

## Health Research and Information Protection

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ACTION for Health

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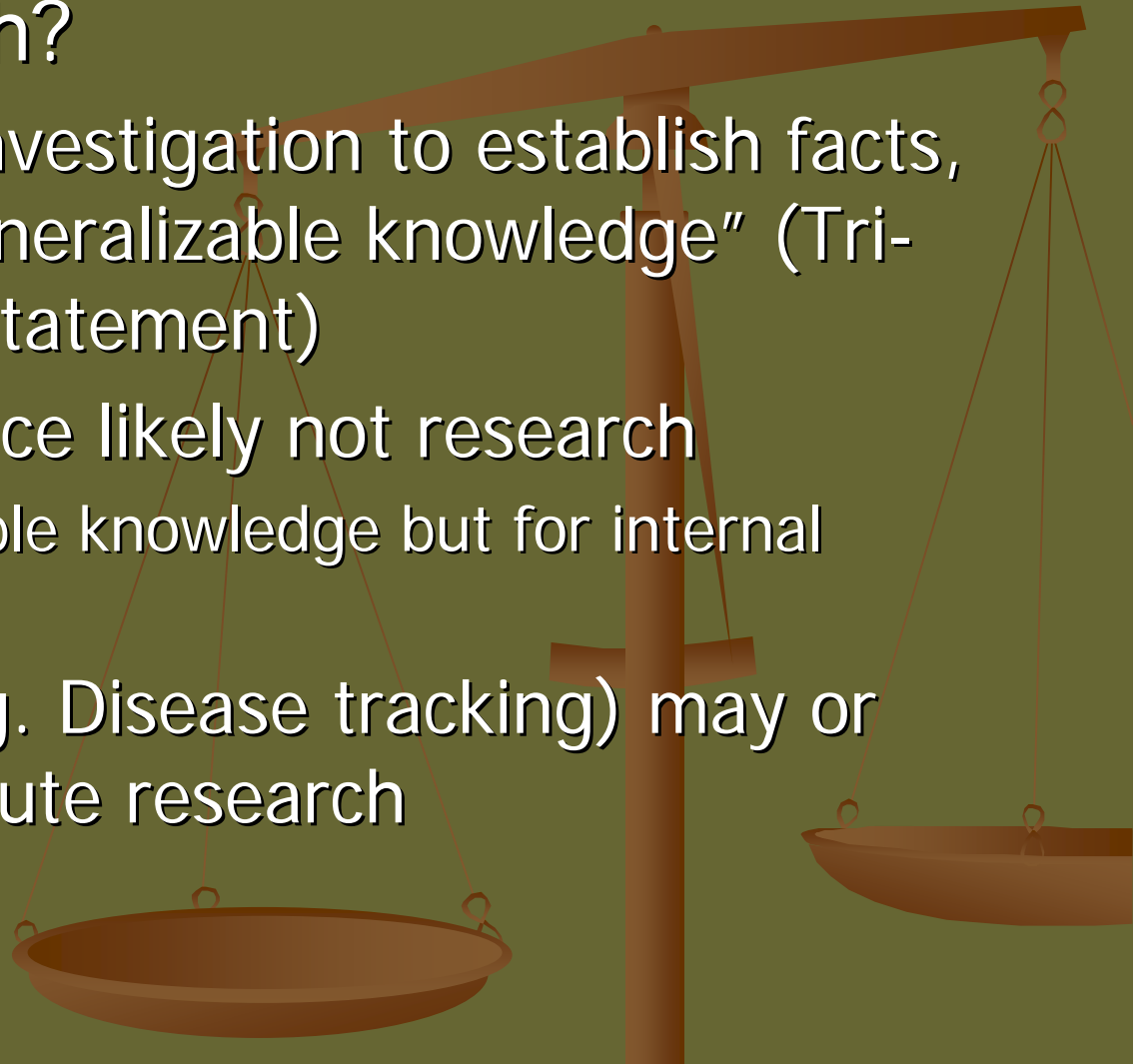
# Health Research and Privacy



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# Collection, Use & Disclosure of Health Information in the Course of Research

- What is research?
  - “a systematic investigation to establish facts, principles or generalizable knowledge” (Tri-Council Policy Statement)
  - Quality Assurance likely not research
    - Not generalizable knowledge but for internal purposes
  - Surveillance (eg. Disease tracking) may or may not constitute research



# Collection of Information

- Gathering excess information contrary to law (PIPEDA)
- Only collect what is necessary for research



