OREGON CLINICAL & TRANSLATIONAL *Research Institute*

OHSU

Data Sharing Requirement & Data Use Agreements

DATE: November 17, 21 PRESENTED BY: Deb Golden-Eppelein, Bridget Adams & Robin Champieux

Overview of current practices & requirements to establish DUAs

It is OHSU policy to establish a DUA whenever research or healthcare data about humans is to be shared.

You should request a DUA whether the data is identifiable or de-identified.

IRB approval may be required for research data but is not always needed for healthcare quality improvement/assessment projects.

During the process of getting IRB approval, you may be asked to obtain a DUA.

Terminology

Data Use Agreement (DUA) (aka Data Transfer & Use Agreement (DTUA) or Data Sharing Agreement (DSA) is an agreement that contains the required regulations and other terms.

Health Insurance Portability and Accountability Act of 1996 (HIPAA; see 45 CFR Sect. 164.501 of the Privacy Rule). Covers research or health information data that is identifiable.

Limited Data Set is a limited set of identifiable patient information as defined in the under HIPAA;

A “limited data set” of information may be disclosed to an outside party without a patient’s authorization if certain conditions are met:

- the purpose of the disclosure may only be for research, public health or health care operations.
- the person receiving the information must sign a data use agreement with OHSU.

Facial identifiers have been removed as related to the individual or his or her relatives, employers or household members.

Terminology cont.

- Name
- street addresses (other than town, city, state and zip code);
- telephone numbers;
- fax numbers;
- e-mail addresses;
- Social Security numbers;
- medical records numbers;
- health plan beneficiary numbers;
- account numbers;
- certificate license numbers;
- vehicle identifiers and serial numbers, including license plates;
- device identifiers and serial numbers;
- IP address numbers;
- biomURLs;
- metric identifiers (including finger and voice prints); and
- full face photos (or comparable images).

- **The health information that may remain in the information disclosed includes:**
- dates such as admission, discharge, service, DOB, DOD;
- city, state, five digit or more zip code; and
- ages in years, months or days or hours.

Terminology cont.

- De-identified data is coded and does not contain any of the elements covered under HIPAA.
- DMS is the acronym NIH uses to refer to the Data Management and Sharing policy as revised and effective 1/25/23.
- FERPA is a special set of rules that protect student privacy. These rules. Disclosure can include, rotation timelines, numbers of students in good standing, but no Personally Protected Information (PPI)
- GDRU is a set of regulations governing PHI/PPI of European human subjects under the jurisdiction of the European Union.

Best Practices

- If you are unsure of whether IRB approval is required, get a determination.
- Make sure your protocol and consent forms allow for release of data outside of OHSU
- Decide in advance if you will want to publish or allow publication with or by the colleagues you are sharing with.
- Determine whether it is appropriate to request special disposition instructions once the reason for sharing has ended.
- Determine if there will be a cost for sharing the data.
- Who can access the data? Should you be specific or more general?

Best Practices cont.

- Is the data you will share high risk?
  - Protection of the data is required by law/regulation,
  - OHSU is required to self-report to the government and/or provide notice to the individual if the data is inappropriately accessed, or
  - The loss of confidentiality, integrity, or availability of the data or system could have a significant adverse impact on our mission, safety, finances, or reputation.
  - Will it require a security review?

- If you think so or are not sure, let's talk about it before we do anything.

NIH Policies that Impact You and OHSU

- Current NIH policy on data sharing only requires data management and sharing plans to be submitted when any budget year in a grant application equals or is greater than $500,000 per year.
- Significant changes:
  - Requires data sharing plans be included in all research submitted to NIH with very limited exceptions.
  - In the final Policy, NIH strongly supports the sharing in repositories rather than keeping the data separate with a single researcher, however, NIH does not mandate this.

NIH Policies that Impact You and OHSU

- scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of the award/support period, whichever comes first.
- Scientific Data is: “The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.” We agree that data quality is an important concept to convey to ensure that scientific data are useful and to prevent data sharing from becoming a perfunctory administrative requirement, but rather one that should be done with the understanding that these data are intended to be used by others. Therefore, we have added to the definition that the data should be of sufficient quality to validate and replicate research findings. Even those scientific data not used to support a publication are considered scientific data and within the final DMS Policy’s scope. We understand that a lack of publication does not necessarily mean that the findings are null or negative; however, indicating that scientific data are defined independent of publication is sufficient to cover data underlying null or negative findings.

