PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

GUIDELINE ON SHARING CLINICAL DATA WITH EXTERNAL ENTITIES

PURPOSE:

The purpose of this Guideline is to establish requirements to ensure that the sharing of clinical data with external entities, both non-profit and for-profit organizations, is consistent with the charitable mission of Partners HealthCare ("Partners") and its affiliated Hospitals and Institutes, as well as with applicable Partners policies and federal, state, and local regulations and laws. This Guideline is not intended to govern the sharing of clinical data with outside health care providers for the purpose of patient care; with other entities for healthcare operations (e.g., such as obtaining products or services); or to restrict data sharing that may be required by law (e.g., required reporting to public health agencies or by federal funding agencies). This Guideline is also not intended to govern the sharing of research data (information generated or collected as part of a research study or clinical trial) with external third parties. Sharing of research data should adhere to NIH or other funder policies, and conform to data sharing stipulations as outlined in the appropriate research study consent forms.

DATA SHARING REQUESTS:

The intent to share potentially identifiable clinical data with a Third Party must be reviewed and approved by the Partners Clinical Data Sharing Committee ("Committee") prior to release of the data. ('Identifiable' pertains to the identity of patients or providers, please see Definitions for more information). It is the responsibility of Investigators, Clinicians, or Administrators intending to share data with a Third Party to determine if the data set can be used to identify patient(s) and/or providers. Every Data Sharing arrangement covered by this Guideline must be covered by an appropriate Data Sharing Agreement that has been reviewed, approved, and signed by Partners Innovation in consultation with OGC as necessary, except as otherwise determined by the Committee. If Data Sharing is part of an IRB approved study, and conforms to contractual obligations under a sponsored research agreement, and is covered by federal funding agency Data Sharing provisions, it is exempt from Committee review.

To maximize collaborative, commercial, and potential revenue opportunities and to address privacy, security, conflict of interest and other concerns, we expect data sharing requests be sent to the Clinical Data Sharing Committee.

GUIDELINE:

Requirements: The sharing of potentially identifiable clinical data from Partners with any Third Party must comply with all applicable regulatory requirements, including, but not limited to, requirements relating to informed consent and authorization (or approved waiver of informed consent and authorization); the HIPAA Privacy Rule; and all pertinent federal and state laws and regulations. Data Sharing must be consistent with the charitable mission of Partners and its affiliated Institutions. It must be reasonably likely to improve patient care, related operations, or advance biomedical knowledge.

Data may be used by the Third Party recipient organization only for the purpose stated in the recipient's data sharing agreement. Neither the Third Party recipient nor the Partners or affiliated Institution employee, staff or faculty participating in or supporting a specific data sharing request may transfer the Data to any other entity, party, or organization. To the extent possible, when shared, Data should have all 18 HIPAA or other identifiers irreversibly deleted (no Protected Health Information (PHI)) and no link or code should be maintained for re-identification. (Patients or providers may still be identifiable even when all PHI has been removed). Data need to be properly encrypted and securely transferred (http://rc.partners.org/security). Whenever appropriate, and to the extent possible, Data that are enhanced by a Third Party should be shared back with Partners and may be considered a nonfinancial contribution-in-kind. Third Parties are not allowed to leverage Data for marketing activities.

Considerations: Financial or nonfinancial compensation/remuneration[1], for the Data may be required as determined by the Committee. Payments must be in accordance with other Committee, Partners and IRB policies, for example policies relating to incentive payments. The following will be taken into account:

a. The actual costs incurred in preparing and submitting Data to a Third Party,

b. The associated maintenance cost of the underlying support infrastructure (e.g. data storage),

c. The fair market value ("FMV") of any de-identified Data. FMV can be defined as an estimate of the value or price that a similar service or solution would receive in the open market. The Committee will consider FMV estimates on a case-by-case basis, taking into account the available relevant information. FMV methodology will be determined by the Committee and will be reviewed on a periodic basis.

d. Additional costs may be incurred by the Third Party for analytic services associated with the Data Sharing, including the development of summary-level reports.

Conflict of Interest: Any Partners or affiliated Institution employee, staff or faculty participating in or supporting a specific data sharing request must comply with applicable conflict of interest policies including, but not limited to, the Partners Policy for Interactions with Industry and Other Outside Entities. Any Partners or affiliated Institution employee, staff or faculty involved in obtaining Data, or in obtaining informed consent and authorization for obtaining or sharing Data, or in Data Sharing with a for-profit company or other entity, may not have any financial interest in that same entity that exceeds the current thresholds permitted by applicable Partners policies pertaining to participation in clinical research.[2] In addition, such individuals may not have a fiduciary relationship[3] with a for-profit entity recipient of Data.

