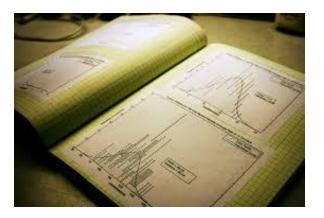
#### E-NOTEBOOK





#### DATA IN LABORATORY NOTEBOOKS

- Include all original data
- Paste all data materials (photographs, negatives and similar)
- Insert all other materials (CD, DVD, readings) in plastic sleeves
- Store the oversized materials and magnetic media properly with coding scheme included in the lab book
- Bindings must be sewn or glued
  - Plastic comb, wire spiral, or ring binders are unacceptable
- Data books may be inventoried
  - Master data book log
  - This policy applies in industry





### POLICIES IN INDUSTRY

- Only bound laboratory notebooks are acceptable
- Entries must be countersigned weekly or more often
- The rules are firmer as the notebooks may be used as evidence for patent protection





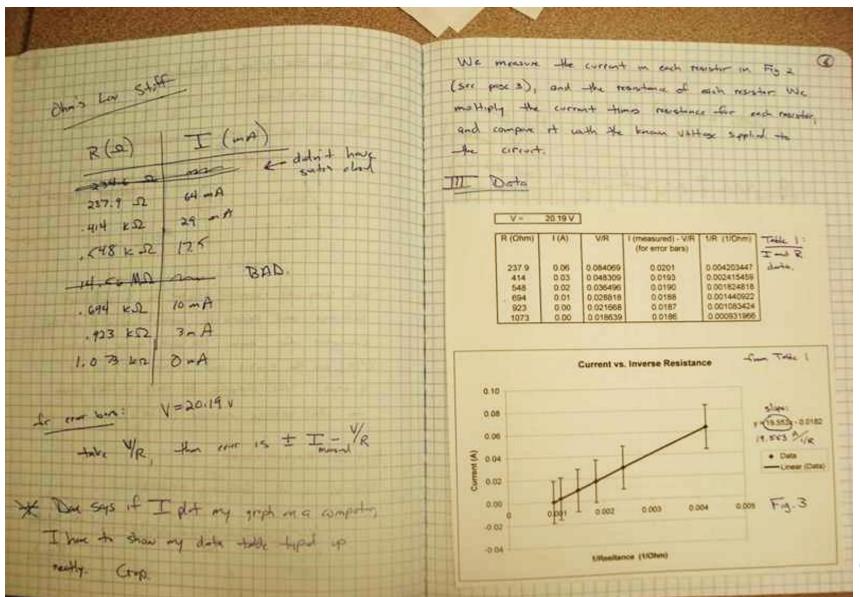


#### ELECTRONIC RECORD KEEPING

- ELN Electronic Laboratory Notebook
  - Database software
  - Generic electronic notebooks
  - Scientific electronic notebooks
- CENSA Collaborative Electronic Notebook Systems Association
- Access
- Excel



#### NOTEBOOK





## **NOTEBOOK**

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	(3. Wipe of that does however,	Questions I mass of the ice on s conclensation on to where the ice is the conclensation or in't leave residue as the amount isn't and histogram, a con	he cutside of the melting.  What is a cleaning impleaded by the andersolion added by the after the m	ment amous.
Team L 2 3 4 5 6 7 8	Des Trital  12.12 12.70 11.87 13.85 11.86 12.15 12.98 13.98	aged or only slight  Observations:	Change in Mass  Changes.  Changes.	Valin

# SAMPLE FORMAT FOR EXPERIMENT DESCRIPTION

Title of experiment

Objective, purpose

Rationale for doing experiment

Procedures and reagents

Experimental design and performance

Details of samples, set-up, what you did

Results: primary data, calculations, graphs Interpretation, conclusions, next step