# Collection of Information



- Identifiable information

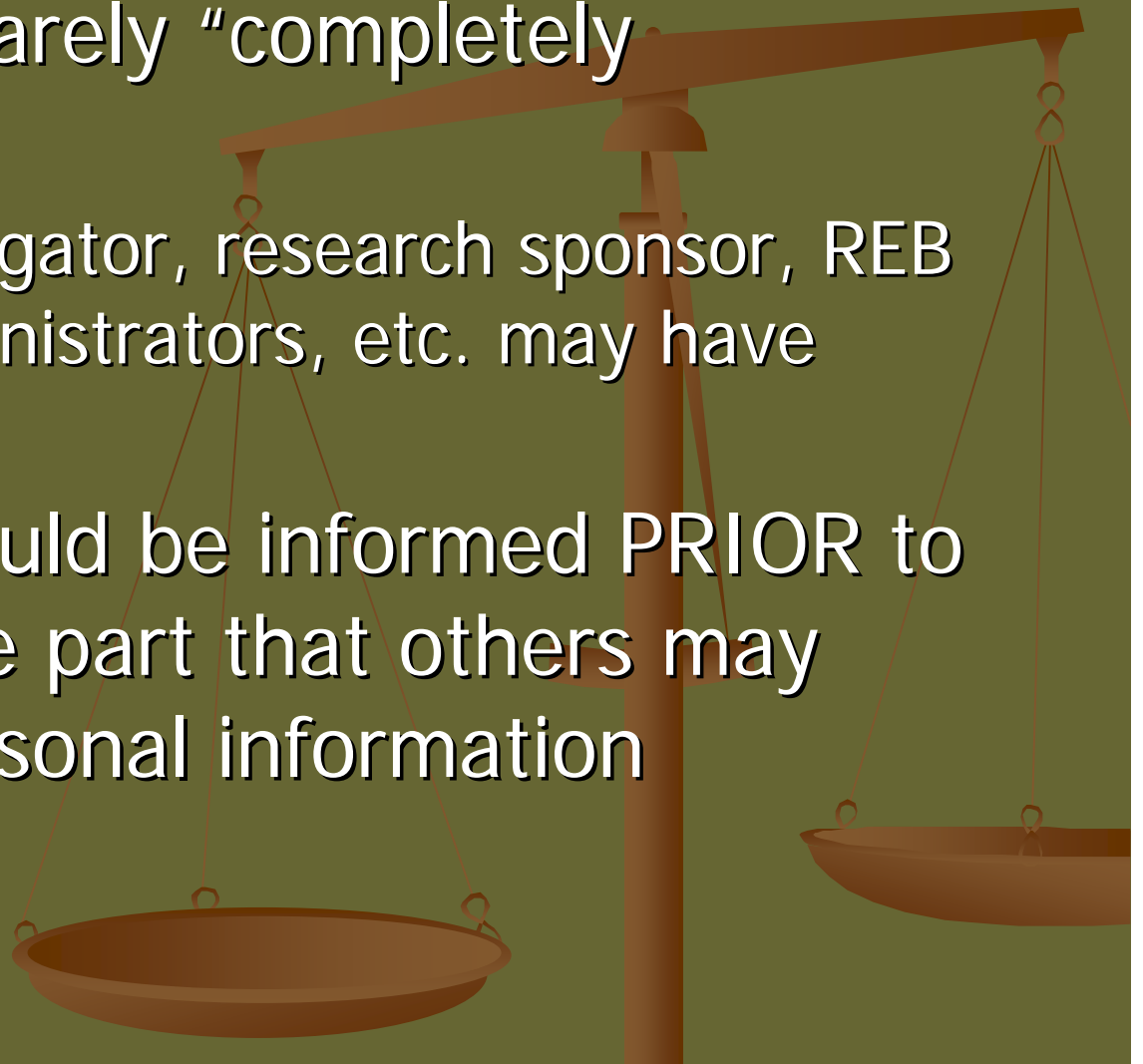
- Information which may identify either directly or indirectly a specific individual; or which may be manipulated by a reasonably foreseeable method to identify a specific individual, or which may be linked by a reasonably foreseeable method with other accessible information to identify a specific individual. (CIHR)

- Examples:

- Geographic location, named facilities & service providers; dates; uncommon or highly visible characteristic of individual, etc.