NIH Policies that Impact You and OHSU

- Concepts to consider for DMS plans when proposing to use data derived from human subjects
  - no new requirements for protections for research with human participants. Existing laws (e.g., Certificates of Confidentiality), regulations (e.g., the Common Rule), and policies (e.g., the NIH Genomic Data Sharing Policy) continue to apply. However, through this Policy and associated supplemental information and other activities, NIH promotes thoughtful practices regarding the treatment of data derived from human participants.
  - encourage investigators to consider, while developing their Plans, how to address data management and sharing in the informed consent process, such that prospective participants will understand what is expected to happen with their data.
  - any limitations on subsequent use of data (which may apply to non-human data as well) should be communicated to those individuals or entities preserving and sharing the scientific data. This ensures that factors that may affect subsequent use of data are properly communicated and will travel with the data.
- DMS plans may no longer say “TBD”. Must be specific.

Implementation

- I am the lead.
- Drafted timeline to plan and implement.
- Begun a task deliverables list that will expand as we get closer.
- Coordinate and pull together groups that are stakeholders in implementation, education, costing and resources.
- Work groups will be scheduled to begin meeting in January, 2022.

NIH Policy Links & Resources

- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html
- NOT-HG-21-023 - Notice Announcing NHGRI Guidance for Third-Party Involvement in Extramural Research
- NOT-HG-21-022 - Notice Announcing the National Human Genome Research Institute's Expectation for Sharing Quality Metadata and Phenotypic Data
- NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
- NOT-OD-20-013 - Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance
- NOT-MH-21-265 - Notice of Biospecimen Sharing Policy for the National Institute of Mental Health, Including Requirements for Induced Pluripotent Stem Cell Resource Development and Sharing

NIH Policy Links & Resources

- Attachment A – NIH Data Sharing Policy (September 2020) https://www.hhs.gov/ohrp/sachrp-committee/recommendations/august-12-2020-attachment-a-nih-data-sharing-policy/index.html
- For an example of NIH-supported or -stewarded repositories see Open Domain-Specific Data Sharing Repositories (September 2020) https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html

- NIH Rigor and Reproducibility https://www.nih.gov/research-training/rigor-reproducibility
- Wilkinson, M., Dumontier, M. et al, The FAIR Guiding Principles for Scientific Data Management and Stewardship (March 2016) https://www.nature.com/articles/sdata201618
- NIH Grants Policy Statement 2.3.11 Availability and Confidentiality of Information (October 2019) https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.11_availability_and_confidentiality_of_information.htm
- NIH Strategic Plan for Data Science (June 2018) https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pd

Questions?

- Email me at goldenep@ohsu.edu
- Send any current DUA’s to duainbox@ohsu.edu.

OHSU LIBRARY: DATA SERVICES FOR NIH DMS COMPLIANCE

DATA MANAGEMENT PLANNING

Guidance on writing data management plans and tools for making the process more efficient

DATA DOCUMENTATION & ORGANIZATION

Assistance identifying and applying data standards and best practices for organizing your data

PREPARING DATA FOR DISCOVERY & SHARING

Expertise and checklists for creating FAIR data

SUBMITTING TO REPOSITORIES

Help choosing and depositing data in public repositories

OHSU Library Website
https://www.ohsu.edu/library

Contact Us
https://ohsu.libanswers.com

Data Consultation Appointment
https://librarycalendar.ohsu.edu/appointments

OHSU IRB Repository Resources

- OHSU IRB Policies and Forms webpage https://www.ohsu.edu/research-integrity/irb-policies-and-forms
- Repositories Help Sheet
- Repository Protocol Checklist
- Repository Sharing Agreements (de-identified, identifiable)
- Repository Submittal Agreement
- Repository Tracking Template (Excel and Word)

- Be sure your consent form and protocol allow you to submit data to a repository

OCTRI Resources:

- OCTRI Informatics can consult on establishing databases for repositories including considerations for combining data from multiples studies.
- OCTRI Regulatory Knowledge and Support can consult on establishing repository SOPS.
- Email OCTRI@ohsu.edu or complete an OCTRI Resource Request Form