## MAKING CORRECTIONS TO LAB NOTES

Do not erase or use whiteout

Draw a line through what is being changed

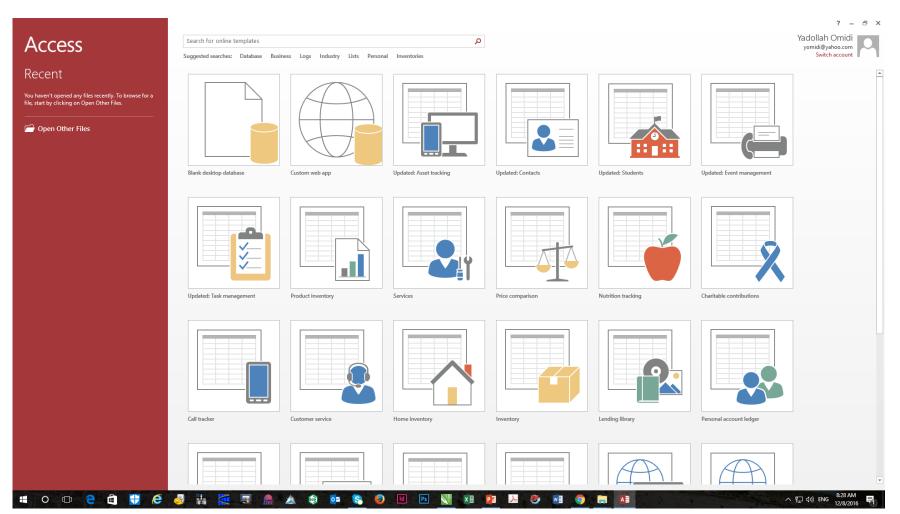
Write above or in the margin; date & initial it

Use a different color ink

Computer record; add a blank line, put in the correction with a date beside it



## ACCESS





### **ACCESS**

Navigate Up Access Serve	er			
<b>★</b> Tasks	List Datasheet By Stat	us		
<b>★</b> Employees	Filter the list	+ (1)	(	
★ Projects	(New)	Project Name		
★ Customers	(··/	Priority	2 - Medium	
		Start Date		
		Changed Date	3/20/2012 4:40:09 PM	
		Active		
		Owner		
		Customer	$\oplus$	
		Tasks		
		Task Title	Priority 5	
		There are no match	There are no matching items.	

#### Project management (SharePoint web app)

Provided by: Microsoft Corporation

Manage projects by breaking work items into tasks, associating them with customers, and assigning them to employees. Like all Access 2013 apps, the Asset tracking template requires Sharepoint so you can share content with others. Customize by adding more tables, new views of table data, or adding logic for your particular needs.

Download size: 17 KB

Should I create an Access 2013 app or an Access desktop database?

Create your app, then use it and share it on the web.

App Name

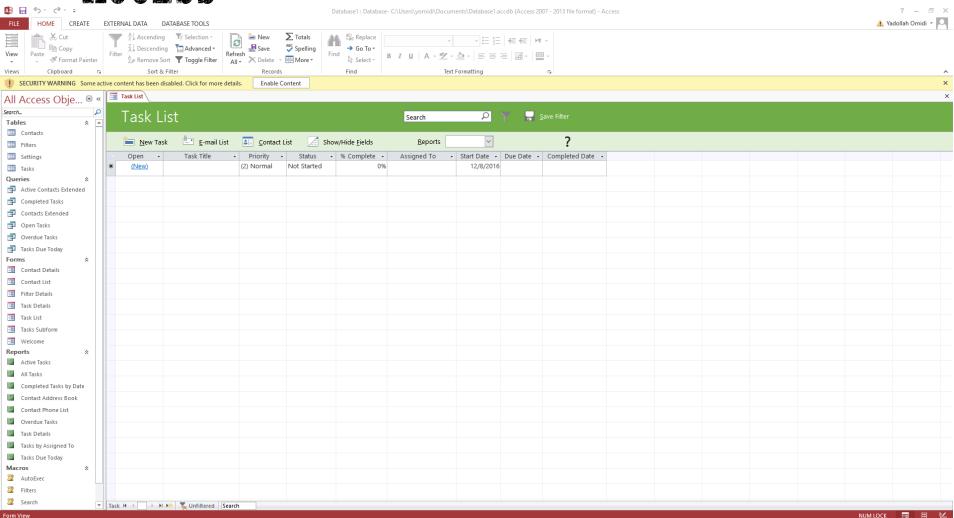
My New App
Web Location

Get help finding your web location





#### ACCESS





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## CONCERNS ABOUT COMPUTER RECORDS

Difficulty inputting some primary data
Scanners are improving; some data
difficult

Ease of manipulation; temptation to alter data

Loss of data - need to backup

Constantly changing computer systems

Computers; operating systems

Hacking or duplication (for sensitive information)



#### HOW LONG TO KEEP NOTEBOOKS?

#### Provenance

- NIH policy mandates 3 years after the end of the project (grant funding period)
- FDA policy mandates 10 years after use
- Patent policy mandates 23 years after issue of the patent
- All data collected as part of funded project are owned by the grantee institution
- Data books of all investigators (PI, postdocs, grad students, technicians) are the property of the institution

- https://www.princeton.edu/ main/news/archive/S18/65/ 99O25/index.xml
- http://mitadmissions.org/bl ogs/entry/life as a physics major resear
- http://rrcns.readthedocs.io/ en/latest/provenance track ing.html



