Kentucky Health Data Trust Initiative

Best Practices for Building and Managing a Data Use Process for Researchers

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Interagency Governance Workgroup

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Introduction

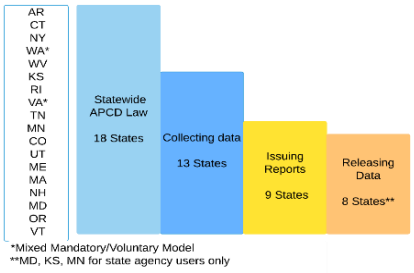
With an operational data warehouse with robust and validated files, the Trust may choose to offer access to qualified researchers who present appropriate methodologies for projects that are consistent with the Trust's mission.

The purpose of this document is to lay out the steps needed to build a structure for researchers to obtain access to the data. For the purposes of this discussion, "access to the data" includes many different models, including but not limited to files in standard format, customized extracts, and user-generated reports within a data enclave. However, since academic researchers are usually less interested in summary tables and files without unique identifiers, the Trust may decide to provide less detailed files to meet the needs of a broader user community.

In keeping with the themes of transparency and collaboration, the process described below identifies opportunities to engage external stakeholders and other interested parties in decision making about access or release. If the Trust does not hold data from sources other than state agencies, then participation by external entities such as health insurers would not be required at that time.

Many of the APCD data access processes and procedures are derived from states' experience with collecting and releasing Hospital Discharge Datasets (HDD). The HDD release model provides many of the "lessons learned." As shown in Figure 1, of the eighteen states with mandatory APCD legislation, half currently issue reports and eight release data to qualified users. As APCD data contributors, states, and researchers become more familiar with data release processes, the collective expertise will increase and continue to inform the roll out of data access policies and procedures.

Figure 1: APCD Data Release, 2015



The steps in this document focus primarily on providing access to academic researchers. APCDs are still exploring the opportunities to link clinical and claims data. As this evolves, data release processes may need to evolve as well to incorporate new permissions.

Specific Actions to Establish Data Access for Researchers

Step 1. Decide which data elements are never released, which ones may be released and which ones do not need to be vetted.*

a. Will direct identifiers ever be available to researchers?

b. Decide whether data will be available in different configurations such as standard extracts, custom extracts, and aggregated summary tables.

c. Decide whether the Trust will work towards creating a "data enclave" that allows complex queries within a secure environment, removing direct identifiers when exported.

d. Decide whether requests need special review for FTC anti-competitive issues.

e. Decide whether to provide a "public use" file, what that would include, and how often it would need to be refreshed with updated data.

f. Decide whether state agencies are required to go through the Data Release Review Committee (DRRC) to obtain access to data for research projects.

Step 2. Determine acceptable uses and users.*

a. What types of research are consistent with the Trust? What ones are not?

b. Is there a blanket rule for types of researchers that will not be granted access to the data?

c. Will the Trust charge fees for preparing files or to access the data?

d. Will the Trust charge fees for reviewing data applications (i.e. application fee)?

e. What types of data products will be available and to whom? Single-use files, multi-use, subscription services, etc.? State agencies, researchers, graduate students, etc.?

Step 3. Determine pre-publication review process. For example, how long before proposed publication do documents need to be submitted to the DRRC? Will the DRRC be reviewing the documents for adherence to privacy rules only (i.e. cell suppression rules, no possibility for re-identification, etc.), for content, methodology, or other?

Step 4. Inventory HIPAA and other state data use requirements.*

a. Develop clear explanation of state law and rule, particularly intersections when data sets are co-mingled.

b. Create policy summaries (if not otherwise available) for prospective users and members of the review committee.

Step 5. Create a Data Release Review Committee (DRRC)

a. Determine the DRRC's scope of authority: is it decision making or advisory?

    i. If an advisory role, who makes the final decision?

b. Will the DRRC be empowered to decide whether:

    i. The research question is consistent with the purpose of the Trust?

    ii. The research methodology is appropriate?

c. Will the DRRC also serve as the HIPAA Privacy Board?

d. Identify DRRC seats: state agencies, payers, providers, consumers, etc.

e. Determine who will chair/facilitate the DRRC.

f. Determine length of term, appointment process, meeting schedule and develop member agreement for members to sign.

g. Obtain nominations and appoint members.

Step 6. Decide whether a pre-publication "scientific advisory review" body is needed. If so:

a. Will it be a subset of the DRRC or will it be a separate entity?

b. Will it be advisory or decision making?

i. If advisory, who has the final authority to let the report be published/disseminated?

c. Determine scope of review – will this committee:

i. Confirm that the analysis conforms to the proposed methodology described in the application?

ii. Weigh in on the validity of the analysis?

iii. Review the analysis for alignment with data display rules (cell suppression size, age groups, three digit zips, etc.)?

iv. Make a determination about whether the report complies with FTC Safe Harbor rules?

Step 7. Build a process flow (see Figure 2, showing how Rhode Island approached this) so that all understand how decisions progress.

a. Provide training to committee members.

b. Create policies and procedures around process.

Step 8. Confirm staffing requirements.

a. Administrative support: managing data use applications, transmitting to the DRRC, fee collection, DUA filing and renewal, data destruction documentation.

b. Technical support: assisting requesters in clarifying data requests, creating and transmitting files, providing support as users start working with the files.

c. Legal assistance for researcher data use agreement drafting (R-DUA).

Step 9. Write researcher data use application form and agreement.

a. Consider building a two step process:

i. Preliminary short application to confirm that the research question can be answered with available data

ii. Longer form application if the data are suitable

b. Determine webpage location for data release materials and any public use files.

c. Create web links to application and informational materials.

d. Create data dictionary and post with informational materials.