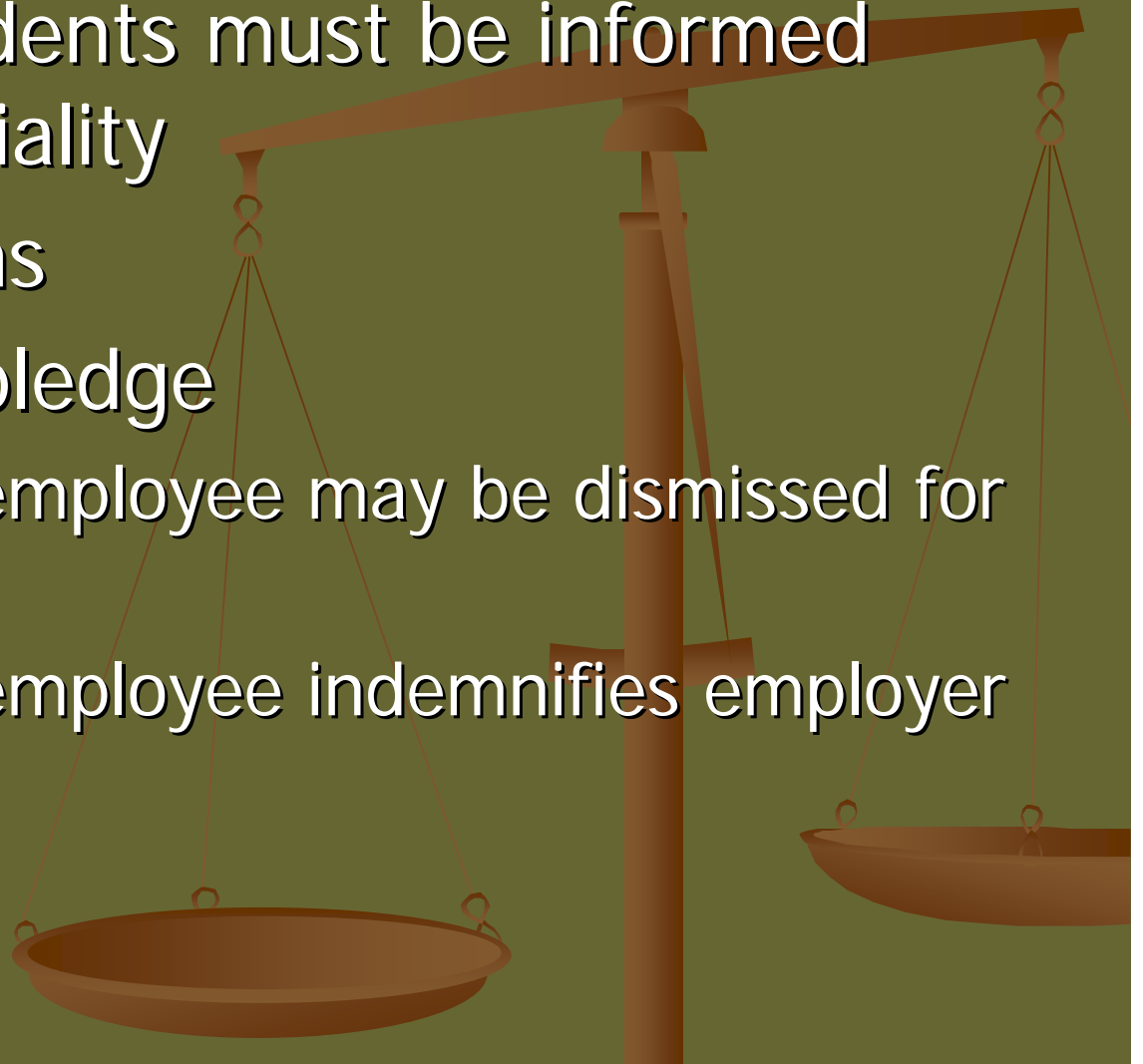
# Access to information

- Information is rarely “completely confidential”
  - Principle investigator, research sponsor, REB members, administrators, etc. may have access
- Participants should be informed PRIOR to agreeing to take part that others may access their personal information



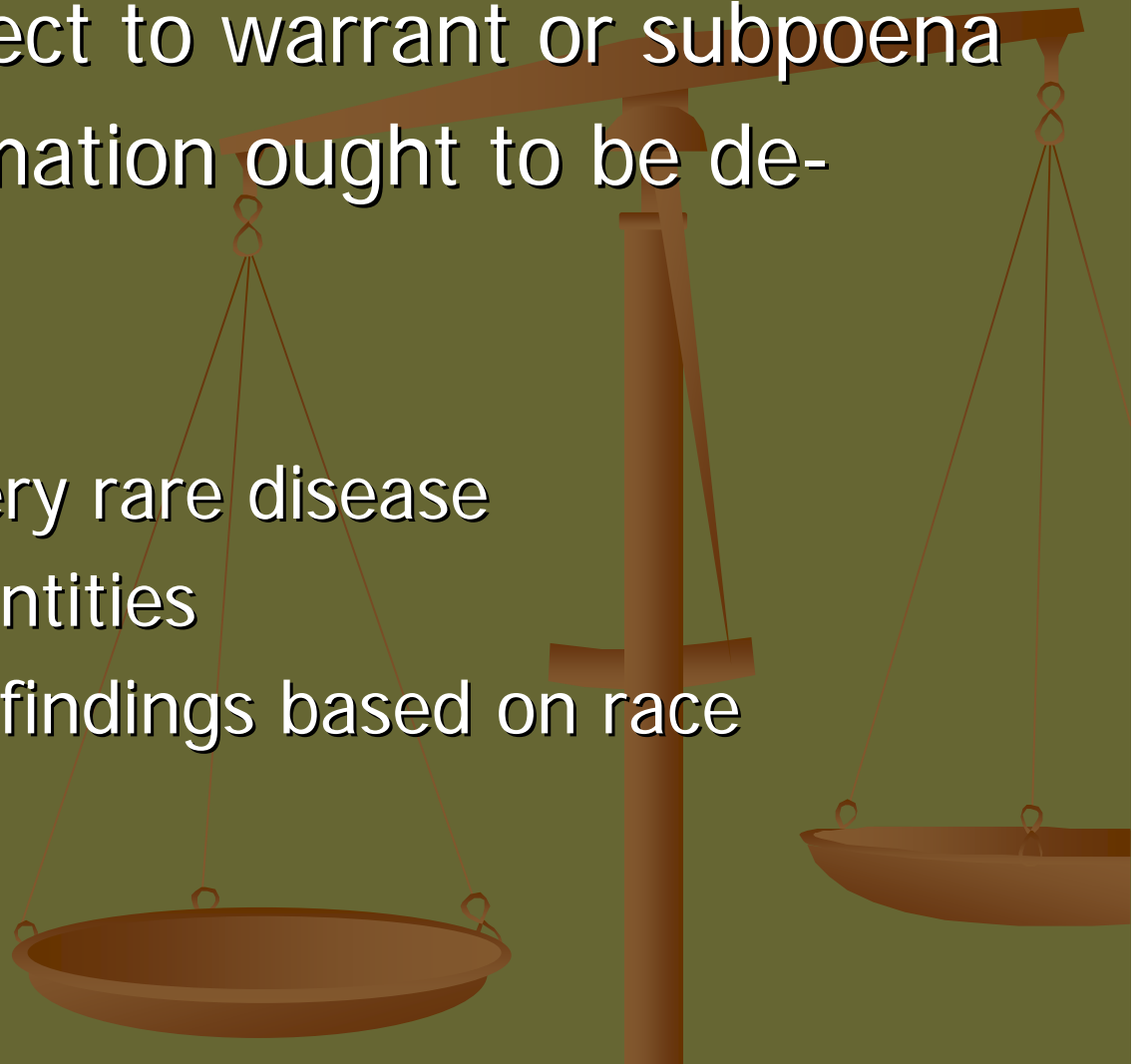
# Access to information

- Employees, students must be informed about confidentiality
- Training sessions
- Confidentiality pledge
  - Including that employee may be dismissed for violations
  - Including that employee indemnifies employer for damages



