Guidelines for Secondary Use of Personal Health Information for Research

This section will:

- summarize the requirements under PIPA regarding patient consent for the use of personal health information for research purposes
- identify key considerations for physicians who wish to disclose personal health information to external health researchers

Physicians must obtain express consent for secondary uses, such as research, before using personal health information that was initially collected for clinical purposes. While express consent for the change in use from clinical to research purposes can be either written or verbal, having the patient sign a consent form is best practice.

Express consent is also required if a physician wishes to disclose personal health information to external health researchers, such as those affiliated with universities, health authorities or other health care organizations. If it is impractical to seek consent, PIPA authorizes the disclosure of personal health information without consent for research purposes if **all of the following conditions are met**:

- The research purpose cannot be accomplished unless the personal information is provided in an individually identifiable form.
- The disclosure is on condition that it will not be used to contact persons to ask them to participate in the research.
- Linkage of the personal information to other information is not harmful to the individuals identified by the personal information and the benefits to be derived from the linkage are clearly in the public interest.
- The organization to which the personal information is to be disclosed has signed an agreement to comply with:
    - PIPA
    - the policies and procedures relating to the confidentiality of personal information of the practice that collected the personal information
    - security and confidentiality conditions
    - a requirement to remove or destroy individual identifiers at the earliest reasonable opportunity

- prohibition of any subsequent use or disclosure of that personal information in individually identifiable form without the express authorization of the practice that disclosed the personal information

- It is impracticable for the practice to seek the consent of the individual for the disclosure.

There is an important exception to this authorization to disclose personal health information for research purposes without consent. PIPA prohibits the disclosure of personal health information for market research purposes to drug companies or other businesses without consent.

The use of personal health information for research may require review and approval by a research ethics board. Where such review is required, the practice must refrain from disclosing personal health information for research purposes until the researcher has obtained the requisite approvals.

Best Practices

After consent from the patient is obtained, or the conditions outlined above are met, consider:

- de-identifying personal health information to whatever extent is feasible and practical before disclosing to external health researchers
- retrieving and/or securely destroying records once the research is complete
- immediately ceasing collection, use or disclosure of the personal health information unless otherwise permitted under PIPA when a patient withdraws their consent to the collection, use, or disclosure of personal health information for research purposes

If a patient believes their personal health information has been inappropriately collected, used, or disclosed for research purposes without consent, he or she may complain to the practice's privacy officer for review and investigation. If the patient believes the matter cannot be resolved internally, the patient has the right to bring the concern to the attention of the College of Physicians and Surgeons or to the OIPC.