

**Outcome Measure Harmonization and Data
Infrastructure for Patient-Centered Outcomes
Research in Depression: Data Use and Governance
Toolkit**



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Prepared by:

OM1, Inc.,¹ with subcontractors:
American Board of Family Medicine²
American Psychiatric Association³

Investigators:

*Haley S. Friedler, M.P.H.¹
*Michelle B. Leavy, M.P.H.¹
Eric Bickelman, MDiv., P.M.P.²
Barbara Casanova, B.S.³
Diana Clarke, Ph.D.³
Danielle Cooke, B.S.¹
Andy DeMayo, J.D.¹
Bailey Egan, B.S.²
Debbie Gibson, M.S.c.³
Sarah Hajjar, M.P.A., P.M.P.²
Richard Gliklich, M.D.¹

**Co-Lead Authors*

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The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Executive Summary

Patient registries are important tools for advancing research, improving healthcare quality, and supporting health policy. Registries contain vast amounts of data that could be used for new purposes when linked with other sources or shared with researchers. This toolkit was developed to summarize current best practices and provide information to assist registries interested in sharing data.

The contents of this toolkit were developed based on review of the literature, existing registry practices, interviews with registries, and input from key stakeholders involved in the sharing of registry data. While some information in this toolkit may be relevant in other countries, this toolkit focuses on best practices for sharing data within the United States. Considerations related to data sharing differ across registries depending on the type of registry, registry purpose, funding source(s), and other factors; as such, this toolkit describes general best practices and considerations rather than providing specific recommendations. Finally, data sharing raises complex legal, regulatory, operational, and technical questions, and none of the information contained herein should be substituted for legal advice.

The toolkit is organized into three sections: “Preparing to Share Data,” “Governance,” and “Procedures for Reviewing and Responding to Data Requests.” The section on “Preparing to Share Data” discusses the role of appropriate legal rights to further share the data and the need to follow all applicable ethical regulations. Registries should also prepare for data sharing activities by ensuring data are maintained appropriately and developing policies and procedures for governance and data sharing.

The “Governance” section describes the role of governance in data sharing and outlines key governance tasks, including defining and staffing relevant oversight bodies; developing a data request process; reviewing data requests; and overseeing access to data by the requesting party. Governance structures vary based on the scope of data shared and registry resources.

Lastly, the section on “Procedures for Reviewing and Responding to Data Requests” discusses the operational steps involved in sharing data. Policies and procedures for sharing data may depend on what types of data are available for sharing and with whom the data can be shared. Many registries develop a data request form for external researchers interested in using registry data. When reviewing requests, registries may consider whether the request aligns with the registry’s mission/purpose, the feasibility and merit of the proposed research, the qualifications of the requestor, and the necessary ethical and regulatory approvals, as well as administrative factors such as costs and timelines. Registries may require researchers to sign a data use agreement or other such contract to clearly define the terms and conditions of data use before providing access to the data in a secure manner.

The toolkit concludes with a list of resources and appendices with supporting materials that registries may find helpful.

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Chapter 1. Introduction

1. Background

Patient registries are an important tool for systematically collecting data and evaluating patient outcomes. A patient registry is “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more stated scientific, clinical, or policy purposes.”¹ Patient registries can provide valuable information to describe the course of a disease, understand treatment patterns and outcomes, examine the effectiveness, safety, and value of products and interventions, and measure and improve quality of care. With their flexible design and ability to address a wide range of purposes, registries have attracted substantial interest and funding in recent years, with over 6,900 patient registries listed on ClinicalTrials.gov.

Together, these registries represent an enormous investment in research infrastructure and a tremendous data resource that could be used to address new research questions in a timely and efficient manner.^{2,3} In recent years, the potential benefits of data sharing have been noted by many groups, including the National Academy of Medicine, the Office of the National Coordinator for Health Information Technology, and the International Committee of Medical Journal Editors.⁴⁻⁶ In addition, some funding organizations, such as the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute, have adopted data sharing policies.^{7,8} As discussions around data sharing become more common, registries may wish to explore the potential for sharing data or develop formal policies for data sharing. Yet, sharing patient registry data with external researchers (i.e., researchers not affiliated with the registry) is complex due to a combination of ethical concerns and legal and regulatory questions.⁹⁻¹⁴ These questions, combined with resource constraints, can inhibit secondary use of registry data to increase knowledge and improve care and policy.¹⁵⁻¹⁸

The purpose of this toolkit is to describe best practices and to provide a set of practical resources to support registries that are interested in sharing data with external researchers.

2. How This Toolkit Was Developed

This toolkit was developed through a multistep process involving a review of the relevant literature, review of registry websites and existing policies and procedures, interviews with existing registries and external researchers accessing registry data, and input from key stakeholders.

PubMed and Google were utilized to search for literature related to registry governance, policies, and/or procedures for sharing data. For the purposes of the literature review, sharing data referred to the sharing of registry, clinical trial, and other health-related data with external researchers. An external researcher was defined as any person or party requesting data from an organization wherein the requestor does not have rights to the data. Key search terms included *patient registry*, *data governance*, *registry governance*, *data sharing*, *data access*, and *registry data sharing*. Literature eligible for review was not filtered by study design and included primary studies, systematic reviews, opinion articles, and white papers. As laws and regulations differ across countries and among states, the review focused on data sharing practices within the United States as a whole.

Abstracts and summaries of the identified literature were screened for relevance, and those that did not describe topics such as the governance of data sharing, practices or policies for sharing data, challenges or concerns with sharing data, or suggestions for improving data sharing, were excluded. Literature solely discussing internal data use and/or the sharing of data with internal researchers was also excluded. The selected papers were then reviewed for

confirmation of inclusion, and relevant references in the selected literature were also evaluated for inclusion. All eligible literature was then screened for best practices in the following three domains: governance structure, data sharing policies, and data access procedures.

In addition to review of the literature, the websites of existing registries and data repositories were reviewed for information on the same three domains. Registries and repositories with publicly available details on governance, policies, and procedures for sharing data with external researchers were included. In addition to governance, policies, and procedures, documents such as data request forms, data use agreements (DUAs), data sharing agreements (DSAs), and informed consent forms were reviewed. Registries and repositories included for review were diverse in size, purpose, resource-availability, and disease-area, and included areas of special interest, such as rare diseases and mental health.

Following the literature review, registry stakeholders were identified and contacted for interview. Interviews were conducted with stakeholders, including representatives from six registries: the National Cardiovascular Data Registry (NCDR)¹⁹ from the American College of Cardiology (ACC); CancerLinQ²⁰ from the American Society of Clinical Oncology (ASCO); the PRIME Registry²¹ from the American Board of Family Medicine (ABFM); PsychPRO²² from the American Psychiatric Association (APA); Genetic Alliance²³; and the National Institute of Mental Health (NIMH) Data Archive (NDA).²⁴ Interviews focused on the same three domains as the literature review, utilizing the “Questions to Consider When Sharing Data with External Parties” found in Appendix A. Responses were consolidated and reviewed.

The processes, considerations, and examples contained within this toolkit were developed based on the best practices found through the literature, registry websites, and stakeholder interviews described above.

3. How To Use This Toolkit

This toolkit can be used in conjunction with *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*¹ to inform decisions about policies, procedures, and governance for sharing data. The *User's Guide* provides detailed information about the principles of registry ethics, data ownership, privacy, informed consent, and governance. This toolkit expands on the *User's Guide* chapters to describe how these principles apply in the context of sharing registry data with external researchers.

This toolkit outlines key considerations relevant to sharing registry data, discusses best practices related to governance, and describes data sharing processes and workflows. Registry sponsors may use this toolkit during the planning and design of a new registry or when creating or updating policies and procedures for existing registries.

The toolkit is organized into three components: preparing for data sharing by understanding legal, ethical, and other considerations (Chapter 2); governance considerations, including an example governance model (Chapter 3); and policy and procedural considerations for reviewing and responding to data requests, including questions to consider for approval and an example data use agreement (Chapter 4). While these topics are described separately, many of the processes discussed in each section occur in parallel.

Policies and procedures should be created with registry resources, registry data, and legal, ethical, and technical input in mind. The contents of this toolkit are suggestions to consider and are not prescriptive. The contents of this toolkit do not represent legal advice. Registries interested in sharing data externally should closely involve and defer to the advice of their own legal counsel. In addition, while the considerations in this toolkit may be applicable worldwide, this toolkit is designed and intended for sharing data exclusively within the United States. For those located or interested in sharing data outside of the United States, local laws, technologies, requirements, and practices may differ from those presented here, and appropriate legal counsel in the applicable jurisdiction(s) should be consulted.