# Disclosure of Information

- All records subject to warrant or subpoena
- Published information ought to be de-identified
- What about...
  - Persons with very rare disease
  - Institutional identities
  - Eg. Differential findings based on race





# Security of Information



- Organizational measures

- Limits on who can access research data, confidentiality pledges, data-sharing agreements, etc.

- Technological measures

- Encryption, de-identification, monitoring systems

- Physical measures

- Locking systems, blocking public access to records

# Governing Structures

- Legislation
- Standards & Guidelines



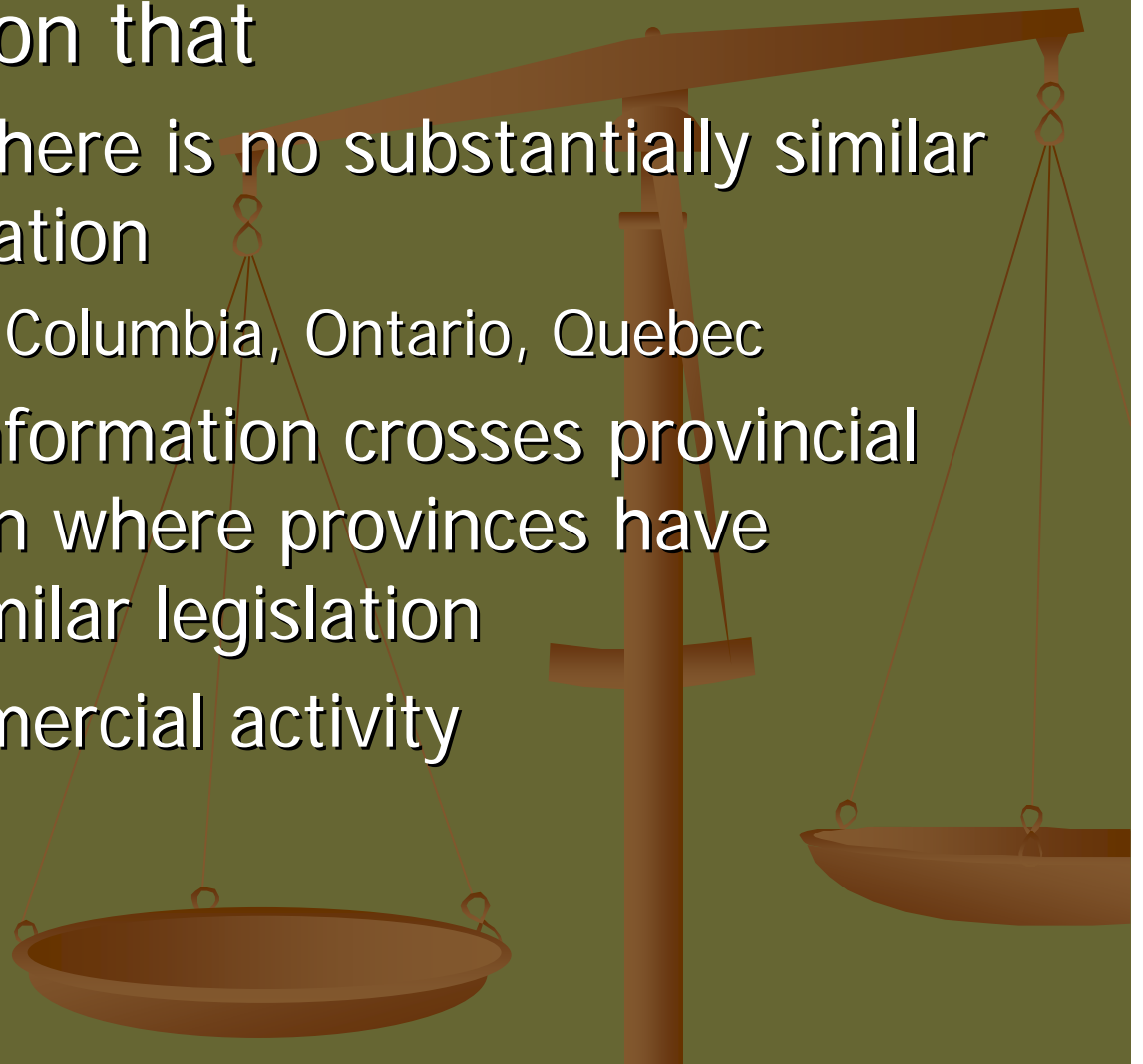
# Legislation



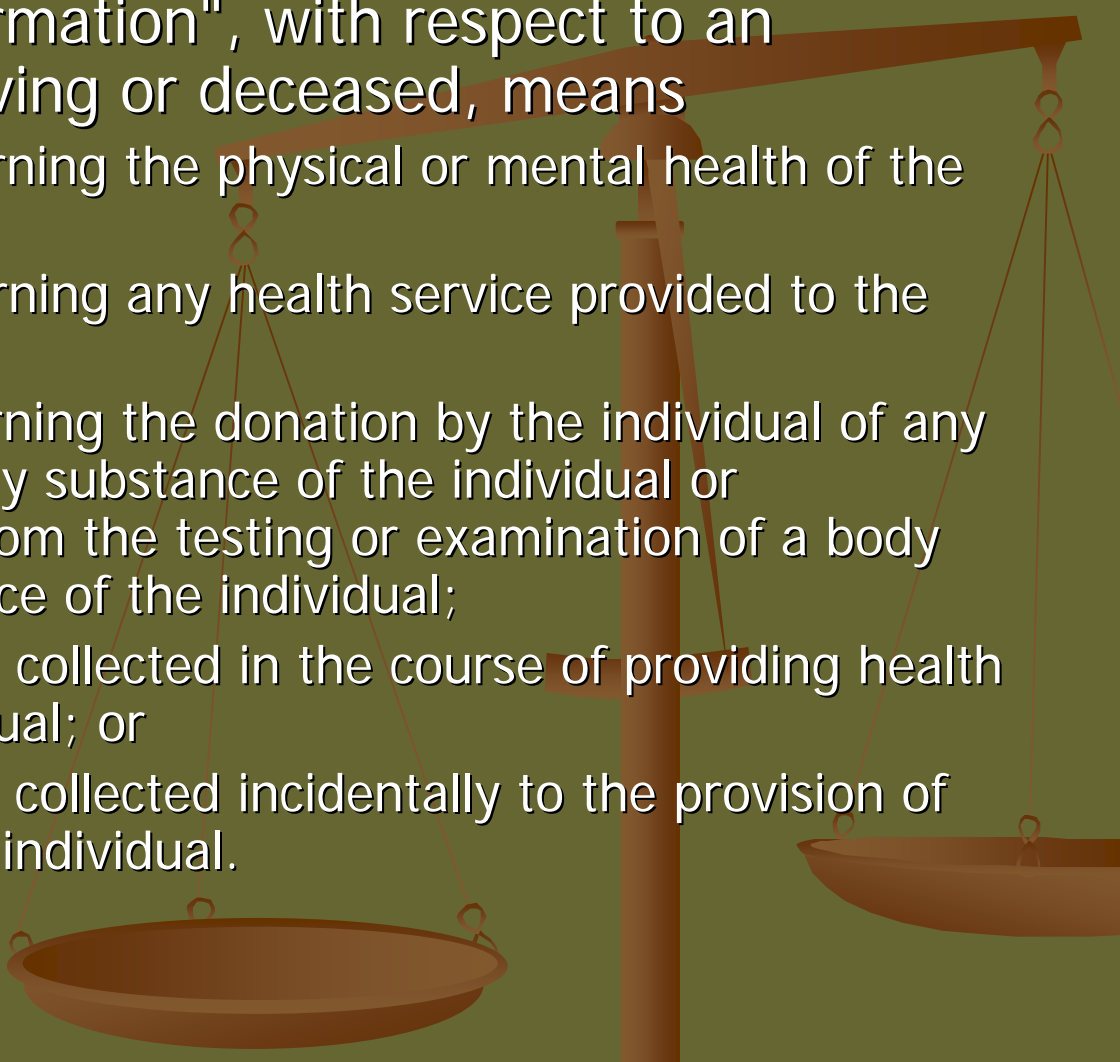
- *Personal Information Protection and Electronic Documents Act (PIPEDA)*
- Public Sector Information Legislation
- Private Sector Information Legislation

# PIPEDA

- Federal legislation that
  - Applies where there is no substantially similar provincial legislation
    - Alberta, British Columbia, Ontario, Quebec
  - Applies when information crosses provincial boundaries even where provinces have substantially similar legislation
  - Applies to commercial activity



