

ImproveCareNow Policy and Procedures for Sharing Data

Overview

The ImproveCareNow Data Management Division is charged with quickly supplying data sets to investigators conducting research projects that have been approved by the ImproveCareNow Research Division. The ImproveCareNow Data Management Division does not have oversight of what constitutes an approved/approvable research project. Responsibility for these decisions lies with the ImproveCareNow Research Division. The ImproveCareNow Data Management Division will not release data until the Director of the ImproveCareNow Research Division makes a formal request.

A common procedure and protocol will be used for all data requests. This will be done using a standard request form and could be done on paper or via a web-page. Policies and procedures will be designed so that the default position is to accept the proposal and request for data unless they fail to meet the following:

1. Not qualified (need to define and include in an FAQ)
2. Will not sign the data sharing expectations document
3. Research questions proposed cannot be answered with the ICN dataset.
4. Is not affiliated with or does not have access to an IRB that will provide review and enforce sanctions if the requestor fails to meet the expectations (e.g., re-identifies data). Data sharing expectations document needs to be submitted to the requestor's IRB along with the protocol.

All participating ImproveCareNow physician leads (current and future) as well as qualified researchers requesting to use the data will be provided with the ImproveCareNow Commons and Data Sharing Expectations documents. They will be asked to sign the expectations document that covers expectations about how data can be requested, made available and authored.

Procedure for Sharing Data (Intramural Researchers)

1. All intramural ImproveCareNow members are asked to sign the ImproveCareNow Data Sharing Expectations document as part of participating in the network.
2. When ImproveCareNow member has a research idea for which s/he wants to use the ImproveCareNow database to answer, s/he submits proposed research question(s) and analytic methods plan to ImproveCareNow Research Division Director and Data Management Division Director for preliminary approval.
3. Research Division Director distributes proposal to 2-3 reviewers in the Research Division. The reviewers review, provide feedback and either accept or reject the proposal. In addition to scientific rigor, the proposal is reviewed for evidence of keeping to the community norms set-forth in the Data Sharing Expectations document.

4. If accepted, ImproveCareNow member obtains approval from their own IRB.
5. ImproveCareNow member submits IRB approval letter to ImproveCareNow Research Division Director.
6. ImproveCareNow Research Division Director notifies Data Management Director of IRB approval and any other needed approvals.
7. The ImproveCareNow Research Division Director will send approved requests for data sets to the ImproveCareNow Data Management Division Director and Lead Data Manager. Requests must include contact information for the requestor (email and physical address- FedEx will not deliver to a PO box), which version of the database is being requested (PIBD02, PIBD03, i2b2 when available, or a combination) and the requested media type (CD or DVD).
8. Upon receipt of an approved request and under direction of the ImproveCareNow Data Management Division Director, the Lead Data Manager will create data files as either SAS data set(s) or .csv files. *Note that .csv files are not available for researchers using Excel 2003 due to a limit of 256 columns in Excel.*
9. Once created, the Lead Data Manager will password protect and burn to a CD or DVD depending on file size and site preference.
10. The Lead Data Manager will give CD or DVD to the Project Coordinator for shipping.
11. The Project Coordinator will send the CD or DVD by FedEx, with signature required, to the physical address of the requestor. FedEx will not deliver to a PO Box.
12. The Lead Data Manager will email the password for the data set(s) to the requestor once the CD or DVD has been shipped. Passwords then become the responsibility of the requestor.
13. Any data set(s) sent out will be archived by the Lead Data Manager.
14. The Lead Data Manager will maintain a list of all data sets that are sent out. The list will include the name of the file(s) transferred, the date transferred, the name and address of the recipient, and the location of the file(s) transferred.

Procedure for Sharing Data (Extramural Researchers)

1. External researcher submits proposed research question(s) and analytic methods plan to ImproveCareNow Research Division Director and Data Management Division Director for preliminary approval. The question and plan is reviewed based on scientific rigor and also if the research question can be answered using the ImproveCareNow database.
2. If the proposal receives preliminary approval
 - o The ImproveCareNow Research Division Director sends the Data Sharing Expectations document to the researcher to sign and send back.

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- Researcher submits full proposal to their own IRB for approval as well as to the ImproveCareNow Research Division Director who will review it to ensure it is keeping to the community norms set-forth in the Data Sharing Expectations document.
3. If proposal is approved by the researcher's IRB and ImproveCareNow Research Division Director:
 - Researcher submits IRB approval letter to ImproveCareNow Research Division.
 - ImproveCareNow Research Division Director notifies Data Management Director of IRB approval and any other needed approvals.
 4. Repeat Steps 7-14 from above "Intramural Researchers)

Notes and Exceptions

In order to ease the burden on the ImproveCareNow Data Management Division and to avoid additional requests within research projects, only complete data sets will be provided. Individual researchers should keep this in mind when developing their research protocols with IRBs.

The aim of the ImproveCareNow Data Management Division is to respond to data requests within 5 business days, but this may not always be possible. Every attempt will be made to communicate expected timing of data release with both the requesting researcher and the ImproveCareNow Research Division Director.

The ImproveCareNow Data Management Division will be available to assist with clarifications revolving around the structure and content of the data sets provided, but will not be a resource for IRB issues.

Any requests for data sent to the ImproveCareNow Data Management Division directly will be referred to the ImproveCareNow Research Division Director.