#### IMPACT OF FRAUD OR SUSPICION OF FRAUD

- What happens when questions are raised about the validity of work?
- Concerns about relying on data
- Lost time to defend against charges
- Lost time to investigate charges
- Damage to careers, friendships
- Public loses confidence in science





#### KEYS TO RELIABLE RECORD KEEPING

- Provide a table of contents in each book
- Keep all records up to date
- Number experiments in a series in order
- Put primary data in the lab notebook if possible; if not, put in easy to find place
- Make corrections in different color and date





#### ... and researchers agree!

## Rigor or Mortis: Best Practices for Preclinical Research in Neuroscience

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\*Correspondence: osteward@uci.edu (O.S.), rita.balice-gordon@pfizer.com (R.B.-G.) http://dx.doi.org/10.1016/j.neuron.2014.10.042

Numerous recent reports document a lack of reproducibility of preclinical studies, raising concerns about potential lack of rigor. Examples of lack of rigor have been extensively documented and proposals for practices to improve rigor are appearing. Here, we discuss some of the details and implications of previously proposed best practices and consider some new ones, focusing on preclinical studies relevant to human neurological and psychiatric disorders.

Neuron 84: 572-582 (2044)



#### GLP: GOOD LABORATORY PRACTICE

- **GLP** is an FDA regulation.
- **Definition**: GLP embodies a set of principles that provides a framework within which laboratory studies are planned performed, monitored, reported and archived.
- GLP is sometimes confused with the standards of laboratory safety like wearing safety goggles.







#### WHY WAS GLP CREATED?



- In the early 70's FDA became aware of cases of poor laboratory practice all over the United States.
- FDA decided to do an in-depth investigation on 40 toxicology labs.
- They discovered a lot fraudulent activities and a lot of poor lab practices.
- Examples of some of these poor lab practices found were
- Equipment not been calibrated to standard form, therefore giving wrong measurements.
- Incorrect/inaccurate accounts of the actual lab study
- 3. Inadequate test systems





#### FAMOUS EXAMPLE



- One of the labs that went under such an investigation made headline news.
- The name of the Lab was Industrial Bio Test. This was a big lab that ran tests for big companies such as Procter and Gamble.
- It was discovered that mice that they had used to test cosmetics such as lotion and deodorants had developed cancer and died.
- Industrial Bio Test lab threw the dead mice and covered results deeming the products good for human consumption.
- ■Those involved in production, distribution and sales for the lab eventually served jail time.



#### MISSION OF GLP

- Test systems
- Archiving of records and materials.
- Apparatus, material and reagent facilities.
- Quality assurance programs.
- Performance of the study.
- Reporting of study results.
- Standard operating procedures (SOP)
- Personnel and test facility organization



## STANDARD OPERATING PROCEDURES (SOP)

- Written procedures for a laboratories program.
- They define how to carry out protocol-specified activities.
- Most often written in a chronological listing of action steps.
- ■They are written to explain how the procedures are suppose to work
- Routine inspection, cleaning, maintenance, testing and calibration.
- Actions to be taken in response to equipment failure.
- Analytical methods
- Definition of raw data
- ■Keeping records, reporting, storage, mixing, and retrieval of data



## RCPN

## INSTRUMENTATION VALIDATION

- This is a process necessary for any analytical laboratory.
- Data produced by "faulty" instruments may give the appearance of valid data.
- The frequency for calibration, re-validation and testing depends on the instrument and extent of its use in the laboratory.
- Whenever an instrument's performance is outside the "control limits" reports must be discontinued
- Equipment records should include:
  - Name of the equipment and manufacturer
  - Model or type for identification
  - Serial number
  - Date equipment was received in the laboratory
  - Copy of manufacturers operating instruction (s)





#### INSTRUMENT VALIDATION (CONT)

- Equipment records should include:
- ■Name of the equipment and manufacturer
- Model or type for identification
- ■Serial number
- ■Date equipment was received in the laboratory
- Copy of manufacturers operating instruction (s)





#### ANALYST CERTIFICATION

- Some acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established for each analyst.
- Qualification can come from education, experience or additional trainings, but it should be documented
- Sufficient people
- Requirements of certification vary





#### LABORATORY CERTIFICATION

- Normally done by an external agency
- Evaluation is concerned with issues such as
- Adequate space
- ■Ventilation
- Storage
- Hygiene





#### ISO/IEC 17025:2005

- ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling.
- It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
- ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations.
- Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.



### GLP BY WHO





### GLP BY NIH

Guidelines for SCIENTIFIC RECORD KEEPING in the Intramural Research Program at the NIH

National Institutes of Health Office of the Director