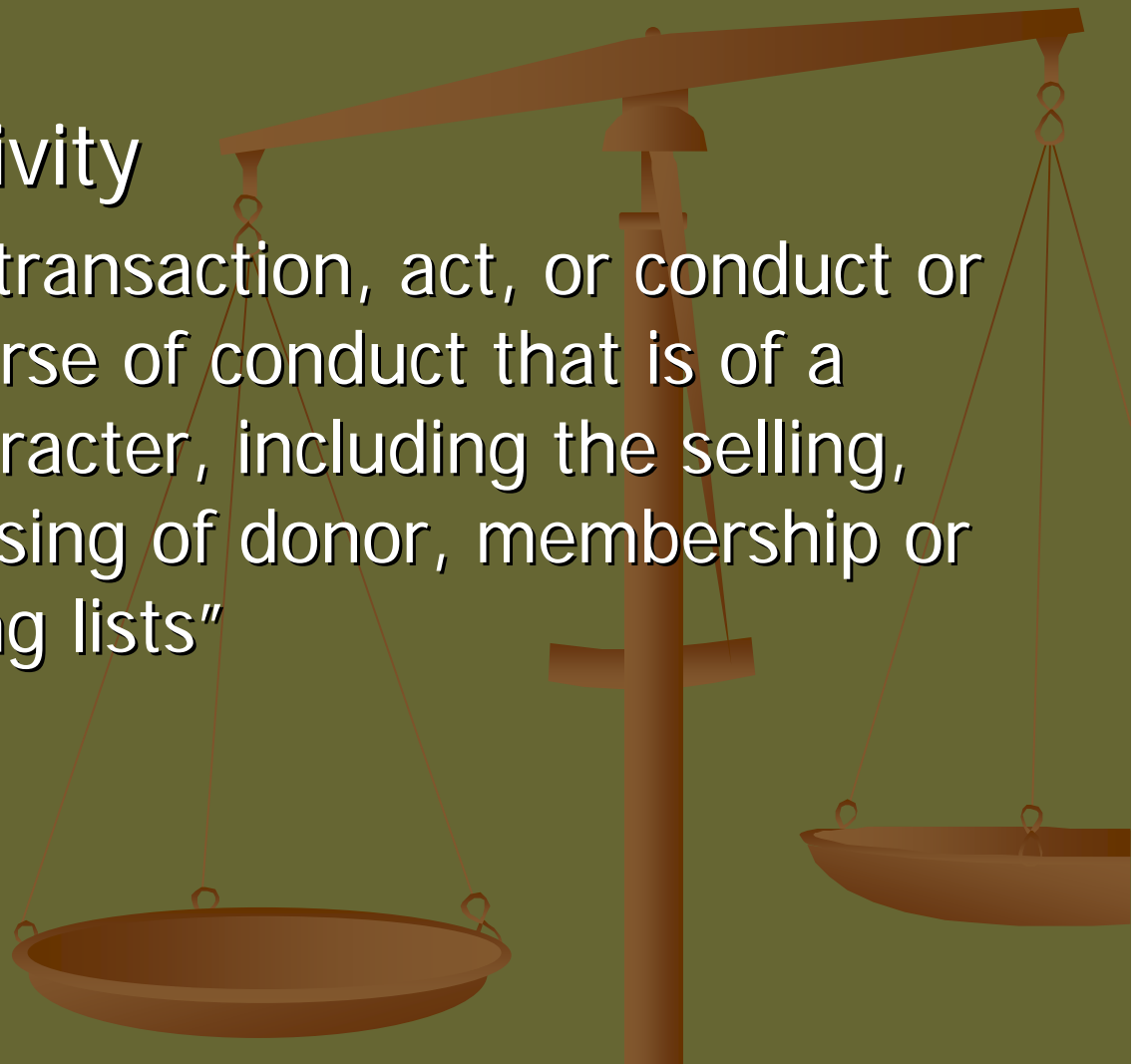
# PIPEDA

- "personal health information", with respect to an individual, whether living or deceased, means
    - (a) information concerning the physical or mental health of the individual;
    - (b) information concerning any health service provided to the individual;
    - (c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;
    - (d) information that is collected in the course of providing health services to the individual; or
    - (e) information that is collected incidentally to the provision of health services to the individual.
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# PIPEDA

- Commercial Activity

- “any particular transaction, act, or conduct or any regular course of conduct that is of a commercial character, including the selling, bartering or leasing of donor, membership or other fundraising lists”

