Resource Guide 4: Developing Data Use Agreements

Introduction

This resource guide provides an introduction to data sharing or data use agreements (DUA). The guide includes: the development process, key components and questions for consideration when developing a DUA, especially one involving American Indian/Alaska Native (AI/AN) health information.

What is a Data Use Agreement?

A Data Use Agreement (DUA), is a contractually binding agreement used for the transfer of data collected by organizations, where those data are confidential or otherwise subject to restrictions on their use. These data may or may not include protected health information (PHI). The DUA is signed by all parties involved in a data transfer. A DUA specifies the necessary steps and constraints required to ensure privacy protections for study participants (or patients) and addresses data ownership rights.[1] Plans and procedures regarding publication and dissemination related to the data should also be specified in the DUA. Establish a DUA any time (1) data are collected from or about your patients or agency, or (2) access to already existing patient or agency data are requested for a specific project, research study, or any other purpose.

Steps to Develop a DUA

1. Meet with representatives of each of the parties involved in the data transfer. Discuss the key components of the agreement (detailed below) from the varied perspectives and needs of each party.

2. Identify a lead DUA representative who will draft language, share drafts with parties for review and input, and collate revisions from all parties.

3. Include key components needed for the specific project or data use plan in the DUA. Refer to example DUAs for projects similar to the planned project.

4. Circulate the draft DUA for review by legal or contract experts, organizational leadership, and other organizational representatives who may be involved in sharing or using the data (medical records, information technology, research review committee, etc.).

5. Additional review by legal or contracts experts may be required after revisions from the other parties are incorporated.

6. Obtain final agreement on the DUA terms, conditions, and language from all participating parties. Circulate the final DUA to the parties' representatives for organizational approval and signatures. Send final signed copies of the fully executed DUA to all parties.

7. When data are transferred, provide a copy of the signed DUA to the data recipients as a reminder of the terms of use for the data.

> The DUA representative could be at the requesting organization or at the data source organization, depending on vested interest in the terms of the DUA or the expertise and resources available to develop and manage the DUA process.

> Additional resources, links to other materials, and our DUA template are available on the UIHI website.

Components of a DUA

The following key DUA components will strengthen the agreement and clarify data use procedures before starting a project:

- Background/General Project Scope – Include an overview of the project, the collaborating organizations or parties involved, and the purpose of the DUA.

- Descriptions of the Data and Definitions – Describe the type and nature of the data being collected and the collection method. Include specific language about any PHI that may be included. If the *data list* is long, include an appendix listing all the data variables individually such as diagnosis codes, service dates, age, medication or treatment codes and a related data dictionary.

- Data Access, Ownership and Limitations – Explain how the data will be used, *who will have access* to the data during the project,[1,2] who retains *ownership* of the data, allowances or restrictions on *secondary use* of the data and specific constraints on the data use and disclosure. For example, many DUAs do not allow sharing data with any entities or individuals (including disclosure or distribution) outside the purpose of the agreement.

- Security – Describe the safeguards required to ensure the secure storage, access, and exchange of the data. If desired, describe detailed security measures such as locked offices and files for physical records, password protection on shared servers, and encryption of electronic media.

- Publication and Presentation of Results – Explain the process for developing, *reviewing*, and approving any results for public presentation and dissemination.[2] If applicable, include exact language about acknowledgements that may need to be included in all publications (e.g., acknowledgments to community members, funder requirements, etc.).

- Additional Terms and Conditions or Agreement Details – The DUA should include the start and end date of the agreement, instructions on data destruction and notification of destruction to data owners, requirements for modifying or amending the agreement, conditions of agreement termination, and signatures and contact information of party representatives.

A *data list* is particularly important for complex projects with extensive data variables being transferred. Having an agreed upon list prior to the data transfer will clarify expectations and understanding about the nature of the data, what is and is not available, and in what format the data is available.

Who will have access?
Some organizations require that all data users such as data technicians, analysts, and project staff sign a confidentiality agreement.[1,2]

Ownership is important because the data owner decides how and when the data is used and disseminated. Federal courts have ruled that if data are shared without any written agreement restricting future use of the those data or that the data source retains ownership of those data, then the data recipient can use those data as they please. This means a data source must clearly state that they retain data ownership even after sharing the data with the recipient. Consult with legal counsel about the ownership concerns specific to your organization.

Secondary use of the data means using or analyzing the data for purposes outside the original project scope and terms of the DUA.

Develop a mutual review process for a variety of publications including articles, presentations and reports. If you want to specify details, set reasonable response time frames for the review and approval steps. See the example DUA that includes a detailed publication review process.[2]

Different DUAs organize *additional terms* in varied ways. Each could be a separate item in a DUA or they could be grouped together at the beginning or end of the DUA. Include these details in a way that works best for your agreement.

Questions for Consideration

As you develop your DUA, consider the following questions and whether or not your data use agreement needs to address these issues:

• Are there additional terms the DUA requires in order to ensure you have adequate control over the collection methods, use, security, and destruction of the data being shared?[3]

• Different parties may have different assumptions about how data are to be disseminated.[4] Some researchers may think research data are to be shared as publically as possible so that others may benefit from the knowledge gained. This may be in conflict with the assumptions of some data source organizations that may restrict the dissemination to specific organizational or study purposes.

• Who owns the source data after the data is transferred and who owns the products of the research?

• Will you allow secondary use of the data for new projects or analyses? If so, what approval process will you need in order to ensure accountability for secondary data analyses?

• What role will your agency play in the data analysis and interpretation? What results are desired to provide benefit to the requestor, the data source, and the AI/AN community?[1, 5]

• Does the data source organization support the data requestor's project goals and recognize the benefit of publication for the AI/AN community?[3] Does the review and publication process ensure constructive framing of data or study findings?

• Is there information not eligible for public dissemination? For example, are some cultural information such as traditional medicine practices intended only for community members and need to be withheld from publication? Is there a clear shared understanding of what those confidential elements are and does your DUA language specify such restrictions?[4]

• Are materials other than data being exchanged, such as biologic samples or genetic material? If so, additional protections and constraints need to be ensured.[3] See additional resources available on the UIHI website.

> Some projects have direct benefits to individuals, for example providing medical services like screening for a disease. Other studies may not provide individual benefits but contribute to greater knowledge that benefits the specific community or society as a whole. It is important to ensure a balance between the benefits of the project and the risks to patient's welfare, privacy, and confidentiality.

Summary

This resource guide provides an outline of the steps to develop your own DUA along with a description of the key components to include and some critical questions for consideration when establishing DUAs. A strong DUA can help guide a project through a secure data transfer and use process so that patients' privacy rights are protected, the expectations of all parties are clarified in advance, and publication processes and project outcomes are transparent and culturally relevant. DUAs can facilitate ethical research in AI/AN communities that is vital to uncovering new knowledge that can help improve the health of the AI/AN population.

Citations and Resources

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3. Chawla Sahota P. (n.d.). Research review checklist for American Indian and Alaska Native communities. Research Review Toolkit, Accessed December 2, 2011: http://www.ncaiprc.org/files/Research%20Review%20Checklist%20for%20AIAN%20Communities.pdf

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5. Resnik DB and Kennedy CE. (2010). Balancing scientific and community interests in community-based participatory research. Accountability in Research, 17:198-210. Accessed December 20, 2011: http://www.ncbi.nlm.nih.gov/pubmed/20597018

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We welcome your feedback, questions, thoughts and suggestions.

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