Chapter 2. Preparing To Share Data

Before sharing data, it is important to know what rights are or will be associated with the data in the registry.¹⁵ Prior to sharing data with external parties, the registry must have appropriate rights to do so. Rights in this context refer to both legal rights to share the data and compliance with informed consent, other ethical regulations, and Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules. While data rights, informed consent, other ethical considerations, and the impact of HIPAA rules are discussed separately below in Sections 1, 2, 3, and 4, all four components should be considered in parallel, as none is secondary to the others.

In addition to legal and regulatory considerations, this chapter addresses operational steps to prepare for data sharing in Section 5. Preparations include considerations for how the registry will share information about the data sharing process, what questions the registry may need to answer about the data, and procedures for tracking accepted proposals, publications, and/or presentations utilizing registry data.

1. Rights to the Data

Legal rights to the data are typically secured in the site participation agreement. Certain rights may also be secured in HIPAA Business Associate Agreements if applicable. These data rights may be secured proactively, i.e., during the contracting process with persons or institutions submitting data and prior to any data submission, or rights may be secured retroactively, i.e., following data acquisition. Securing rights proactively may improve efficiencies for downstream sharing of data. For example, a registry that does not proactively secure rights to further share data and later decides to share data externally may need to re-contract with the submitting part(ies) in order to do so. This may prove difficult, costly, or in some cases, impossible.

In cases where the registry did not proactively secure the rights to further share data, options for the registry may include:

- Recontracting with submitting parties to retroactively secure these rights for all data submitted for any research purpose
- Recontracting with submitting parties to retroactively secure these rights for select data submitted for any research purpose
- Securing rights from the submitting parties for select data for specific research purposes, i.e., on a case-by-case basis

For recontracting with submitting parties, a registry may prefer to secure rights for all data submitted for any research purpose (or for any research purpose as determined by the registry). This could help alleviate the need for future re-contracting to secure data rights and may avoid additional management needed to ensure only data with proper rights are shared.¹⁵ If, however, the submitting party is unwilling to provide rights to share all data externally, and/or there are certain datasets that the registry does not plan to share externally (e.g., identified datasets), securing these rights for select data may be preferred.

Whichever contracting path is chosen, a registry should ensure that key data rights are obtained, including the right for a registry operator to own de-identified data or otherwise in-license the de-identified data for specific uses/purposes.

While having rights to share data externally as determined by the registry is ideal, registries may consider allowing submitting parties to sign off on data access requests using their site data prior to approval. When securing rights on a case-by-case basis, processes should be developed in conjunction with the relevant parties to ensure the steps for securing rights as well as roles for all parties involved are clear. Development of these processes may include considerations for:

- The scenarios that require submission of a request for rights

- Who is involved and each person or party's responsibilities
- The criteria for acceptance or denial of a request
- Regulations for the rights granted (e.g., time limits, extent of sharing permitted, types of data that can be shared, and/or repercussions for misuse)
- Timeline and budget expectations for each party involved

In order for submitting parties to provide rights to share data, the parties themselves must have the appropriate rights.²⁵ In the event that the submitting parties are unauthorized to provide these rights, it may be necessary to work with the submitting party to identify who holds the rights to the relevant data. If rights cannot be secured, the data cannot be shared with external parties.

For additional questions to consider, please refer to Appendix A, Section 1.

2. Informed Consent

In some cases, patients may be required to provide informed consent prior to participating in the registry. When consent is required, it is important to determine if existing patient consent includes language that allows further sharing of data.^{15, 18, 26, 27} Where such language does exist, it is important to identify if there are any restrictions on the purpose for sharing data, the recipients of the data, or the type of data shared.²⁸ Examples of such scenarios include the following: (1) informed consent includes language that allows for the further sharing of data, but excludes the sharing of genetic data; (2) informed consent includes language that allows for the further sharing of data, but only for research in a specific disease area; and (3) informed consent includes language that allows for the further sharing of data, but does not allow data to be shared with commercial entities. Examples of informed consent language for sharing data can be found in the *Guide to Social Science Data Preparation and Archiving* from the Inter-university Consortium for Political and Social Research (ICPSR)²⁹ or in the *Tools for Data Sharing* from the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard.³⁰

For additional information on informed consent, including the specific elements of information required to be included in an informed consent and potential waivers of informed consent, please refer to Chapter 8 of the *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*.¹

3. Impact of HIPAA Rules

A registry should determine whether the requirements of the HIPAA Rules will apply to the sharing of health information. Many registry participants are covered entities, and as such, may be required to obtain HIPAA authorizations signed by patients before identifiable health information is shared with a registry. The terms of such authorizations should be reviewed carefully, as they may vary from entity to entity. As an example, some HIPAA authorizations may permit a registry to de-identify health information and use the de-identified dataset freely for research purposes, while other authorizations may expressly prohibit such activity. It is also noted that the HIPAA authorization requirement is in addition to any informed consent requirements described in Section 2 above. A waiver of the HIPAA authorization requirement also may be sought from the applicable institutional review board (IRB) in order for identifiable health information to be shared.

In the event that only a limited data set is shared by a participant to a registry, a data use agreement (and not a HIPAA authorization or waiver) may be sufficient. Similarly, the rights granted to the registry under a data use agreement should be reviewed to ensure that the registry received appropriate permissions to conduct its intended research.

For additional information on the impact of the HIPAA Rules, including HIPAA authorizations (and IRB waivers thereof), please refer to Chapter 7 of the *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*.¹

4. Other Ethical Considerations

Finally, registries should consider whether it is ethical to share the registry data. The impact of sharing the data on the registry patients should be evaluated to ensure no undue harm would be caused by sharing data and to consider whether sharing may benefit the patients. These considerations include both identifiability and security of the data.^{31, 32} In some cases, a registry may want to establish and engage an ethics review committee prior to sharing the registry data.

Risks associated with sharing data, such as the risk of patient discrimination, increase when data is identifiable or may be linked to other data sources. Specific concerns for linking data include potential re-identification. For example, if a researcher using the registry data links the data to another source that makes it possible to infer the identity of the patients in the data due to unique combinations of variables, the data may no longer be considered de-identified under applicable regulations. The scope of this toolkit is limited to the sharing of de-identified data.

Registries must ensure that sharing data does not compromise the security of the data. This includes both maintaining data in a secure environment and either transferring or providing access to registry data through secure methods, such as with a secure file transfer protocol (SFTP). If a registry does not have a secure way to share data with external researchers, risk of a data breach may make sharing the data unethical. For example, if a registry sends data to an external researcher in an unencrypted email and the email account is hacked, an unauthorized party may gain access to the patient data and disclosure of sensitive health information may occur.

There may be additional ethical concerns for special populations, such as registries for rare diseases. While this toolkit can be applied to such registries, considerations of identifiability and benefits to patients may be of particular concern. For additional information on ethical considerations, please refer to Chapter 7 of *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*.¹

5. Setting Up for Success

Sharing data externally requires a coordinated effort between individuals at all levels of the registry, from executive leadership to data managers. Key steps for preparing to share data may include:

- Maintaining data in a manner that allows for data sharing
- Preparing to answer questions about the suitability of the data for addressing different types of research questions
- Sharing information about the request process
- Maintaining or posting a list of accepted proposals, publications, and/or presentations based on registry data

In order to effectively share data externally, data must be structured and maintained in a manner that facilitates ease of sharing.^{18, 33} Data should be clearly organized and, where possible, aligned with appropriate data standards.¹ Additionally, data should be held in a system that facilitates secure access.

Registries should consider what information about the registry data is currently available, in order to be prepared to answer questions from researchers interested in using their data. Such researchers may have questions about, for example, available variables, variable definitions, and population counts. Understanding the data contained within the registry is a key step in sharing the data with external researchers. Accompanying documents, such as a data dictionary and/or

variable list should be maintained and made available, where possible, to ensure clear understanding of data, both internally and externally. Information such as diseases represented, populations identified, demographics, and relevant counts can be useful for external researchers to evaluate feasibility before requesting access. For example, if a researcher is interested in a specific population, but the registry does not have sufficient patients in the population to effectively answer the research question, having this information ahead of time will prevent unnecessary inquiries. Examples of such information can be found on registry websites such as the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Program³⁴ and the Cystic Fibrosis Foundation Patient Registry.³⁵

Registries may choose to publicly disclose the process for external researchers to access data, or they may choose to only share this information with selected parties. If a registry is only interested in providing data to a select group of researchers, such as researchers at a specific institution, the registry may share the process for accessing data directly with the desired group. For sharing publicly, development of a registry website, if one does not already exist, is a good place to start. A website can serve as a central point of contact and information for all parties interested in accessing the registry data. This may also include information about the registry data as discussed above. The information on the website will allow external researchers to learn about the registry's purpose and scope, understand how they can request data, and make informed decisions about whether the registry may be a good data source for their research interests.