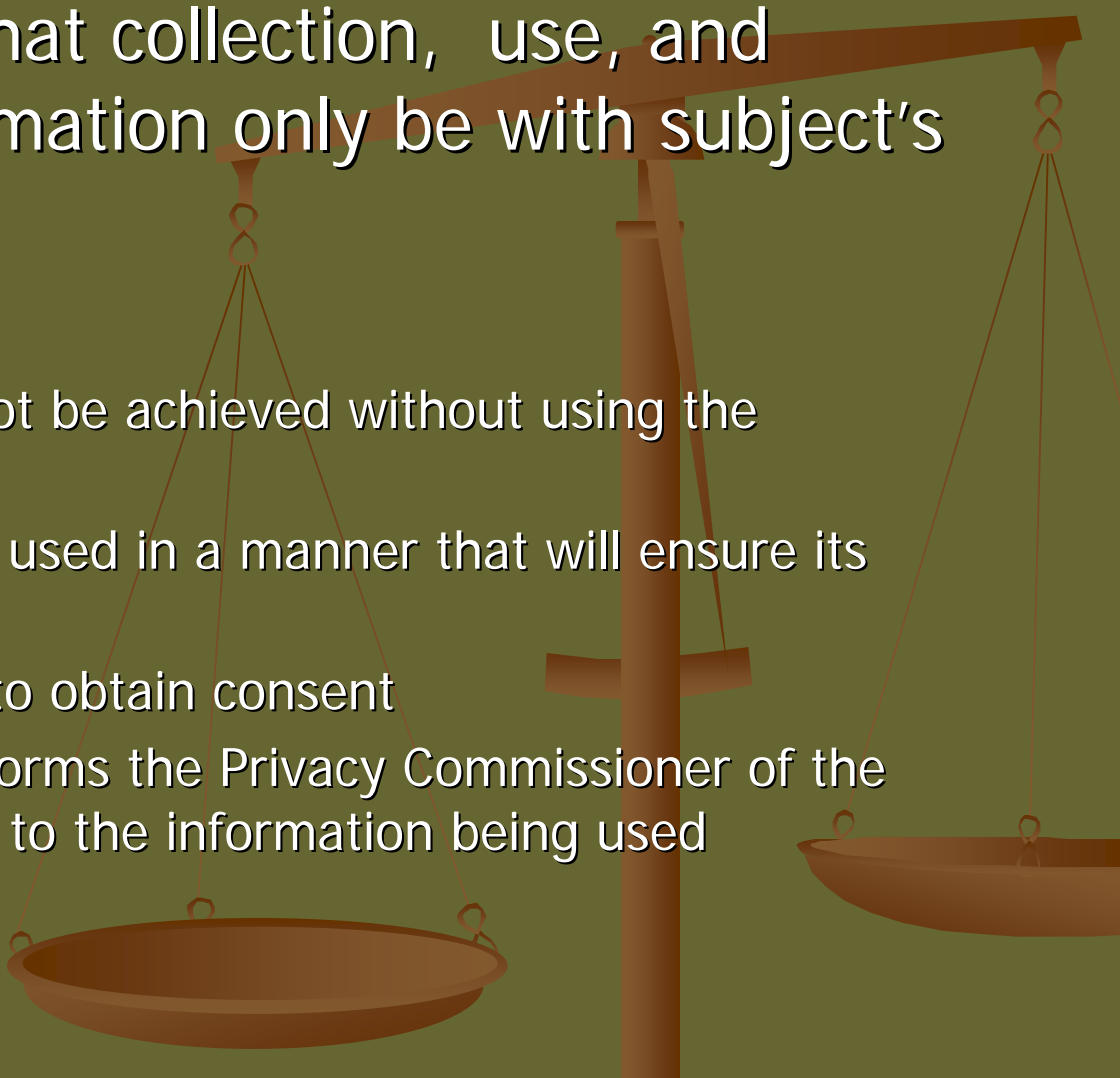


# PIPEDA



- Is research a commercial activity?
  - Is there a profit motive?
  - Is it funded by private or public funds?
  - Is it conducted for private or public benefit?
- Activities of physicians and healthcare providers in non-hospital settings are considered commercial

# Consent and PIPEDA

- PIPEDA requires that collection, use, and disclosure of information only be with subject's consent
  - Exceptions:
    - The purpose cannot be achieved without using the information
    - The information is used in a manner that will ensure its confidentiality
    - It is **impractical** to obtain consent
    - The researcher informs the Privacy Commissioner of the intended use prior to the information being used
- 



# Consent and PIPEDA



## ■ Disclosure

- Transfer of information outside of organization would constitute disclosure
- Conditions for disclosure without consent
  - The purpose cannot be achieved without disclosing the information
  - It is impractical to obtain consent
  - The researcher informs the Privacy Commissioner of the intended use prior to the information being used

