Privacy, Policy, and Health Data

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PHIPA –
What it means (and what it doesn't)

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- In addition, my views do not necessarily represent the views of the organization as a whole.

Research under PHIPA

- PHIPA is one of the most misunderstood pieces of legislation I've ever observed.
- PHIPA is fundamentally an enabler of the work that you do in clinical trials, despite the widespread perception that it's a barrier.
    - Sets out authorities for conducting research on the foundational understanding that a) health research is an important thing and b) basic protections for the personal health information are expected.
    - Avoids codifying exactly what research conduct is or is not, allowing enormous flexibility in what can be done
    - Specifically, defines research as PHIPA defines research as "a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research" .
- The IPC – the regulator of PHIPA – has as one of its key priorities "Trust in Digital Health", which specifically refers to the promotion of the (privacy-protective) use of personal health information for the public good.

Research expectations under PHIPA

- Research is allowed as a general use by the custodian, with a research plan and REB approval.
- Disclosure for research requires an application in writing, a research plan, and a copy of an REB approval.
  - The research plan must describe the affiliation of researchers, the nature and objectives of the research, and the anticipated scientific benefit.
  - The REB must consider the data minimization principles, appropriate privacy and security safeguards, the public interest of the research, and the practicality of obtaining consent to perform the research, and must specify any conditions for the research.
  - The discloser and researcher must have an agreement.
- The researcher must comply with the REB, must use the PHI only for the specified purpose, must not publish identifiable information, must not disclose PHI except by law, must not make contact with the subjects without their consent, and must notify in bases of breach.

UTOPIAN Decision (PHIPA Decision 243)

- The recent UTOPIAN decision (PHIPA Decision 243) was a major finding about the conduct of research studies, and found that
  - there was a failure to comply with the section 44 PHIPA obligations for research
  - the IPC found that the university failed to provide custodians with a research plan and the REB decision approving the plan.
  - the university collected personal health information without valid REB approval at times when the REB approval had lapsed, and failed to provide notice of one of these breaches.
  - the investigator was also not satisfied with the university's claim that the Provider Agreement was effectively amended by sending the amendment emails about changes to the collection, finding that the university should have taken steps to ensure that custodians clearly, unambiguously and unequivocally communicated their acceptance of the proposed amendment to the Provider Agreement, instead of relying on silence.

Key Takeaways from PHIPA 243

- Researchers must ensure that they provide custodians with all required information under PHIPA so that custodians can make an informed decision about their participation in a health research project.

- When significant amendments are made to a health research plan, researchers should take steps to ensure custodians clearly and explicitly communicate their acceptance of the proposed amendments. For instance, in this case, copies of the revised Provider Agreement with the updated consent form could have been sent with the request that custodians execute these, by including a link in the email for the custodians to click to indicate acceptance, or similar means.

- Researchers should reconsider their traditional methods of notifying patients about research (by way of posters in physicians' physical offices) and reassess their effectiveness particularly in a context of virtual health care. For instance, a research plan could be varied in such a way as to propose an alternative and more effective form of notice where virtual care is more prevalent.

- Researchers should be transparent and maintain open lines of communication with custodians about the collection and use of personal health information to build up their trust in the research

- Researchers should periodically reassess the robustness of their de-identification procedures to minimize re-identification risks that evolve over time with changes to the research plan and/or changes to the dynamic research environment.

Other Relevant Points

- REB approval does not grant **legal** authority to collect, use, or disclose PHI!
- PHIPA specifies that only one REB approval is required for a research project.
  - Multiple approvals are the business of the organizations requiring them, not of the law.
- Your organization's protocols for research – including for clinical trials - must be robust, and can help set the minimum standards for agreements for data sharing.
  - It sets the law and legal expectations generally for you.
- Getting consent from individuals: PHIPA specifies this as a legitimate use when the personal health information used by the custodian for this purpose is limited to the name and contact information of the individual and the name and contact information of the substitute decision-maker, where applicable.

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