Registries also may choose to maintain a list of accepted proposals, publications, and/or presentations based on registry data. Maintaining such a list can help the registry track research questions answered with the registry data and may reduce duplication of efforts and/or help the registry secure additional funding. These lists may be held by the registry privately, or a registry may choose to share them publicly, such as on the registry website.

Chapter 3. Governance

Successful sharing of data requires planning and coordination to ensure that the policies and procedures for sharing data with external researchers are developed and carried out. Registries should outline the specific governance structures needed to share data. The outline should define what the governing body must do to prepare, how the governance will be structured, and what processes must occur in order to share data. This chapter addresses considerations for the key tasks, structure, and procedures of governance associated with the sharing of registry data.

For a detailed description of general registry governance, please refer to Chapter 9 of *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*.¹

1. Key Governance Tasks

Several governance tasks should be considered when sharing data externally:

Securing rights to share data—As described in Chapter 2, appropriate rights are required for sharing data externally. Securing these rights requires governance oversight through the development and implementation of the processes and materials, including deciding when and how to secure rights and for what data.

Defining and staffing relevant oversight bodies—Defining the governance structure is a key component of sharing data externally. Necessary steps include the creation of any required committees or other oversight bodies; clear delineation of their purpose, composition, responsibilities, and operating procedures; identification of the necessary personnel; and documentation of the workflow for data sharing. Governance structure is discussed further in Section 2 of this chapter.

Developing a data request process—A process must be developed for how interested parties can submit requests for use of the data for a specific purpose. Example processes are outlined in Chapter 4. Once defined, this process should be shared with all involved parties. The governance procedures required for this process are discussed in Section 3 of this chapter.

Determining costs and budget for data access requests—There are costs associated with sharing data externally, including costs related to the technology and the time involved in the development and carrying out of data sharing processes. Governing bodies must determine how the registry will pay for these costs and whether to require application and/or data access fees from interested parties to supplement or cover these costs. This should be done early and in conjunction with development of the data request process. For additional information on registry funding, please refer to Chapter 2, Section 2.4 of *Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition*.¹

Review of data requests—Governing bodies may play a role in reviewing data requests, as defined in the data request process. Individuals responsible for and involved in each step of this process should be identified, with roles clearly defined, to help ensure smooth operations. The governance procedures required for this process are discussed in Section 3 of this chapter.

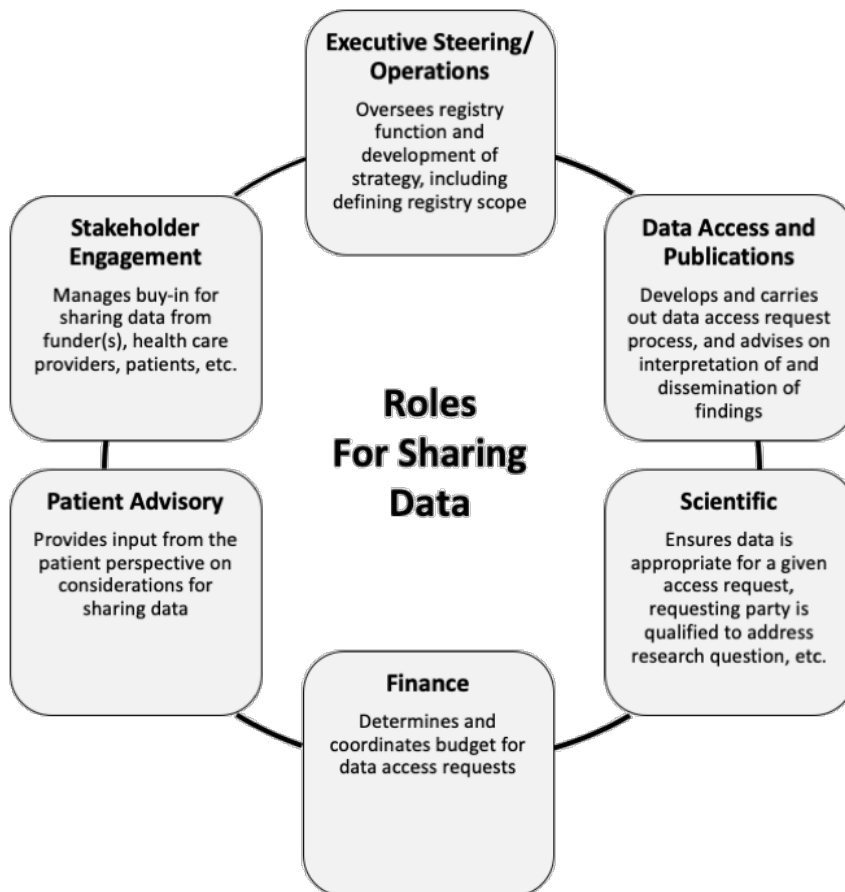
Overseeing access to data by the requesting party—Governance oversight is needed to ensure data are accessed appropriately by an external party, either through transfer of the data to the external party or by providing access within a secure environment held by the registry. Registries may consider identifying individuals responsible for sending data, setting up and revoking access credentials, overseeing security measures, and other key steps based on the registry's process. The governance procedures required for this process are discussed in Section 3 of this chapter.

2. Governance Structure

Key considerations for developing governance structure include determining who is involved and how they are involved. In many cases, an executive steering/operations body makes key decisions about sharing data externally. Additional governance roles may include engaging stakeholders in the data sharing process, dealing with finances associated with sharing data, and carrying out processes for data access, including review of publications and/or the dissemination of results. These tasks may be handled by committees or individuals, depending on the registry structure and resources. Whether governance is owned by individuals or committees, their roles in the data sharing process should be clearly defined. Registry resources, as well as the governance tasks required, may inform how many individuals should be tasked with each role. As sharing data requires collaboration between multiple people or groups, the interplay between these people or groups should also be considered when developing the governance structure.

Examples of how various types of roles might function for sharing data externally are illustrated in Figure 3-1 and discussed below.

Figure 3-1. Roles comprising governance for sharing data externally



Executive Steering/Operations—As the primary body responsible for registry strategy and scope, this committee must make the initial decision to share data externally. With input from appropriate legal, scientific, and administrative personnel, this committee is responsible for determining at a high-level what data can be shared, with whom, and for what purposes. This committee must also determine which advisory functions are appropriate to involve in the data sharing process, which require formation of a committee, and to what extent these committees are involved, based on available resources, data types, and any advisory committees that already exist to serve other functions within the registry. Depending on registry resources and structure, this committee may also fulfill the role(s) of one or more advisory committees.

Advisory Functions—An individual, individuals, or committee tasked with the advisory functions may play various roles in the process of sharing data, from engaging stakeholders to reviewing applications to sending data to external researchers. Based on registry resources and the functions necessary to share data, the following advisory committees may be created or tasked with relevant processes. Where resources are limited, other advisory committees or designated individual(s) may be tasked with the responsibilities and roles of the advisory functions described below.

- *Stakeholder Engagement*—Depending on how the registry data were collected, the type of data collected, and/or legal/ethical concerns, sharing registry data may require engagement with stakeholders. Stakeholders may include patients submitting data, other parties submitting data, patient advisory groups, healthcare providers, registry funders/partners/users, parties involved in executing processes for data sharing, legal/ethical/scientific advisors, and/or other associated groups. A stakeholder engagement committee or the individual(s) tasked with stakeholder engagement should work with the appropriate stakeholders to understand and address any concerns around sharing data externally and involve them in the development of data sharing policies and procedures, as appropriate. Obtaining stakeholder support can reinforce trust with parties submitting data, users accessing the data, and/or registry funders and partners, and can positively impact resulting data sharing policies and operations.³⁶ Processes for identifying and engaging relevant stakeholders, as well as addressing stakeholder concerns, should be developed and carried out prior to and alongside the development of data sharing policies and procedures.
- *Patient Advisory*—Registries may consider involving patients in the development of data sharing policies and procedures in a more formalized manner than is done with other stakeholders. This may be in the form of the inclusion of a designated patient advisory committee and/or identification of select patients and patient advocates to serve this advisory function. The patient advisory committee or the individual(s) tasked with this function should serve to provide the patients' perspective on sharing data, including any concerns, preferences, and/or potential benefits as identified from the patients' point of view. Including a patient advisory function in the development and oversight of policies and procedures for sharing data may increase trust with participating patients. As appropriate, processes for identifying and engaging patients and/or patient advocates should be developed early on to ensure patient perspectives are represented in the decisions made surrounding the sharing data.
- *Finance*—The individual(s) or committee tasked with the Finance role may be consulted on and/or develop budgets for all steps of the data sharing process. This includes budget for personnel time required to develop data sharing procedures, the technology needed to securely store and share the data, and all other operations costs once data sharing procedures are in place (e.g., personnel time to review requests, data analysis services if applicable). Both operational budget and study-specific budgets may be required. Criteria for determining the budget should be developed prior to sharing data. Depending on registry resources, a distinct Finance Committee may not be required.
- *Scientific*—The individual(s) or committee tasked with the Scientific role may be called upon to consult on data access requests as necessary. Considerations for including a scientific committee or designated individual(s) may include ensuring feasibility of a given request based on available registry data or providing subject matter expertise on the merits of addressing the proposed research question.

