Data Management Policies and Issues with Life Science Data

February 21, 2012
Case in Point
What is Data?
Issues and Challenges
“You can’t have everything. Where would you put it all?”

– Steven Wright

Picture: http://www.thegrandwilmington.org
Privacy Concerns
Lack of Knowledge
Lack of Time
Cost Outweigh Benefits

Date: _____________________________

$  Too Much  ________________Dollars
Institutional Barriers
Culture of Sharing?
Best Practices for Management

• Data need to be retained
• Data need to be digital
• Data need to be discoverable
• Data should be free and open
National Institutes of Health

- In effect October 2003
- Required for projects $500k and higher
- Participants rights must be protected (HIPAA)
- Data should be free of identifiers
Older adults' attitudes toward noncompetent subjects participating in Alzheimer's research

Jason Karlawish, MD, abcd, Jonathan Rubright, MS, abf, David Casarett, MD, abgh, Mark Cary, PhD, e Thomas TenHave, PhD, eg and Pamela Sankar, PhD cd

aDepartment of Medicine, University of Pennsylvania, Philadelphia, PA, USA
bDivision of Geriatrics, University of Pennsylvania, Philadelphia, PA, USA
cLeonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, USA
dCenter for Bioethics, University of Pennsylvania, Philadelphia, PA, USA
eCenter for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA, USA
fAlzheimer's Disease Center, University of Pennsylvania, Philadelphia, PA, USA
gInstitute on Aging, University of Pennsylvania, Philadelphia, PA, USA
hCenter for Health Equity Research and Promotion, Philadelphia VA Medical Center, Philadelphia, PA

Corresponding author: Jason Karlawish, MD, Associate Professor of Medicine and Medical Ethics, 3615 Chestnut Street, Philadelphia, PA 19104, Fax: 215-573-8684, Phone: 215-898-8997, Email: Jason.karlawish@uphs.upenn.edu

The publisher's final edited version of this article is available at Am J Psychiatry
See other articles in PMC that cite the published article.

Formats: Abstract | Full Text | PDF (324K)

PubMed articles by these authors
- Karlawish, J.
- Rubright, J.
- Casarett, D.
- Sankar, P.

PubMed related articles
- Toward revising the ethical boundaries of research with noncompetent subjects. [Am J Psychiatry, 2009]
- Impaired decision-making ability in subjects with Alzheimer's disease and willingness to participate [Am J Psychiatry, 2002]
- Alzheimer disease ethics--informed consent and related issues in clinical trials: results of a study [Int Psychogeriatr, 2003]

Recent Activity
- Older adults' attitudes toward noncompetent subjects
Figure 2. The reduction in diversity around amino acid substitutions, controlling for clustering. From: Pervasive Adaptive Protein Evolution Apparent in Diversity Patterns around Amino Acid Substitutions in Drosophila simulans.

A. The density of amino acid (red) and synonymous (black) substitutions as a function of distance from an amino acid substitution. The synonymous density was multiplied by 0.4 (the ratio of the average amino acid to the average synonymous densities) in order to make the comparison of densities more transparent. B. A comparison between the average diversity levels around amino acid (red) and synonymous substitutions (black) as a function of the density of amino acid substitutions in their vicinity. Diversity levels and density of amino acid substitutions were measured in a window size of 1kb centered at the substitution under consideration. C. The numbers of amino acid (red) and synonymous substitutions (black) used to estimate the average diversity levels at each density.


Citation  Full text

Fig. 2. Comparison of the amino acid pairs located in the N-terminal cleavage sites (Pn1-Pn1′) and the C-terminal cleavage sites (Pc1-Pc1′) in the tumor antigen and viral antigen epitopes. From:
ClinicalTrials.gov is a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals. Read more...

Search for Clinical Trials

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has 121,021 trials with locations in 179 countries.

Investigator Instructions

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov. Learn about mandatory registration and results reporting requirements and US Public Law 110-85 (FDAAA).

Background Information

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.
# Studies with Results

**Found 9 studies with search of:** Paliperidone | Studies With Results

Hide studies that are not seeking new volunteers.
Hide studies with unknown recruitment status.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Status</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Terminated</td>
<td><strong>A Positron-Emission-Tomography (PET) Study to Measure the Blockade of Dopamine Receptors (D2) in Specific Areas of the Brain in Relation to the Plasma Concentrations of Paliperidone Extended Release (ER) and Oral Risperidone in Schizophrenia Patients and Healthy Controls</strong></td>
</tr>
<tr>
<td></td>
<td>Has Results</td>
<td>Condition: Schizophrenia; Interventions: Drug: Paliperidone ER; Drug: Oral risperidone; Other: PET Scan</td>
</tr>
<tr>
<td>2</td>
<td>Completed</td>
<td><strong>Evaluation of Effectiveness and Safety of Paliperidone Extended Release in Patients With Schizoaffective Disorder.</strong></td>
</tr>
<tr>
<td></td>
<td>Has Results</td>
<td>Condition: Schizoaffective Disorder; Psychotic Disorder; Interventions: Drug: Paliperidone ER; Drug: Placebo</td>
</tr>
<tr>
<td>3</td>
<td>Completed</td>
<td><strong>Evaluation of Effectiveness and Safety of Flexible-dose Paliperidone Extended Release in Patients With Schizoaffective Disorder.</strong></td>
</tr>
<tr>
<td></td>
<td>Has Results</td>
<td>Condition: Schizoaffective Disorder; Psychotic Disorder; Interventions: Drug: Placebo; Drug: Paliperidone ER</td>
</tr>
<tr>
<td>4</td>
<td>Completed</td>
<td><strong>Effectiveness and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Patients With Schizophrenia</strong></td>
</tr>
<tr>
<td></td>
<td>Has Results</td>
<td>Condition: Schizophrenia; Interventions: Drug: Paliperidone palmitate 25 mg eq.; Drug: Paliperidone palmitate 150 mg eq.; Drug: Placebo; Drug: Paliperidone palmitate 100 mg eq.</td>
</tr>
<tr>
<td>5</td>
<td>Completed</td>
<td><strong>A Double-blind, Placebo-controlled Study of the Safety and Efficacy of Paliperidone Extended Release (ER) in the Treatment of Schizophrenia in</strong></td>
</tr>
</tbody>
</table>
National Science Foundation

- DMP required for all proposals submitted on or after January 18, 2011
- No more than two pages
- Directorate-level guidance
NSF DMP BIO Directives
1. Products of Research

- Type of data
- Retention
- Quality control

Image: http://www.hsc.wvu.edu/wvcohorts/database.html
2. Data Storage & Preservation

- Physical
- Cyber resources
3. Data Formats & Metadata

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        <mets:fileGrp>
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            </mets:file>
        </mets:fileGrp>
    </mets:fileSec>
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        </mets:div>
    </mets:structMap>
</mets:mets>
```
4. Data Dissemination & Sharing
5. Roles and Responsibilities
Further Information

• NIH Data Sharing Policy: http://grants.nih.gov/grants/policy/data_sharing/
• NIH Public Access Policy http://publicaccess.nih.gov/
• NSF Data Sharing and Management http://www.nsf.gov/bfa/dias/policy/dmpfaqs.jsp
• E-Science Portal for New England Librarians http://esciencelibrary.umassmed.edu/
The *Journal of eScience Librarianship* is an open access, peer-reviewed journal that advances the theory and practice of librarianship with a special focus on services related to data-driven research in the physical, biological, and medical sciences.

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**Editorial**

Editorial: Welcome to the Journal of eScience Librarianship  
*Elaine R. Martin*  
doi:10.7191/jeslib.2012.1009

**Letter to the Editor**