PARTNERS HEALTHCARE SYSTEM
GUIDELINE ON SHARING CLINICAL DATA WITH EXTERNAL ENTITIES - REFERENCE CHART

This chart is designed as a quick guide to Data Sharing.
Please see the attached Guideline for further information.

Definitions

Third Party: Any individual or entity external to Partners and its affiliated hospitals and institutes.

Committee: The Partners Clinical Data Sharing Committee ('Committee') will review and approve Data Sharing requests and review issues that arise relating to Data Sharing. The Committee is responsible for system-wide implementation and oversight of the Partners Guideline on Sharing Clinical Data.

Data: Refers to clinical data that are generated or collected as part of a healthcare encounter and are maintained in a patient record (e.g. history & physical, imaging, laboratory results). This *excludes* research data: information generated or collected as part of a research study or clinical trial.

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

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).

Guidelines for Data Sharing requests with ANY Third Party

Partners Guidelines	Notes:
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. 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. **This Guideline is not intended to govern the sharing of research data with external third parties. Sharing of research data should adhere to NIH or other funder policies, and conform to data sharing stipulations outlined in the appropriate research study consent form. 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.** **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.**	• Governance: Office of the Chief Academic Officer, and the Partners Clinical Data Sharing Committee. • ***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.***

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. If so, it is the responsibility of Investigators, Clinicians or Administrators 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 accordance with the instructions/approval of the Committee and in accordance with requirements outlined in the Partners Guideline and executed Data Sharing Agreement.	• Data Sharing Agreements will be negotiated and executed by Partners Innovation in consultation with OGC, where appropriate.
Conflict of Interest: Any Partners individual participating in a specific data sharing request, and is or has been involved in the design, conduct, or reporting of results, must comply with the current Partners conflict of interest policies.	• http://www.partners.org/Assets/Documents/About-Us/OII/OII_Policy.pdf
Financial: Financial or nonfinancial compensation/remuneration may be required as determined by the Committee.	•
Basic Regulatory Requirements: • Common Rule (45 CFR 46): Informed consent or approved waiver and other applicable requirements; http://www.hhs.gov/ohrp/humansubjects/commonrule/ • FDA regulations – see Appendix I • HIPAA Privacy Rule (45 CFR part 160, 162, & 164) http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ • All federal, state, and local regulations and laws pertinent to data security and patient privacy.	•
Data Delivery, Use, and Transfer: • Whenever possible, Data should have all18 HIPAA or other identifiers irreversibly deleted (no Protected Health Information) and no link or code should be maintained for re-identification. • Data may only be used for the purpose identified in the data sharing agreement. • Data need to be properly encrypted and securely transferred (http://rc.partners.org/security) • Data may not be transferred by the Partners 'initiator' or the third-party recipient to another entity, party or organization. • Returning Data that has been enhanced by external Third Parties should be considered. • Third Parties may not use Data for marketing activities.	•