REBs & Data Management Plans: Conflict & Coexistence
Susan Babcock and Chuck Humphrey, University of Alberta
CAREB Conference, Vancouver,
Purpose of an ethics review

Intended to maximize the protection of human participants by

● identifying harms and how they will be mitigated and/or communicated;
● ensuring participants understand and agree to how their data will be used for research.

Risk and data are different study to study, thus the ethics and data solutions will vary study to study.
Technology is constantly presenting new ways of conducting research that often raise new challenges to the ethical treatment of human participants in research and research data.
Apple Product Announcement

March 9, 2015
Apple Watch and ...
Apple Product Announcement

ResearchKit
Dr. Stephen Friend
President, Co-founder and Director of Sage Bionetworks speaking at Research Data Alliance on March 10, 2015
The research lifecycle and DMPs

● Our approach looks at mapping ethical issues in research relationships to stages in the research lifecycle involving the stewardship of research data.

● The use of a Data Management Plan is proposed as a tool to identify practices that will support this mapping of relationships to research data management.
Relationship principles and data

- Trust
- Respect
- Transparency
- Privacy
- Consent
- Freedom
Relationship principles and data

- Accuracy
- Truthfulness
- Understanding the research value of the information and its use
Relationship principles and data

- Security
- De-identification
- Governance
- Deposit terms
- Data licences
- Reproducibility
Set of principles and data

- Trust
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Management and stewardship

Managing research data entails the many activities dealing with the operational support of data across the stages of the research lifecycle. This involves the “what” and “how” of research data.

Data Stewardship is about the identity of those responsible for ensuring data management activities are performed to best practice levels and standards across the complete lifecycle. This addresses “who” is responsible for specific data activities.
Research lifecycle
Institutional commitment

- Researchers face an increasing burden in the management of their project-level data due to pressures arising from funders, publishers, disciplinary value changes around sharing, and regulatory frameworks protecting human participants in research.
- Institutions need to coordinate research services and infrastructure better to manage more efficiently these pressures on their research community.
- The place to start is with policy commitments.
University of Alberta Research Policy

1. Research Policy
2. Research Records Stewardship Guidance Procedure
3. Privacy Breach Procedure
4. Research Records Risk Classification Procedure
5. Research Data Management and Preservation Guidelines
“Ensure that principles of stewardship are applied to research records, protecting the integrity of the assets.”

“[DM] plans recognize the stages through which research records will be produced, managed, documented, stored, disseminated and deposited (with either a staging or a preservation repository). Furthermore, these plans will identify the data stewards across a project’s lifecycle.”
Regulatory frameworks

TCPS2 focuses on participant protection, data collection and confidentiality at a personal or project level (researchers and participants).

Privacy legislation addresses the relationship between individuals and institutions and the data held by the former about the latter.
TCPS points to DMPs

Privacy risks arise at all stages of the research lifecycle, including initial collection of information, use and analysis to address research questions, dissemination of findings, storage and retention of information, and disposal of records or devices on which information is stored. Ch 5, TCPS2
How to survive in this environment

- We have a canvas of relationships that set the context for managing research data and for the data stewards who are responsible for the short and long-term care of the data.
- What services, infrastructure, and expertise is needed to help researchers survive in this environment?
Ethics, data, and stewardship

- An administrative tool to help chart a course of action in this environment is a Data Management Plan (DMP).
- We envision a DMP being prepared in advance of an ethics application and the information from the DMP becoming part of the ethics application to address data ethics.
What is a Data Management Plan?

- A Data Management Plan (DMP) is a formal statement summarizing the strategies, services, and practices that a researcher will use to handle her or his data during and after a project.
- The elements of a DMP should reflect categories identifying information descriptive of key factors in a data policy and that are relevant to their implementation in data management practices.
Where do we find DMPs?

- DMPs have been used in some disciplines for many years. Their widespread application has come about through adoption by international funding agencies, such as the NSF and NIH in the U.S. and the Research Councils U.K. (RCUK).
- Use of DMPs also reaches beyond academic research. Science.gc.ca also identifies DMPs in their data sharing policies.
Science.gc.ca: data sharing policies

2.2 Policy Environment

Data sharing policies are most often developed and implemented by research funding agencies and in some cases research projects, and less commonly adopted by universities.[4] While data sharing policies differ across organizations, typical policy elements go beyond asking researchers to retain research data for a given period of time and include more comprehensive requirements to ensure that data are both retained and available to others.

Requirements for data sharing can range from full public open access, to sharing with specific researchers upon request, to access governed through restrictive licenses, depending on the sensitivity of the data, the size and complexity of the data set, their perceived reuse value, and the availability of a repository.

Typical policy elements of data sharing policies are described below:

**Data management plans:** Investigators are required to submit a data management plan with their funding proposals. These plans ensure that researchers consider ahead of time how they will manage and share their data.

**Data quality and standards:** Investigators are required to adhere to international standards that will ensure the data is accessible by others.

**Data documentation:** Data documentation and metadata must accompany data so that the data is understandable by others.

**Method of data sharing:** Investigators are required to either (1) deposit data in relevant subject or institutional repositories; or (2) where there are no repositories hold the data locally, and make it available through a web-based presence; or (3) retain data so that upon request, other researchers can have access to data.