- *Data Access and Publications/Dissemination of Results*—The individual(s) or committee tasked with this role is the primary party involved in sharing data externally. This party, sometimes referred to as a Data Access and Publications Committee (DAPC), is responsible for developing and implementing the policies and procedures for sharing data, reviewing and responding to data access requests, overseeing the communication of results of the studies performed, and all other operational tasks associated with sharing data externally. Appropriate personnel may include individuals with subject matter expertise (e.g., clinical knowledge, biostatistics, epidemiology), legal/ethical experts, and those with in-depth knowledge of the registry operations and data. In some cases, registries may choose to identify individuals who are independent from the registry to perform this function.^{12, 16, 36} Administrative staff may also play a large role in facilitating operations such as the collection of requests, scheduling of meetings, and recording decisions. This party may involve and coordinate with other committees in the processes as needed.

The appropriate governance structure for sharing registry data externally may depend on multiple factors, including the scope of data shared, registry resources, and the registry's processes for sharing data. While data sharing processes for some registries may require minimal governance oversight, other registries may require more significant governance involvement.

3. Governance Procedures

Governance procedures start with the decision to share data externally. The Executive Steering/Operations Committee or similar decision-making body for the registry should determine the scope of what data can be shared, with whom, and for what purposes. Once this decision is made, key individuals should be identified, or a committee developed, to oversee the creation of data sharing policies and procedures. Stakeholders should also be identified and consulted as the policies and procedures are developed. Engaging key stakeholders early in the development of these policies and procedures can ensure buy-in for the resulting process developed. Stakeholders may include, but are not limited to, parties involved in executing processes for data sharing, registry funders, registry business partners, parties submitting data to the registry, patients/patient advocacy groups, registry users, and/or legal counsel. Where applicable, patient advisors should also be identified and consulted throughout development of the policies and procedures.

Based on the agreed upon policies and procedures for sharing data externally, additional committees or individuals may need to be created or identified (Section 2 of this Chapter). Key steps include determining who is in charge of scheduling committee meetings and/or meetings between relevant individuals, how and when they should meet, and how meetings and/or committee processes should be documented. Examples of documentation include committee charters, bylaws, and meeting minutes. Registries should also consider where this, and all other documentation related to data sharing, should be stored.

Governance procedures should be defined for all processes developed for sharing data (Chapter 4) to ensure that these processes have a clear owner. For example, registries that require submission of a data request form should consider who is responsible for determining the format of the request, how this information is shared with relevant parties, and how submitted requests are processed.

Registries must also decide who is responsible for determining whether to grant a request for access to the registry data. Registries may use a DAPC to review requests and reach a decision, or the registry may assign requests to one or more individuals. Where decisions involve a group, registries must consider what will constitute an agreement (unanimous agreement, majority rule) and what must be done in the event of a tie or disagreement.

Additional considerations for governance procedures include:

- Determining what roles, such as subject matter experts or statisticians, must be involved in decision-making
- Deciding when other individuals or committees must be consulted, such as the Executive Steering/Operations Committee for input on scope or Finance for input on study budget
- Identifying who will correspond with the requestor if more information is needed for a given request
- Identifying who will communicate decisions to the requestor

To provide data access, governance bodies must decide the terms and conditions for data access and identify personnel responsible for ensuring these terms are agreed to prior to sharing data. Appropriate personnel must also be involved in the actual sharing of data. For example, registries may have a data manager who coordinates the extraction of the correct data population for a given study and provides it to the requesting party for analysis, in accordance with registry data sharing procedures (Chapter 4, Section 6). The same or other individual or group identified as responsible may then revoke access or ensure deletion, as appropriate, at the end of the study or contract agreement.

Once defined and documented, governance procedures should be disseminated to all relevant parties. Registries may consider posting these procedures publicly, for example on the registry website, to streamline dissemination of information and ensure transparency of the data access process. Registry policies and processes for sharing data may change over time, and the associated governance procedures should be adapted accordingly.

For additional questions to consider for governance procedures, please refer to Appendix A, Section 2.

Chapter 4. Procedures for Reviewing and Responding to Data Requests

Procedures for requesting data should be clearly defined and transparent. The procedures developed for sharing data with external researchers may vary from registry to registry but should be based on registry scope, size, and available resources. This chapter provides an example workflow and describes both procedural and technical considerations for the processes outlined, including determining data availability, deciding who will be allowed to use the data, designing a data request form, developing a review process, and planning for how researchers will access the data once a request is accepted.

1. What Data Are Available?

A first step in developing policies and procedures for data access requests is to determine what type(s) of data will be made available to researchers. A summary of types of data that external researchers may be interested in obtaining, along with considerations for access, is presented in Table 4-1.

Table 4-1. Considerations by type of data for external use

Data Type	Access Considerations
Aggregate Summary-Level Data	If data are only reported in aggregate form, registries may consider allowing unrestricted, open access to the public, including access by patients, citizen scientists, and other interested parties. In this scenario, registries may or may not implement a requirement for requesting data.
De-identified Patient-Level Data	If data are de-identified, but reported at the patient-level, registries may consider allowing restricted access to select parties. These parties may be limited to qualified researchers associated or not associated with the registry, qualified researchers associated or not associated with an academic institution, and/or citizen scientists, patients, or other interested parties who have appropriate qualifications as determined by the registry.
Limited Datasets,* Linkable Patient-Level Data, or Identifiable Data	External sharing of limited datasets, linkable data, and identifiable data are beyond the scope of this toolkit. Registries should seek guidance from appropriate legal, regulatory, and other personnel.

*Limited datasets are datasets that do not contain certain direct identifiers (e.g., name, phone number), but are not de-identified under the HIPAA Privacy Rule as they contain select protected health information (PHI) (e.g., zip code, full date).

Depending on both researcher qualifications and data types, registries may choose to create multiple access levels to maximize shareability of the data.¹⁸ An example of this practice can be found with the NIH All of Us Research Program, which uses access tiers for sharing data.³⁷ Access levels may be assigned during the request process as part of the request review, or they may be implemented based on researcher qualifications, data type, or a combination of both.

This toolkit is intended primarily for registries interested in sharing de-identified patient-level data with external researchers. Registries only intending to share aggregate, summary-level data may not need to implement a data request process. Registries intending to share limited datasets, identifiable data, and/or allow linkage of data should consult with appropriate legal and regulatory experts.

2. Who Can Access the Data?

The next steps in developing data access policies and procedures are determining who is eligible to access the registry data and how they will do so.

2.1 Procedural Considerations for Who Can Access Data

Registries may consider restricting data access to researchers who meet specified criteria, such as researchers who have formal training in clinical research, data analysis, or another relevant scientific discipline.^{10, 36} Registries may also consider restricting data access based on the researcher’s organizational affiliation. For example, registries may choose to only share data with researchers affiliated with organizations associated with the registry. Registries may also choose not to share data with researchers who intend to use the data for commercial purposes.

Considerations for data access by researcher group and by researcher organizational affiliation are presented in Tables 4-2 and 4-3, respectively.

Table 4-2. Considerations for data access by researcher group

Researcher Group	Access Considerations
Researchers Submitting Data to the Registry	Registries may consider providing researchers with access to only their own data or to their data and other registry data. Data access policies for researchers submitting data to the registry may be included in the site participation agreement or other contract with the researcher. When providing other registry data, registries should consider any agreements in place with the researcher or other parties (e.g., patients, other researchers, institutions, or registry partners), the intended use of the data, and/or the type of data (Table 4-1).
Researchers Not Submitting Data to the Registry	Registries may consider providing data access to researchers who do not submit data to the registry. Considerations may include researcher qualifications, any agreements in place with other parties (e.g., patients, other researchers, institutions, or registry partners), the intended use of the data, and/or the type of data (Table 4-1).
Participants Submitting Data to the Registry	Participants submitting data to a registry may also be interested in accessing the registry data. Registries may consider providing participants with access to only their own data or to their data and other registry data. When providing other registry data, considerations may include participant qualifications, any agreements in place with other parties (e.g., participants, institutions, or registry partners), the intended use of the data, and/or the type of data (Table 4-1).
Citizen Scientists	Registries may consider providing data access to citizen scientists under specified conditions, such as: (1) a registry may restrict access for citizen scientists to only aggregate, summary-level data; or (2) a registry may require citizen scientists to have some formal training in statistics or otherwise work with a trained statistician in order to have access to the data.

