

Penn Medicine Guidance on Sharing Data and Biological Samples with Third Parties

Penn Medicine recognizes the value of patient data, biological samples and scientific collaboration in advancing science, clinical care, and other important initiatives consistent with Penn Medicine's mission and values.

We must at a minimum always comply with all applicable laws, regulations and Penn policies, as well as limitations in any informed consent regarding patient data and samples. In addition, based on principles of stewardship of data and samples, Penn Medicine believes protections must often go beyond compliance requirements. For example, federal HIPAA protections or requirements do not apply to data that meets the HIPAA deidentification standard, yet Penn Medicine believes uses of such data must be in alignment with its mission. Similarly, even if lawful, Penn Medicine believes in avoiding even the appearance of the sale of deidentified data or samples.

Because Penn Medicine believes it is critical to preserve the trust of our patients and research subjects, we are committed to sharing patient data and samples according to the guidance described here.

RISK AREAS THAT WARRANT CAUTION AND ATTENTION

Penn Medicine recognizes expanding and varied risks associated with poor stewardship of both identifiable and deidentified data and samples when considering requests from outside organizations.

Many organizations, including but not limited to biopharma, commercial labs, operational service providers, medical associations and other not-for-profits, are increasingly recognizing the value of patient data and samples. These and other third parties frequently propose **secondary uses of deidentified data and samples**. These uses may be, for example, for product development or for undefined commercial purposes. Some of these proposals also include offers of **free or discounted services** or compensation for **unlimited or unrelated uses** of deidentified data and samples.

The deidentification standard under HIPAA is becoming less protective and less reliable as the **possibility of reidentification is increasing**. This increased risk that individuals can be reidentified is due to the greater availability of other data sources coupled with growing expertise in data science and advances in computing power.

Genetic information may be **inappropriately mined** to reveal detailed information related to personal health, including existence or predisposition to disease, likely drug response, ancestry and other information, impacting patients as well as their family members.

The U.S. government has publicly reported that some **foreign entities** are engaging in activities to gain access to and collect Americans' health information, particularly genetic information.

Lastly, some companies are seeking to directly contact Penn Medicine patients and research subjects to

request they sign **additional HIPAA authorizations** or take other steps to use and share their PHI for additional purposes. In light of these risks, the following Guidance applies:

GUIDANCE REGARDING SHARING DATA AND SAMPLES

When otherwise lawful, Penn Medicine may only share patient data, whether identifiable or deidentified, whether primary or secondarily analyzed, and samples under the following circumstances:

Project-Specific Sharing Only. With (1) academic, not-for-profit, or for-profit entities that are collaborating with Penn Medicine or otherwise directly supporting a specific product, service, project or defined scientific collaboration, and that entity will use such data or samples as part of that specific work; or (2) a non-collaborating not-for-profit entity where there is no reasonable alternative source for that entity and the use is consistent with Penn Medicine's mission and values.

Secondary Uses Must Be Restricted. Secondary uses of data and samples are generally prohibited unless they are for quality improvement of contracted services and products or other uses consistent with Penn Medicine mission and values.

Participation in registries, consortia and similar collaborative activities where additional uses are anticipated is permitted if (1) use by academic medicine centers, whether us or our peers, is robust and (2) there is a transparent review process with subject matter expertise and known criteria focused on scientific merit.

It is not permissible to share data or samples for unspecified purposes.

Further, free or discounted services, or compensation to Penn beyond what is necessary for Penn to recover its costs associated with the project, should prompt heightened scrutiny regarding acceptable secondary uses as described above.

Documentation Required. There must be a clear description in written agreements of the intended uses and follow-on uses by the recipient and others. Where deidentified data and samples are involved, such agreements should also prohibit attempts to reidentify. Further, such agreements should require that data and samples be destroyed or returned at the conclusion of the project. If this is not feasible for data, there should be a clear understanding and acceptance of the justification as well as safeguarding of such data according to HIPAA and industry standards.

Situations in which additional scrutiny must be applied:

- **Extra or expansive genetic sequencing.** Proposals involving generating genetic information on patients should be reviewed carefully. This includes, but is not limited to, requiring that the company sequences only what is ordered by a Penn researcher or provider and ensuring that the scope of genetic data generation is consistent with what is written in any applicable research agreement.
- **Foreign entities.** A close review should be applied to any proposal to provide data or samples to third parties outside the U.S., whether for-profit or not-for-profit or academic, where a special

risk may exist, such as a potential national security risk, possible unknown or questionable uses of data or samples, the derivation of genetic information from provided data or samples, or where Penn Medicine has limited ability to exercise oversight. Penn Medicine's Export Controls Compliance Director routinely reviews all agreements submitted through PennERA and RIS as a matter of course. Any agreements not in these systems must be provided directly to the Export Controls Compliance Director for review.

- **Third Parties Contacting Our Patients and Research Subjects.** Additional scrutiny should be applied to companies proposing to contact patients and research subjects for their own purposes – perhaps seeking additional HIPAA authorization for new uses of data. While we do not have the same degree of concern about data uses when a patient is signing a voluntary authorization, we should ensure that any additional authorization is voluntary and does not conflict with any prior Penn Medicine authorizations or policies. We should also ensure that such additional authorization is in alignment with our mission and values.

CONTACTS FOR QUESTIONS OR REQUESTS FOR EXCEPTIONS

- Dr. C. William Hanson, Chief Medical Information Officer, if related to clinical care, quality improvement, product development or operational support.
- Dr. Emma Meagher, Vice Dean, Clinical Research and Senior AVP Human Research, if related to data or samples derived from non-oncology research participants.
- Dr. Bob Vonderheide, Abramson Cancer Center Director and Vice Dean of Cancer Programs, if related to data or samples derived from oncology research subjects.
- Dr. Kate Nathanson, Director of Genetics, Basser Center, if related to genetics / genomics matters.
- Lauren Steinfeld, Chief Privacy Officer, Penn Medicine, for general questions regarding this Guidance.

Issues warranting escalation will be referred to the Penn Medicine Data Governance Leadership Committee for consideration.