Step 10. Create process and timeline for application submission and review, including criteria for evaluating applications. Design and implement data distribution model.

Step 11. Create capacity to provide technical assistance to successful applicants after data files are transmitted.

Step 12. Create capacity for DRRC members to access application materials through a secure portal.

Step 13. Establish method for fee collection, tracking and deposits.

Step 14. Log applications.

a. Staff reviews application and works with requester to resolve questions.

b. Post abstract of request on public website and invite comments for a limited time.

i. Include public comments in review packet on DRRC secure portal

c. Schedule DRRC meeting.

Step 15. Convene the DRRC to review applications based on established criteria.

a. Determine if DRRC meetings need to be open to the public (i.e. are subject to state open meetings laws) and therefore whether DRRC activities and materials have to be posted publicly.

i. If subject to open meeting laws, develop and post meeting schedules, agendas, and minutes publicly

b. Document decisions.

i. If this is an advisory committee, send recommendation to final decision maker and obtain decision

c. Communicate decision to requester.

Step 16. Track approved requests.

a. Ensure that technical process engages and actually produces the necessary data.

b. Collect fees.

c. Deliver files, access keys, documentation, dictionary, etc.

Step 17. Convene "scientific advisory" committee to do pre-publication reviews according to established process.

a. Allow data contributors to review (or delegate this to the scientific advisory committee).

b. Communicate review outcomes to researchers.

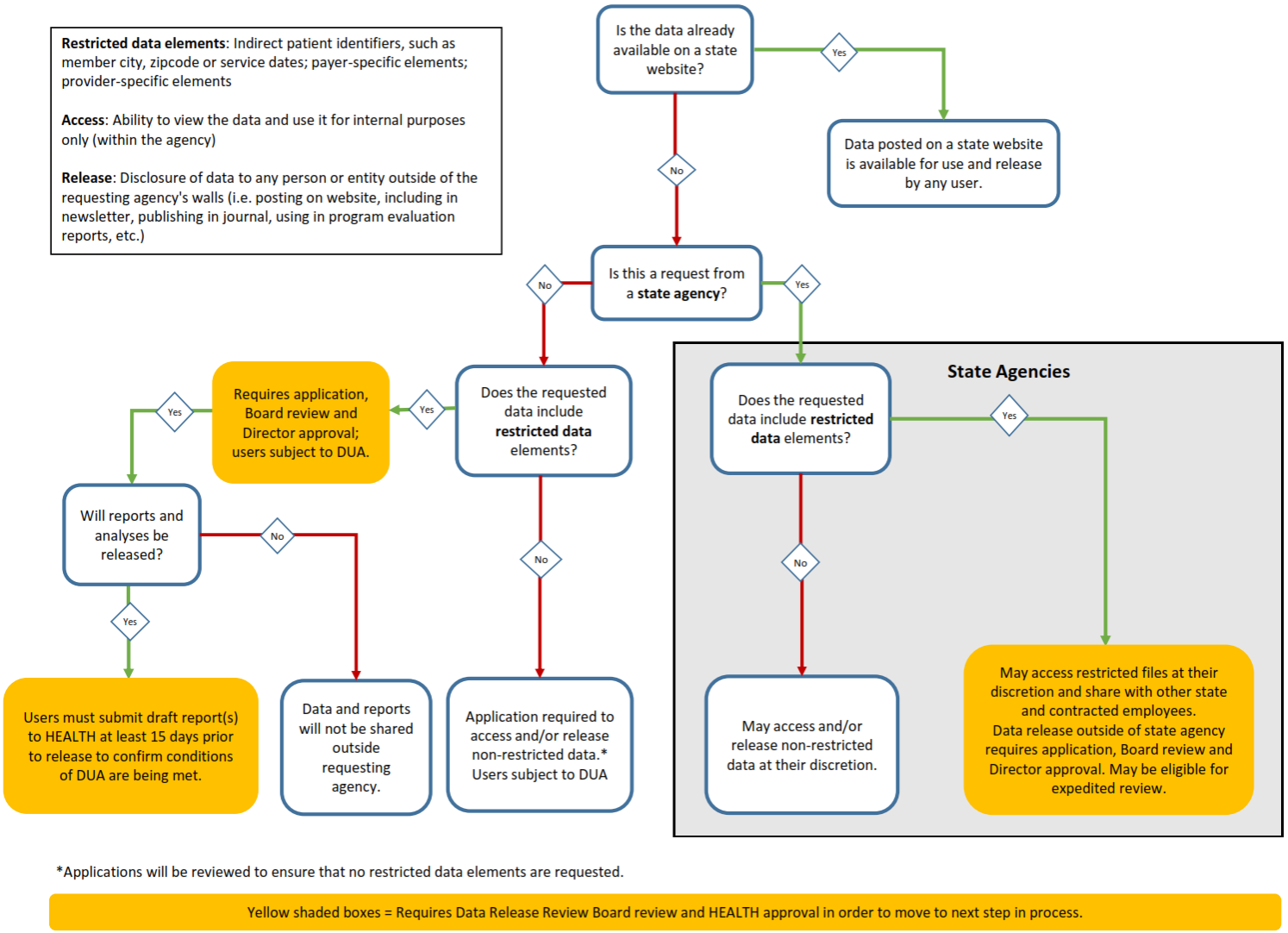
Step 18. "Market" data availability to potential users.

Step 19. Collect feedback about data issues and incorporate into edits.

*In voluntary submission models, this is usually specified in the agreement between the data submitter and the APCD.

Figure 2: Example of a Data Release Flow Chart

Rhode Island APCD - Data Release Flow Chart



*Applications will be reviewed to ensure that no restricted data elements are requested.

Yellow shaded boxes = Requires Data Release Review Board review and HEALTH approval in order to move to next step in process.