2.2 Technical Considerations for Who Can Access Data

Technical considerations related to data access include how access will be monitored and/or restricted and what security measures are needed to ensure data are only accessed by individuals with appropriate permissions. These issues are discussed further in Section 6 of this Chapter. In addition, the technical development of any planned access levels must be considered. For access levels based on data type, datasets must be created and labeled in accordance with the data types associated with access levels. For access levels based on researcher qualifications, qualifications must be obtained and validated according to registry procedures. In addition to providing information on how to access registry data, registry websites may serve as a portal for data access. Creation of external accounts on the registry website is one method of obtaining researcher qualifications and/or implementing access levels. Creation of accounts for external researchers may help both the registry and interested parties keep track of requests made and/or data accessed. Account creation can occur either before, during, or in place of a request for

access. Account creation before a request may allow for validation of credentials up front, allowing registries to streamline requests from only those who are eligible based on registry policies. Alternatively, to reduce resource burden, accounts may be created in place of data requests. These accounts may be granted access to all datasets within a specific access level, which may be based on researcher qualifications, data type, or a combination of both. For example, the NIH All of Us Research Program, provides separate access levels for the general public and for researchers who register with the program. Those in each tier have access to all respective tier-specific data.³⁷

3. Developing a Form for Data Access Requests

Registries must decide if interested parties are required to submit a request to access the data.^{10, 15} For example, a registry may not require submission of a data access request when sharing aggregate, summary-level data with external researchers, but may require a request when sharing individual-level data. When data access requests are required, a well-developed, transparent process can facilitate and promote external researcher engagement. Registries should consider what information will be collected as part of the request process and how the request form will be shared, submitted, and reviewed.

The amount of information a registry plans to collect as part of the data access request may range from just a few key details, such as that required by the NCI SEER Program,³⁸ to a detailed project plan. Registries may decide how much information to collect based on the type of data to be shared, the purpose of the registry, the level of control desired, the resources available, and other factors. The information collected may change over time as the scope, purpose, data rights, and other factors change. Examples of the types of information that registries may collect are presented in Table 4-3. For additional questions to consider for obtaining requests, please refer to Appendix A, Section 2.

Table 4-3. Potential information to collect as part of a data access request

Category	Information To Consider Collecting
Requestor (Individual or Sponsor)	<ul style="list-style-type: none"> • Name • Job title • Organization • Contact information (phone, email, address) • Registry affiliation (e.g., registry member, registry partner, participant submitting data, no affiliation) • Research background • Resume/CV • Proof of Human Subjects Research training
Research team	<ul style="list-style-type: none"> • Name(s) • Role(s) in the project • Qualifications for the role • Job title(s) • Organization(s) • Contact information (phone, email, address) • Registry affiliation (e.g., registry member, registry partner, participant submitting data, no affiliation) • Resume/CV(s) • Proof of Human Subjects Research training
Authorized representative from institution (if relevant)	<ul style="list-style-type: none"> • Name • Job title • Organization • Contact information (phone, email) • Signature

Category	Information To Consider Collecting
Research summary/proposal	<ul style="list-style-type: none"> • Background • Rationale • Objectives • Methods • Intended use of the results (public knowledge, commercial)
Data	<ul style="list-style-type: none"> • Services needed (data access, data analysis, etc.) • Summary of data required • Proposed variable list • Start and end date for data
Statistical analysis plan	<ul style="list-style-type: none"> • Study design • Methods • Patient population criteria • Software/tools that will be used for analysis
Permissions	<ul style="list-style-type: none"> • IRB or ethics committee review/approval and relevant documentation (e.g., documentation of review/approval, approved protocol, plan for submission)
Funding plan/budget	<ul style="list-style-type: none"> • Information on existing funding source(s) (awarded grants, private funding, institutional funding) • Information on planned funding source(s)
Communication plan	<ul style="list-style-type: none"> • Planned submissions to conferences • Planned manuscripts
Timelines	<ul style="list-style-type: none"> • Deadlines for conference/journal submissions • Grant award/other funding periods • Duration of time that data access is required • Any other relevant deadlines to consider
Data management plan	<ul style="list-style-type: none"> • Where data will be stored • Who will have access • Security-related policies and measures in place • Contact information of security liaison
Terms/conditions	<ul style="list-style-type: none"> • Acknowledgement of any terms and conditions • Signed data use agreement

Based on the detail desired by the registry, a request may be in the form of a templated document, a survey form, or an email to a designated contact. For request forms with numerous free text responses or that require a substantial amount of information, consider a templated document. A document will allow researchers to work on their request over a longer period of time and obtain review and feedback from other members of the research team. For forms that contain numerous questions with pre-determined answers or collect only a moderate amount of information, a survey may be the preferred format. For requests that require limited information, a direct email request may be the simplest format. Registries that use this approach may consider setting up an email address dedicated to collecting and/or responding to requests (e.g., datarequests@name-of-registry.com).

Registries must also determine how interested parties will access the data access request. Each format requires consideration for how access will be monitored and/or restricted as defined by the registry's policies. Downloadable templates and integrated surveys can be provided on a publicly accessible page of a website or access to forms and surveys can be restricted to only those with an appropriate account (e.g., if access is limited to researchers participating in the registry). For requests submitted via email, designated email contact information may be provided either publicly or in a restricted manner, depending on the registry's preference.

Finally, registries should determine when requests will be accepted. Registries may opt to allow requests to be submitted at any time or may require requests to be submitted within a specified timeframe. In some cases, registries may issue a call for proposals. While continuous

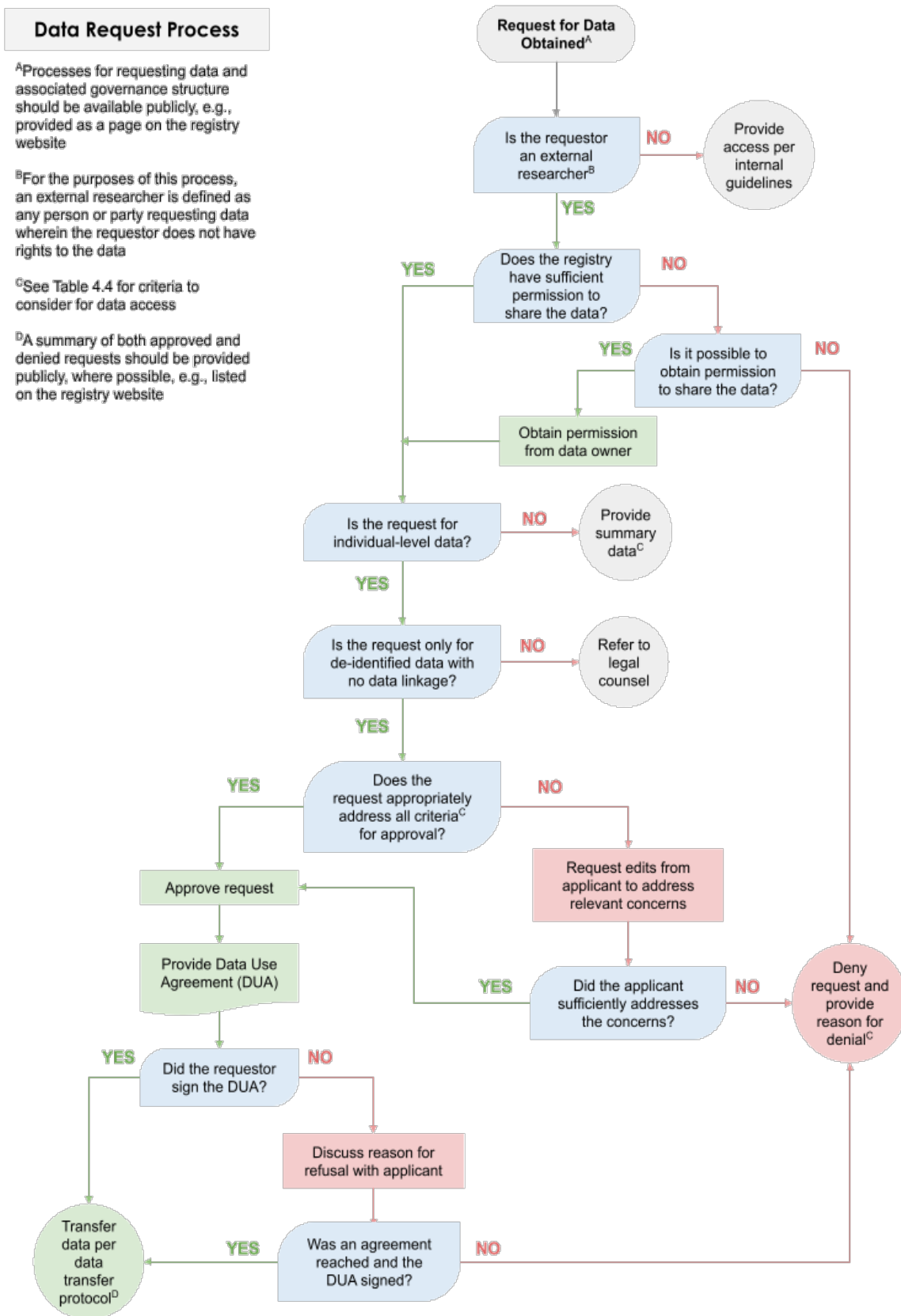
submissions of requests may maximize the sharing of the registry data, this also requires continuous resources to review and process the requests.