**Timing of data sharing:** Investigators must make data accessible within a given period of time after publication of research results.

**Data retention:** Data should be retained for a minimum number of years (on average 5 years)

**Data preservation:** Investigators must deposit their data in a long-term repository, where available, to ensure the preservation of their data.
Data Management Plans in practice

- Templates are developed from an interpretation of data policies.
  - Central themes in a data policy become the main sections of a DMP template.
  - Within each section, relevant questions are asked and guidance information is provided. A researcher then provides her or his answers to each question.
- A consultation process may be introduced to support the use of DMPs.
1. What plans are in place for someone to assume responsibility for the data if changes happen in the personnel overseeing the project’s data, including the Principal Investigator (PI)?

Succession plans are vital across the whole research lifecycle. Securing successors in the event that a key individual leaves during the project phase ensures that the data will still be cared for. Indicate the succession order for the care for these data in the event that someone leaves. If the PI leaves, responsibility typically falls to a co-investigator or the department or division overseeing this research. Data ownership can be considered in the wider context of data stewardship, that is, ongoing stewardship is still required even though a substantive change occurs in the personnel of a project. This does not necessarily mean, however, a transfer of ownership, but rather a reassignment of responsibility for the data.
Sections for a data stewardship policy

- Data description
- Documentation and metadata
- Backup and storage
- Preservation
- Data sharing and reuse
- Responsibilities and resources
- Ethics and legal compliance
A DMP consultation process

1. Start a new research project
2. Prepare an initial draft of a DMP
3. Meet with a librarian and review the DMP process
4. Incorporate reviewer’s suggestions in the DMP
5. Third-party review of the draft DMP
6. Submit DMP
Welcome.

DMP Builder is provided by the University of Alberta Libraries to help you write data management plans.

Learn about Data Management Plans
Looking to share your research data?
Find out more about the Libraries' research data services

Sign in
If you have an existing account.

Sign up
New to DMP Builder? Sign up today.

Please note that we are currently working on CCID authentication. Please create a new DMP Builder account. You will have the option to link your existing account to your CCID when that feature becomes available.
A template view

<table>
<thead>
<tr>
<th>Plan details</th>
<th>University of Alberta Data Management Questions</th>
<th>Share</th>
<th>Export</th>
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<td>Documentation and Metadata</td>
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<td>Data Sharing and Reuse</td>
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<tr>
<td>Responsibilities and Resources</td>
<td>(4 questions, 0 answered)</td>
<td></td>
<td>+</td>
</tr>
</tbody>
</table>
A question view

What documentation will be needed for the data to be read and interpreted correctly in the future? This includes study-level documentation, data-level description, and any other contextual information required to make the data usable by other researchers.

UAAlberta Guidance

Your documentation may include study-level information about:
- who created/colllected the data
- when it was created
- any relevant study documents
- conditions of use
- contextual details about data collection methods and procedural documentation about how data files are stored, structured, and modified.

A complete description of the data files may include:
- naming and labeling conventions
- explanations of codes and variables
- any information or files required to reproduce derived data.

More information about data documentation is available at the UAlberta Data Archive.
Common problems

- REBs will not allow long-term data retention
  - PIs believe REBs want them to destroy their data
- Researchers are not allowed to consult with an REB
  - Call before you dig!
- REB requests for further information are perceived as attacks
  - PI may need to educate REB
Shared solutions

- DMPs, like an ethics review, should be based on reasonable expectations and solutions.
- Perfect is the enemy of the good.
- Institutions, REBs, and PIs share responsibility for ethical conduct for research involving humans and so share responsibility for management of the data arising from that research.
DMPs and the research lifecycle

- Consider the consequences of ethical issues across the full research lifecycle at the beginning of a project.
  - Don’t get trapped by reaching a stage late in the lifecycle before you address an ethics issue.
- Treat as a process.
- Vested interest in thinking in terms of the full research lifecycle.
DMP tools strengthen ethics applications

- Consider instruments or methods that can be used to help mitigate ethical concerns.
  - Consent
    - Unrestricted approval
    - Staged/stepwise approval
      - Further Ethics approval for secondary use
      - Use of data licences
      - Use of secure data facilities
  - Terms of deposit with a repository
    - Data deposit agreements
DMP tools strengthen ethics applications

- Other instruments or methods that can be used to help mitigate ethical concerns.
  - Data modification
    - de-identification algorithms
    - synthetic data
  - Potential linkage with other data
    - banned
    - terms and conditions of linkage
DMPs supporting ethics applications

- Consider instruments or methods that can be used to help mitigate ethical concerns (cont.)
  - Access control
    - Data licence
    - Ethics approval
    - Data enclave
  - Terms for preservation
    - Conditions from consent
    - Cascading consent responsibilities
Support from institutions

- Establish an integrated institutional response.
  - “It takes a village”: meaningful discussions between researchers and data custodians.
  - Libraries, IST, Field Research, Graduate Studies, Research Service Office, Research Ethics Office

- Diversify the composition of REBs
  - Eg, include a librarian

- Active management of policy
Thanks for your attention

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