

# SECONDARY USE OF DATA IN HEALTH RESEARCH: ETHICS AND PRIVACY CONSIDERATIONS

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# Outline

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- Landscape – oversight
- Privacy best practices
- Ethics considerations
- Chicken and egg problem
- And that's not all!
- Where to from here?

# Secondary Use of Data

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- Secondary use refers to the use of data originally collected for a purpose other than the current purpose.
  - ▣ Accessing data that has already been collected for a different purpose to answer a research question (e.g. research using medical charts)
  - ▣ Re-analyzing an existing research data set to answer a different research question

# Landscape – legislation

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- Provincial health-specific privacy legislation (NL – PHIA)
- Establish rules for the collection, use and disclosure of personal health information (PHI)
- Balances an individuals right to privacy with the practical requirements of the health care system to collect, use and disclose PHI

# Landscape - approvals

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- Typically access to data for secondary use research requires two approvals:
  - ▣ Research Ethics Board (REB) approval; and
  - ▣ Approval from the data custodian (i.e. organizational approval/data access committees).

Ethics = ethical acceptability of the study (principles based review) with the aim of protecting research participant's rights

Data access committees = permitted under legislation, privacy considerations, operational impact, feasibility

# REB and Data Access

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- REB application:
  - Identify data sources
    - Data custodians
    - Variables
    - Identifiable?
  - Data flow
    - Front end access or disclosure?
    - Linking? Code?
    - Who has access?
  - Privacy
    - Organizational safeguards
    - Technical safeguards
    - Physical safeguards

# Ethics - consent

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- Privacy legislation permits the disclosure of PHI without consent for research purposes when REB approval is obtained (NL)
  - ▣ Most lax standard compared to other provinces
- TCPS2, Chapter 3: consent
- Waiver of consent considerations

# Consent - principles

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TCPS2	PHIA
Free	Not obtained through deception and coercion
Informed	Knowledgeable
Ongoing	Of the individual



# Consent - elements

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TCPS2 (informed)	PHIA (knowledgeable)
Assurance that participants are under no obligation to participate, are free to withdraw, information that is relevant to decision to continue or withdraw consent, including limitations of withdrawal of data	Individual may give or hold consent
An indication of what info will be collected and for what purposes, who can access the information, anticipated uses, duty to disclose and how confidentiality will be maintained	Information on use and disclosure
Statement of research purpose, identity of researcher, identity of the funder, the duration and nature of participation, description of research procedures, explanation of the responsibilities of the participant	The purpose of the collection

# Ethics – privacy

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- TCPS2, Chapter 5: privacy and confidentiality
- Privacy:
  - ▣ Minimal data used
  - ▣ Limit use of personal identifiers
- Confidentiality:
  - ▣ Limit access to personal identifiers
  - ▣ Limit access to analytic data files
  - ▣ Release of aggregate results
- Security:
  - ▣ Secure transmission of files
  - ▣ Files on secure server (analysis & storage)

# Request Process - NLCHI

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- Intake and Assessment
  - ▣ Central Intake (Information Request Coordinator)
  - ▣ Consultation meeting
    - Gather requirements/determine feasibility
      - Study information: study design, study sample, objectives, groups of interest, outcomes, time period
      - Identify data sources
      - Identify data elements
      - Type of data (de-identified vs. identifiable)
      - Data flow
- Cost estimate and Agreement Initiated
  - ▣ Resource planning (extraction/linkage)

# Request Process - NLCHI

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- Application Review
  - ▣ Key considerations:
    - Permitted under legislation
    - Type of data (de-identified vs. identifiable)
    - Minimum amount of PHI requested
    - Data accuracy
    - Ethics approval obtained and information in application corresponds to ethics application
    - Consent requirements
    - Data flow, data management, data storage, retention, and disposal, etc.

# Request Process - NLCHI

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- Approval
  - ▣ Agreement/Letter of Approval
    - Future uses and/or disclosures require additional approval
    - Do not attempt to re-identify information
    - Do not publish cell counts  $<5$
    - Data must be stored on an organization asset
    - Research team must comply with their organization's policies and procedures
    - Data retention disposal
    - Notify NLCHI of changes with the research study or research team
    - Secure transfer
- Data Preparation and Data Review
  - ▣ Compare prepared dataset against what was approved
  - ▣ Cell count/re-identification risk assessment

# REB Review vs. Custodian Privacy Review

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- Conceptually parallel processes that require similar content

Review elements	
Data sources	Data storage and disposal
Data elements	Data retention
Data flow	Limits of use
Identifiability/re-identifiability	Privacy safeguards

- Where does one mandate end and the other begin?
- And are there any gaps?
- NS – research plan, how is this managed?

# Classic and problem



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1. All custodians in NL require REB review and approval prior to consideration of access request.
2. NS – Emergency Health Services (EHS) steering committee requires the protocol and REB application be submitted to them PRIOR to sending to the REB.
3. Health Data NS(HDNS) – application to the HDNS committee can occur prior to, at the same time, or after applying to the REB.
4. NS Department of Health and Wellness Data Access Committee conducts preliminary review and issues ‘feasibility review letter’ to support application to REB, once approved by ethics return for final review.

# Pros and Cons

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		PROS	CONS
1.	REB approval first	?	REB heavy lifting/poor quality submissions Amendments Time consuming No other approvals required
2.	Data access review first	Better quality applications to REB Institutions that are not well resourced carry the review load	Out of order ? Time consuming
3.	Either/or	Flexibility for researchers	Inconsistent process Difficult to regulate
4.	Preliminary data access review prior to REB approval, then finalize	?Happy medium for REB and custodian	Back and forth for researchers/administrative burden



# But that's not all!

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- Several initiatives in 2017 shed light on some other issues we seem to be having with secondary use of data:
  - PHIA review
  - Provincial Secondary Use Working Group
  - OIPC Guidance piece

# Common Misconceptions

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- ❑ Privacy legislation is a barrier to research.
- ❑ Approvals not required if using de-identified data.
- ❑ If ethics approval is obtained, no other approvals are required.

# Challenges

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- Custodians
  - ▣ Lack of resources required to process research requests
  - ▣ Inconsistent processes between organizations
- Researchers
  - ▣ Find it difficult to identify data custodians
  - ▣ Custodians – individuals or organizations who have custody or control of PHI to perform their power or duties

# Where to from here?

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- Next steps:
  - Listserv?
  - Source document for Maritimes?
  - Risks?
  - Privacy breaches in research context?

# Contact

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THANK YOU!