As discussed in Chapter 3, Section 3, appropriate governance must be in place to carry out these processes, including identifying appropriate personnel to create, disseminate, collect, organize, manage, and own submitted requests.

4. Reviewing and Responding to Data Access Requests

Following submission of a data access request, the request must be sent to the appropriate party or parties, as identified by the registry (see Chapter 3, Section 2) for review. A sample workflow for reviewing data access requests is presented in Figure 4-1. The steps in this workflow are described further below.

Figure 4-1. Sample workflow for sharing data externally



Additional sample workflows for sharing data have been published by Michigan Medicine.²⁷ The criteria for approval and/or denial of a request should be clearly outlined prior to reviewing a request. Criteria for approval should be based, in part, on what information is

collected as a part of the request itself, as well as key registry concerns.^{12, 16, 36} Examples of criteria to consider when reviewing data access requests are presented in Table 4-4.

Table 4-4. Data access request review criteria to consider

Category	Questions for Consideration
Request completeness	Does the request have all the required information filled out?
Registry scope/purpose	Does the registry have sufficient rights to share the data needed to address the request? Does the request align with the purpose and/or scope of the registry?
Feasibility	Is the request feasible with the registry data available to share? Does the registry have the required variables for analysis? Is there sufficient data on the population desired? Is there sufficient time to obtain the appropriate data and/or do the analysis in the timeline required?
Merit	Does the request have scientific merit? Is the question scientifically sound?
Requestor qualifications	Does the person requesting access to the data have appropriate subject matter expertise to address the research question? Does the person requesting access to the data meet the registry's criteria for accessing the required data? Does the study team have the appropriate technical skills to address the study objectives?
Conflict of interest	Are any conflicts of interest substantial enough to bias, invalidate, or call into question the results of the study? Is there an appropriate plan to manage any conflicts?
Research summary/proposal	Are the proposed objectives clear and/or valid to address the research question? Is there sufficient justification to perform the study? Is the purpose for the study allowed within the registry's policies? Will addressing this research question benefit the patients included?
Existing research	Has this research question been addressed before using the registry data? Will addressing this research question add to existing knowledge? Are there any other studies either within the registry, or by a third party, which are using the data to address the same or a similar research question? If so, is there potential for collaboration as opposed to two separate studies?
Statistical analysis plan	Does the requestor provide a detailed plan for statistical analysis? Are the methods planned sufficient and appropriate to address the study objectives? Are the population criteria appropriate for the study? Is there a qualified member of the team to perform the analysis? Are the software/tools appropriate for the planned analysis?
Patient privacy	Can the study be reasonably performed without substantial risks to patient privacy? Does the request have a sufficient plan to protect patient privacy?
Ethics	<ul style="list-style-type: none"> • Does the study require review by an IRB or ethics committee? • If so, is appropriate documentation of review/approval provided or is there a detailed plan for submission and review?

Category	Questions for Consideration
Data management plan	<ul style="list-style-type: none"> • If sending data to the requestor, is there an appropriate location to store the data? • Who will have access to the stored data? • Do all parties with planned access have appropriate qualifications/permissions to access the data needed? • Are there sufficient physical, technical, and procedural security measures to protect the data in place or planned? • How will a data breach be handled?
Communication plan	<ul style="list-style-type: none"> • Does the requestor provide an appropriate communication plan, if required by the registry? • If dissemination of results is required by the registry, are there plans to submit the results to a conference or journal? • If dissemination of results is required by the registry, are there other means of disseminating the results planned? • Are the planned publications appropriate for the study? • Do these plans align with the registry's communication goals? • Will the registry have an opportunity to review and/or sign off on publications prior to submission?
Funding	<ul style="list-style-type: none"> • How much will it cost the registry to extract the required data and provide any necessary support services? • If relevant, how much will it cost the registry to perform the planned analysis? • Does the requestor have funding for this study? • If funding exists, is it sufficient to complete this study? • If funding exists, are there any conditions around the funding that would limit use of the data? • If funding does not exist, who will provide the funds? • Does the study require funding from the registry?
Terms and conditions	<ul style="list-style-type: none"> • Did the researcher acknowledge the required terms and conditions?

Based on the relevant questions in Table 4-4, the registry may approve or deny a request, or the registry may ask the requestor for additional information or clarifications before making a decision. The process for obtaining information should be determined in advance and carried out in accordance with the governance procedures of the registry. Once any necessary additional information is obtained, the new information should be reviewed by the responsible party. This may require additional meetings of the parties responsible for data request review. If the supplemental information provided is sufficient, approval may be granted or denied as determined by the responsible party or parties. If supplied information is insufficient, additional information may be further sought or the request may be denied.

Once a decision is made, the decision should be communicated to the requestor in a manner determined by the registry, along with next steps. Reasons for request denial may include: an external researcher refused to sign a data use agreement (Section 5 of this Chapter); the study is not feasible with the registry data; or the request is deemed not scientifically sound. For request denials, registries may consider providing a process to appeal the decision. If an avenue for appeals is warranted, appropriate processes should be defined and relevant roles assigned per the governance structure. For approved requests, next steps may include requesting any final revisions to the proposed project, providing a contract defining the terms of use (Section 5 of this Chapter), and/or providing data access (Section 6 of this Chapter).

For additional questions to consider for reviewing and responding to requests, please refer to Appendix A, Section 3.

5. Data Use Agreements

Once a request has been approved, a DUA or similar contract should be signed. The DUA will dictate the legal terms and conditions for use of the de-identified registry data (for limited

data sets or identifiable data, refer to appropriate legal counsel). This contract serves to govern who can access the data, for how long, and for what purposes. Additional considerations include data ownership and rights, security measures required, and terms for disseminating research results.^{15, 18, 36}

Registries may choose to send a written contract to the requestor or may provide such a contract through electronic acceptance of “Terms and Conditions” on the registry website. In either event, the agreement should be binding.

Additionally, registries may opt to provide a standard DUA for all data access requests or develop study specific DUAs that may or may not allow for negotiation with the requesting party. For example, if a registry decides to allow open access to aggregate, summary-level data, interested parties may only be required to acknowledge and accept the appropriate terms. If, however, a registry is granting access to restricted data through a more detailed application process, interested parties may be required to review and sign a study specific DUA. Registries should also consider whether any additional parties, such as an institutional representative, must agree to the data use terms.

For questions to consider during development of a DUA or other such contract, please refer to Appendix A, Section 4. An example DUA can be found in Appendix B. *NOTE: The example contract is a framework only, with placeholder concepts for consideration by registries. This does not constitute legal guidance, nor is it intended to be a substitute for appropriate legal involvement or review. Registries should consult with their own legal advisors prior to developing, formalizing, and/or implementing contract language.*

Other examples of DUAs can be found on the NCI SEER Program website,³⁹ the National Institution of Child Health and Human Development (NICHD) Data and Specimen Hub (DASH) website,⁴⁰ as well as in the *Guide to Social Science Data Preparation and Archiving* from ICPSR²⁹, and the *Tools for Data Sharing* from the MRCT Center of Brigham and Women’s Hospital and Harvard.³⁰

6. Providing Data Access

The final step in sharing data externally is providing the external researcher with access to the data. Registries may elect to provide in-house analytic services such that researchers receive analysis results only or provide direct access to the data itself.

Registries that elect to perform statistical analyses in-house must determine how to coordinate the efforts with the external researcher, including setting up meetings, defining review periods and timelines, and refining study cohorts and analysis. Registries must also consider how long the requestor will have access to statistical analysis services for the data. This may be flexible and based on the duration of the project or may be a fixed time interval. Provision of in-house analytic services allows the registry to retain full control over the data, but it is also the most resource intensive.