Committee: A Partners Clinical Data Sharing Committee shall be established to oversee implementation and ensure consistency among all Partners affiliated institutions on issues pertaining to data sharing. The Committee shall act in accordance with the Partners Guideline on Sharing Clinical Data with External Entities. The Committee is authorized to establish additional guidelines and/or policies for specific data categories as needed; communicate these requirements to the research community; and to oversee review, approval and monitoring of data sharing requests to ensure these arrangements do not cause patient or institutional harm and are in accordance with the general principles articulated in this Guideline.

ROLES AND RESPONSIBILITIES:

Investigator or Administrator Data Sharing Responsibilities:

- It is the responsibility of Investigators, Clinicians or Administrators intending to share data with a Third Party to determine if the data set can be used to identify patient(s) and/or providers.

- It is the responsibility of Investigators, Clinicians, or Administrators intending to share data with a Third Party to bring data sharing requests to the Committee for review and approval prior to sharing the data or executing a Data Sharing Agreement.

- Once the request has been approved and the Data Sharing Agreement executed, the aforementioned Investigator, Clinician, or Administrator is responsible for sharing the data in

[1] HIPAA regulations prohibit the "sale" of PHI (including a Limited Data Set) without the individual's written authorization for the sale, limiting any remuneration a HIPAA-covered entity can receive in exchange for PHI in the absence of such authorization to the entity's reasonable costs to prepare and transmit the PHI to the recipient.

[2] This Guideline adopts that rule even though sharing clinical data does not constitute participating in Clinical Research or Basic Research under the Harvard Medical School conflict of interest policy. See more specifically http://www.hms.harvard.edu/integrity/conf.html.

[3] A fiduciary relationship is created when one serves on the Board of Directors or has an executive position with a company.

accordance with the instructions/approval of the Committee and in accordance with requirements outlined in the Partners Guideline and executed Data Sharing Agreement.

Partners Innovation Data Sharing Responsibilities:

- Partners Innovation is responsible for negotiating and executing Data Sharing Agreements. The Data Sharing Agreement must be consistent with any terms and/or conditions the Committee attached to its approval of the Data Sharing request.

DEFINITIONS:

Data: means clinical data that are generated or collected as part of a healthcare encounter and are maintained in a formal patient record (e.g. imaging, molecular information, laboratory results). The following types of data are included within this definition:

- Aggregated Data: Summary-level data that does not include individual level information.
- Fully Anonymized Data: Individual-level data in which all 18 HIPAA or other identifiers are irreversibly deleted (no Protected Health Information) and no link or code is maintained for re-identification.
- Coded Data: Individual-level data that excludes the 18 HIPAA or other identifiers but does include a link or code that can be used to re-identify individuals. This information may be considered "indirectly identifiable."
- Limited Data Set: Individual-level data that excludes 16 categories of HIPAA direct identifiers but may include city, state, ZIP code, elements of date, and other numbers, characteristics or codes not listed as HIPAA direct identifiers.
- Identifiable Data: Individual-level data that includes HIPAA identifiers or that because of specific details is inherently identifiable.

Identifiable: Pertains to the identity patients or providers. In addition to PHI or HIPAA identifiers, identity considerations include cohort size, rare disease(s), unique combination of patient traits, any data set that includes data in line-item format (e.g. each individual patient has their own line in the Data set or has a unique image).

Data Access: Authorization of a Third Party to interact directly with specified data files within the Partners computing system (i.e., "within the Partners firewall") without the ability to extract, edit or add data to the file.

Data Transfer: Extraction and movement of data from within Partners to a Third Party.

Data Sharing: Data Access or Data Transfer to a Third Party.

Third Party: An individual or entity external to Partners and its affiliated institutions.

Data Sharing Agreement: a written agreement between Partners and the Third Party recipient, signed by the Third Party recipient and consistent with any terms and/or conditions the Committee attached to its approval of the Data Sharing request.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Partners Policies on Interactions with Industry and Other Outside Entities
Informed Consent of Research Subjects
Portable Device Security

REFERENCES:

45 CFR part 46
45 CFR parts 160 and 164