Registries that elect to provide direct access to the data must decide if the researcher will have access to all the registry data or only data meeting the study inclusion and exclusion criteria. In the latter case, registries must implement a process for defining the inclusion and exclusion criteria with the external investigator and assign appropriate resources to extract the relevant data. For all direct access options, appropriate documentation must be available for external researchers to understand the data contents. Documentation should include a data dictionary and any other relevant materials essential for researchers to perform the analysis correctly. Additionally, the registry may need to provide support during the analysis process, should any questions or issues arise.

The registry must also determine how the requestor will obtain access to the data.^{15, 18, 36} When determining how to share data with external researchers, key considerations include data type, researcher qualifications, researcher access level, resource intensity, feasibility of use, data security, and data traceability. Data access methods include allowing on-demand download of

pre-defined datasets, enabling download of specified datasets on a case-by-case basis, or providing access to a secure computing environment. These options are described below:

- **On-demand data download:** Registries may store relevant datasets on the registry website, with access limited to those with appropriate login credentials.
- **Request-specific data download:** Registries may use a SFTP or other secure standards used by cloud services to transfer specific datasets to the researcher.
- **Secure computing environment:** Registries may opt to develop or employ a virtual or physical data enclave. For virtual enclaves, requestors must have the appropriate technology in order to access the environment. For physical enclaves, requestors must access the data in-person at a secure computing environment. In-person environments require the appropriate physical space and technology for access. Skilled personnel may also need to be on call in order to address or troubleshoot any issues that arise as external researchers access the data.

For direct access where the external researcher is able to download the data, registries must consider data retention, including how long a researcher can keep the data and what the researcher must do at the end of that period. For example, a registry may determine access to the data is fixed at one year, at which point the requestor must delete the data and provide written confirmation. This method may be the least resource intensive, but it also provides the external researcher with full control over the data. The terms and conditions of data use, including disposal of data, and any enforcement methods should be discussed. This approach may not be ideal for registries providing researchers with access to all registry data.

For direct access via a secure computing environment, registries must have appropriate personnel to grant and revoke access in accordance with the registry policies. As with other access methods, duration of access for both virtual and physical environments may be fixed or dependent on study duration.

For additional questions to consider for providing data access, please refer to Appendix A, Section 5.

Chapter 5. Resources and References

1. Resources

Registries for Evaluating Patient Outcomes: A User's Guide, Fourth Edition¹

Editors: Gliklich, RE, Leavy, MB, Dreyer, NA

Link: <https://effectivehealthcare.ahrq.gov/products/registries-guide-4th-edition/users-guide>

Inter-university Consortium for Political and Social Research (ICPSR): Guide to Social Science Data Preparation and Archiving, 6th Edition²⁹

Link: <https://www.icpsr.umich.edu/web/pages/deposit/guide/index.html>

Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard: Tools for Data Sharing³⁰

Link: <https://mrctcenter.org/resources/?project=tools-data-sharing>

NIH Collaboratory: Living Textbook of Pragmatic Clinical Trials⁴¹

Link: <https://rethinkingclinicaltrials.org/>

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Appendix A. Questions To Consider When Sharing Data With External Parties

1. Questions for Obtaining Data

The following questions may be considered when determining how data will be obtained to allow for sharing data externally:

1. What is the process for obtaining data from the sites?
2. What types of data are accepted?
3. Who has the rights to share data?
4. How much control over the data is retained by the original party sharing the data?
 - a. Who holds ownership of the data once it is shared?
5. How do you secure the rights to the data?
 - a. What uses of the data are allowed within those rights?
6. Do you require a data sharing agreement?
 - a. If yes, does it grant permission for further sharing of data?
 - b. If yes, who are you able/not able to share data with?
 - c. If yes, what types of data are you able to share (de-id/id/linking)?
 - d. If no, what is your process for obtaining permission to share data?
 - e. If yes, are you willing to share an example contract?
7. What checks are done on the data before allowing others to access it?
 - a. Who performs these checks?
8. What security measures are in place to protect the data when obtaining and storing the data?
9. What roadblocks do you expect to encounter when obtaining data?
 - a. How will these be handled?

2. Questions for Governance

The following questions may be considered when determining the registry governance for sharing data externally:

1. What is the governance structure of the registry?
2. Who is (what committees are) involved in the oversight of sharing data?
 - a. What is each person's (committee's) role overall?
 - b. What is each person's (committee's) role in reviewing requests for data access?
 - c. What interplay between committees is required to successfully share data?
3. Who is on each committee?
 - a. What types of roles do they fill (subject matter expert, statistician, etc.)?
 - b. How are they chosen?
 - c. Are there term limits?
 - d. How many people are on each committee?
 - e. Is this publicly available?
4. How does the committee operate (in person meetings, virtual meetings, etc.)?
 - a. How are the committee processes documented (e.g., committee charter, bylaws)?
 - b. Who manages/owns these processes (e.g., respond to emails, schedule meetings, etc.)?
5. What constitutes agreement for a committee (majority vote, unanimous decision, etc.)?
6. How is the budget determined for data access requests?
 - a. Who/What funds the sharing of data?
7. Who develops/developed the policies for data sharing?

- a. What stakeholders are/were involved in the development process?
- b. How frequently are the policies updated?
- 8. How are registry communications handled?
- 9. What roadblocks do you expect to encounter with registry governance?
 - a. How will these be handled?

3. Questions for Reviewing Data Access Requests

The following questions may be considered when determining how data access requests will be reviewed for sharing data externally:

- 1. What is the process for submitting a request for accessing data?
 - a. Is this process publicly available?
 - b. How does this differ by data type (aggregate summary-level, de-identified, identified, linked)?
- 2. What is the process for reviewing data access requests?
 - a. Who reviews the data access requests?
 - b. How long does the review take?
- 3. Who is allowed to access the data (internal/external researchers, citizen scientists)?
 - a. What types of data are each party allowed to access (aggregate summary-level, de-identified, identified, linked)?
 - b. How do you determine if a study is feasible with the data in the registry?
- 4. What are the key criteria for allowing data access (merit, conflict of interests, etc.)?
 - a. Which criteria are grounds for immediate denial?
 - b. Which criteria allow for more information to be obtained from the requestor?
- 5. If a request for data access has a similar question as an existing research project, what is the process for handling that request?
- 6. What are the expectations for communication plans?
 - a. Does the registry need to review publications before submission?
 - i. If yes, what is the process for reviewing publications before submission?
- 7. How is the decision communicated to the requestor?
 - a. If the decision is to deny the request, is there an appeal process?
 - i. If yes, what is the appeals process?
 - b. Are the decisions publicly posted?
- 8. How is the registry described and/or acknowledged in publications?
 - a. What is the process for ensuring this happens?
- 9. What roadblocks do you expect to encounter with reviewing requests?
 - a. How will these be handled?

4. Questions for Developing a Data Use Agreement

The following questions may be considered when developing a data use agreement for the purposes of sharing data externally:

- 1. Who is the agreement between?
 - a. Who must sign the agreement?
 - b. Who is held responsible for the contents of the agreement?
- 2. Who holds ownership over the data?
- 3. What rights to the data, if any, are provided to the researcher?
 - a. What rights to the data are retained by the registry?
- 4. Who is allowed access to the shared data?
 - a. Can the data be shared within the researcher's institution?
- 5. What security measures must be taken by the researcher to protect the data?

6. What are the terms for use and manipulation of the data?
 - a. If de-identified, is re-identification allowed?
 - b. Is linking the data to other data sources allowed?
 - c. What are the minimum counts per strata allowed for publication of results?
 - d. Can a researcher use the data to address research questions other than those originally submitted and approved?
 - e. Is approval from an IRB required for the study?
7. How long is the agreement valid for?
 - a. How long does the requester have access to the data?
 - b. How should the data be handled at the end of the access period?
 - i. If using a data enclave model, who is responsible for revoking access?
 - ii. If sending a data file to the requester, what should the requester do at the end of the access period (e.g., delete with written verification)?
8. Is citation of the registry data required in publications?
 - a. How should it be cited?
9. What role does the registry have in communications using the data?
 - a. Is review and/or sign-off of abstracts/manuscripts by the registry required prior to submission?
 - b. Is the requester free to publish whatever they would like to using the registry data?
10. How will the agreement be enforced?
 - a. Will the registry conduct audits to ensure compliance?
 - b. What action will be taken if the terms of the agreement are broken?

5. Questions for Transferring Data to External Parties

The following questions may be considered when determining how data may be shared externally:

1. How is the data shared with requesters after approval (secure file transfer, data enclave, secure computing environment)?
 - a. How does this differ by data type (de-identified, identified, linked)?
 - b. If sending data to researchers, what is the process for transferring the data?
2. What security measures are in place to protect the data when sharing externally?
3. What are the requirements for data retention for the requestor?
 - a. How long can a researcher keep the data?
 - b. What must the researcher do with it once they are done or the period ends?
 - c. How is this enforced?
4. What roadblocks do you expect to encounter with transferring data?
5. How will these be handled?

Appendix B. Sample Data Use Agreement

NOTE: This example contract does not substitute for appropriate legal involvement and/or review during the development or carrying out of the contracting process. Registries should consult with their own legal advisors prior to developing, formalizing, and/or implementing contract language.

Data Use Agreement

[This is a sample framework only. There are a number of areas for registries to consider. In the event the researcher is an individual (and not an entity), then this Sample Agreement may be modified accordingly. A Registry's actual Data Use Agreement should be reviewed and finalized with the input and approval of legal counsel.]

[Name of Registry], located at [Registry Address] ("Registry") and [Name of Research Entity], located at [Researcher Address] ("Researcher"), enter into this Data Use Agreement ("Agreement") as of [Effective Date] (the "Effective Date").

Background

[May consider inserting a background of the Registry, e.g., its mission, purpose, how the Registry came to possess the Data, general overview of underlying Data contributors, reason(s) for sharing the Data]

A description of the data to be shared hereunder (the "Data") is set forth on Exhibit A attached to this Agreement.

1. Permitted Uses of Data

- a.** Registry hereby grants to Researcher the right to access and use the Data for the purpose expressly set forth in this Agreement.
- b.** Researcher shall use the Data solely to perform the Research (and related activities) described in Exhibit B attached to this Agreement (the "Research"). Any other uses are strictly prohibited without the express prior written permission of Registry. To conduct additional or different research, Researcher must submit a separate proposal to Registry. Any such additional/different research must be approved by Registry and set forth in either an amendment to this Agreement or a subsequent data use agreement with Registry.
- c.** Researcher shall perform the Research and use the Data in strict compliance with: (i) this Agreement; (ii) all applicable laws, rules and regulations (including but not limited to the Health Insurance Portability and Accountability Act of 1996 and all regulations implements thereunder, ("HIPAA"); (iii) all Registry policies, procedures, and governance documents made available to Researcher; (iv) all regulatory approval documents (including but not limited to approvals of Institutional Review Boards ("IRBs"), patient informed consent forms, and patient HIPAA authorization forms; and (v) any documentation submitted by Researcher to Registry in order to gain access to the Data (e.g., Data access request forms, Research proposals).
- d.** Researcher shall be responsible for performing the Research, overseeing Research personnel and for overall compliance with this Agreement. Registry shall have no obligations with respect to any aspects of the Research.

e. Researcher shall use appropriate safeguards to prevent use or disclosure of the Data other than as provided by this Agreement. Researcher shall notify Registry within [may consider inserting a specific timeframe, e.g., two (2) business days, or a more general requirement, e.g., immediately/promptly upon discovery] of any uses or disclosures of Data not permitted by this Agreement.

f. To the extent applicable, Researcher shall obtain and maintain throughout the Research the relevant IRB's permission to use the Data for purposes of the Research. Researcher shall provide Registry with all written evidence of such IRB approvals upon request.

g. Researcher may make available the Data only to those persons expressly identified as Research personnel in Exhibit B. Any other personnel may require an amendment to this Agreement or a separate data use agreement with Registry.

h. Registry (or its agents) may audit Researcher's use of the Data to ensure compliance with this Agreement. Any such audits will be conducted during Researcher's regular business hours with reasonable advanced notice and consideration for Researcher's business operations. Researcher will cooperate, and will ensure that all Researcher personnel will cooperate, with the auditors and will make all records and materials available to them.

i. [May consider inserting other restrictions that may be desirable, e.g., prohibitions on using the Data for specific purposes, use of Data within specific geographic locations only]

2. Cost [or No Cost]

a. Registry is making the Data available to Researcher at no cost to Researcher. [If payment is desired, it may be beneficial to add payment terms, e.g., invoicing procedure, payment due dates].

b. Researcher bears all costs and expenses incurred by Researcher to access and use the Data, and conduct the Research.

3. Representations of Researcher

a. Researcher represents and warrants that (i) it is duly incorporated or organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization; (ii) it has the power, authority and legal right to enter into this Agreement and to perform the activities contemplated hereunder, and that it has taken all necessary corporate action to authorize execution of this Agreement to the extent required; (iii) it has obtained or will obtain, to the extent required, all necessary consents, approvals and authorizations of governmental or regulatory authorities required to be obtained related to the performance of this Agreement and the Research; and (iv) the execution and delivery of this Agreement will not conflict with or violate any requirement of any applicable law or regulation and does not conflict with or constitute a default under any contractual obligation enforceable against it.

b. [Depending on the nature of the Data, it may be advisable to add detailed security requirements for Researcher to follow, e.g., use of encryption, password security

requirements, separation of Data from other datasets, linking Data with other datasets. Security requirements also may be set forth in a Registry policy cross-referenced here].

4. Limitation of Liability

[May consider including a cap on liability/damages].

5. Indemnification

[May consider including indemnification language (e.g., “Researcher shall indemnify, defend, and hold harmless Registry and its officers, employees, agents, and representatives from and against any and all claims, damages, losses, fees, expenses, and liability arising from use of the Data.”)];

6. Disclaimer

[May consider including a disclaimer of warranties related to the accuracy, integrity, reliability, or completeness of data, as well as a disclaimer of standard warranties of title, non-infringement, merchantability, fitness for a particular purpose. May also consider adding language so it is clear that underlying registry data contributors have no responsibilities regarding the Data.]

7. Data Ownership; Confidentiality

- a. All Data is and shall remain the sole and exclusive property of Registry. No ownership rights in or to the Data are transferred to Researcher hereunder.
- b. Researcher agrees that it will not disclose to others or use for its own benefit or the benefit of others, any Data or other Confidential Information disclosed by Registry in the course of this Agreement. For purposes of this Agreement, “Confidential Information” shall mean methods, processes, know-how, policies, procedures, templates, and other non-public confidential information of Registry. All Confidential Information is and shall remain the confidential property of Registry. Researcher shall keep the Confidential Information in strict confidence and may not use or otherwise disclose the Confidential Information to any third party without the prior written consent of Registry. Researcher shall notify Registry within [insert timeframe, e.g., two (2) business days] of any uses or disclosures of Confidential Information not permitted by this Agreement.
- c. [May consider adding language about publicity/use of each party’s names, e.g., if Registry wants to publicize the fact that Researcher is accessing/using the Data].
- d. [If inventions are contemplated, may consider adding applicable invention ownership/rights language.]

8. Term and Termination

- a. Term: The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as set forth in this Section 8, shall remain in effect [may consider a specified term; e.g., set number of years, or a broader end date, e.g., until completion of the Research].

b. Termination: Either party may terminate this Agreement upon [insert number] days prior written notice to the other party for any reason or no reason. Registry may terminate this Agreement immediately upon written notice to Researcher if Registry is no longer permitted to share the Data with Researcher. In addition, either party may terminate this Agreement upon written notice to the other party in the event of a material breach of this Agreement by the other party, which material breach is not cured within [insert number] days after receipt of written notice thereof.

c. Effect of Termination: [Insert the Registry’s requirement for post-termination activities, e.g., will Data need to be returned or destroyed, can Researcher continue using the Data for a limited period].

9. Publications

a. [Registry may insert its desired publication requirements or otherwise attach or cross-reference its policy governing publications].

b. [Registry may consider adding specific attribution requirements, to ensure that all references of Registry as the source of Data are accurate and consistent in any publications].

10. Miscellaneous

[Registry may consider adding customary contract boilerplate, such as clauses related to assignment, notices, survival, counterparts, force majeure.]

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed this Agreement as of the Effective Date.

REGISTRY

RESEARCHER

By: _____

By:

Print Name: _____

Print Name:

Title: _____

Title:

Date: _____

Date:

EXHIBIT A

Data

[May consider adding: (i) description of the Data being shared; (ii) format of the Data; (iii) method of Data delivery; (iv) classification of the Data (e.g., de-identified data); (v) any specific restrictions on Data usage depending on the nature of the Data (e.g., can Data be used for commercial purposes, is use of the Data limited to academic endeavors, can Researcher benchmark/compare the Data with its own data).

EXHIBIT B

Research

[May consider adding: (i) name of study (including name and ID number of protocol); (ii) detailed description of the Research being conducted and how Data will be used; (iii) whether/which IRB approvals are required; (iv) names/titles/locations of Researcher personnel accessing/using the Data; (v) where the data will be accessed/hosted; (vi) Research timelines; (vii) Research publications anticipated