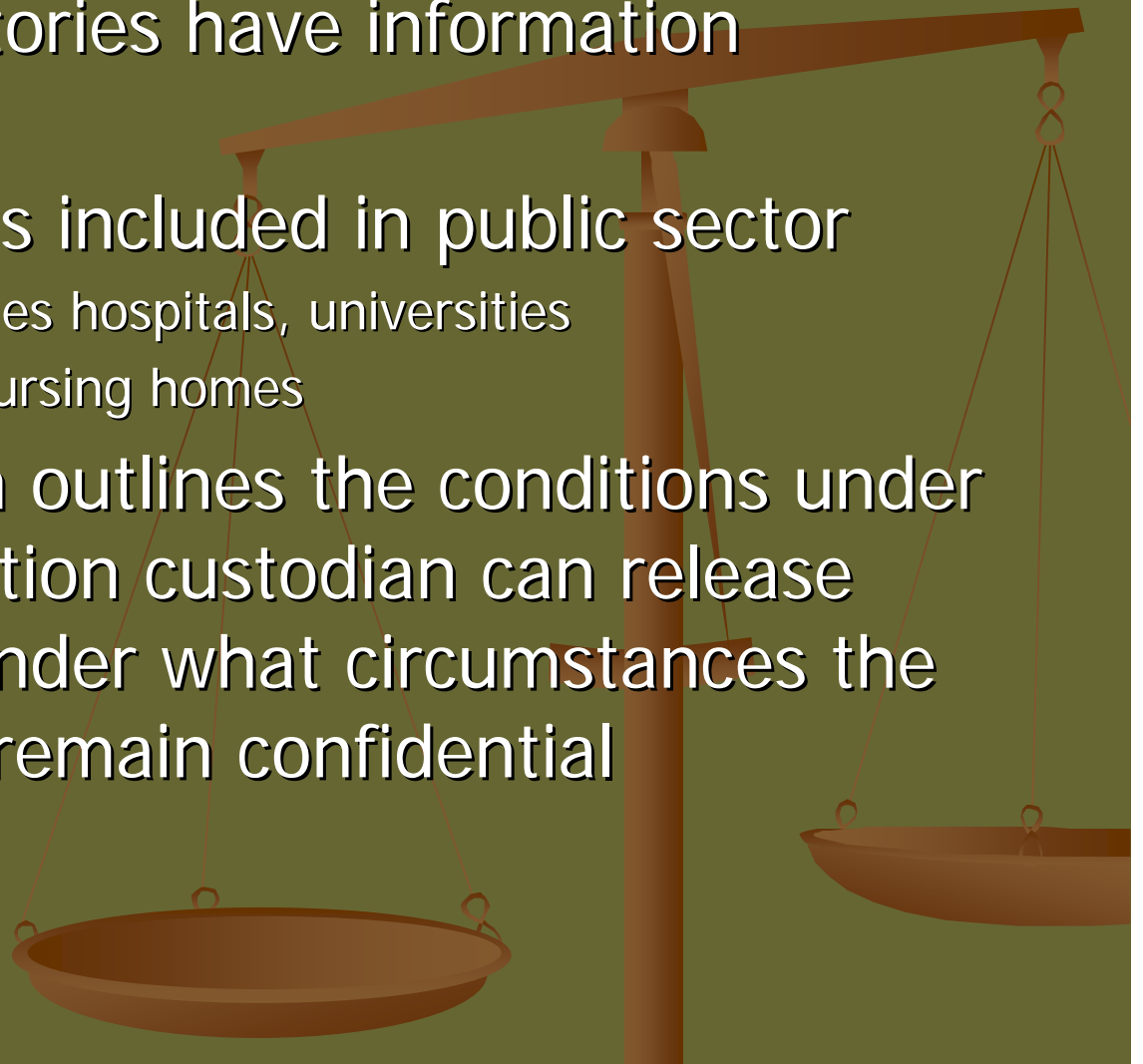
# Consent and PIPEDA

- Exceptions refer only to use and disclosure of information
- Collection always requires consent

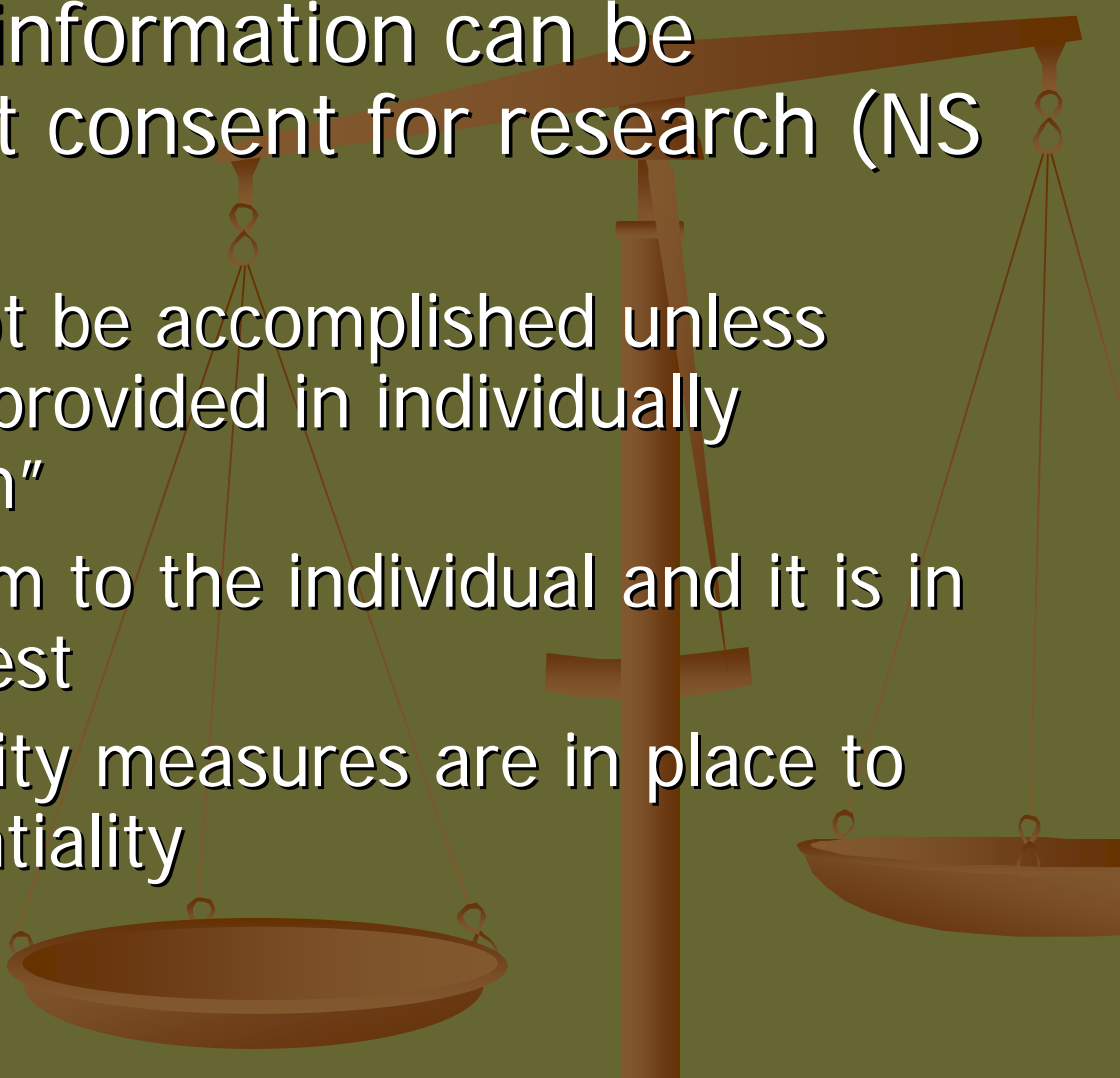


# Public Sector Legislation

- All provinces/territories have information legislation
- Variation in what is included in public sector
  - Nova Scotia includes hospitals, universities
  - Alberta includes nursing homes
- All such legislation outlines the conditions under which the information custodian can release information and under what circumstances the information must remain confidential

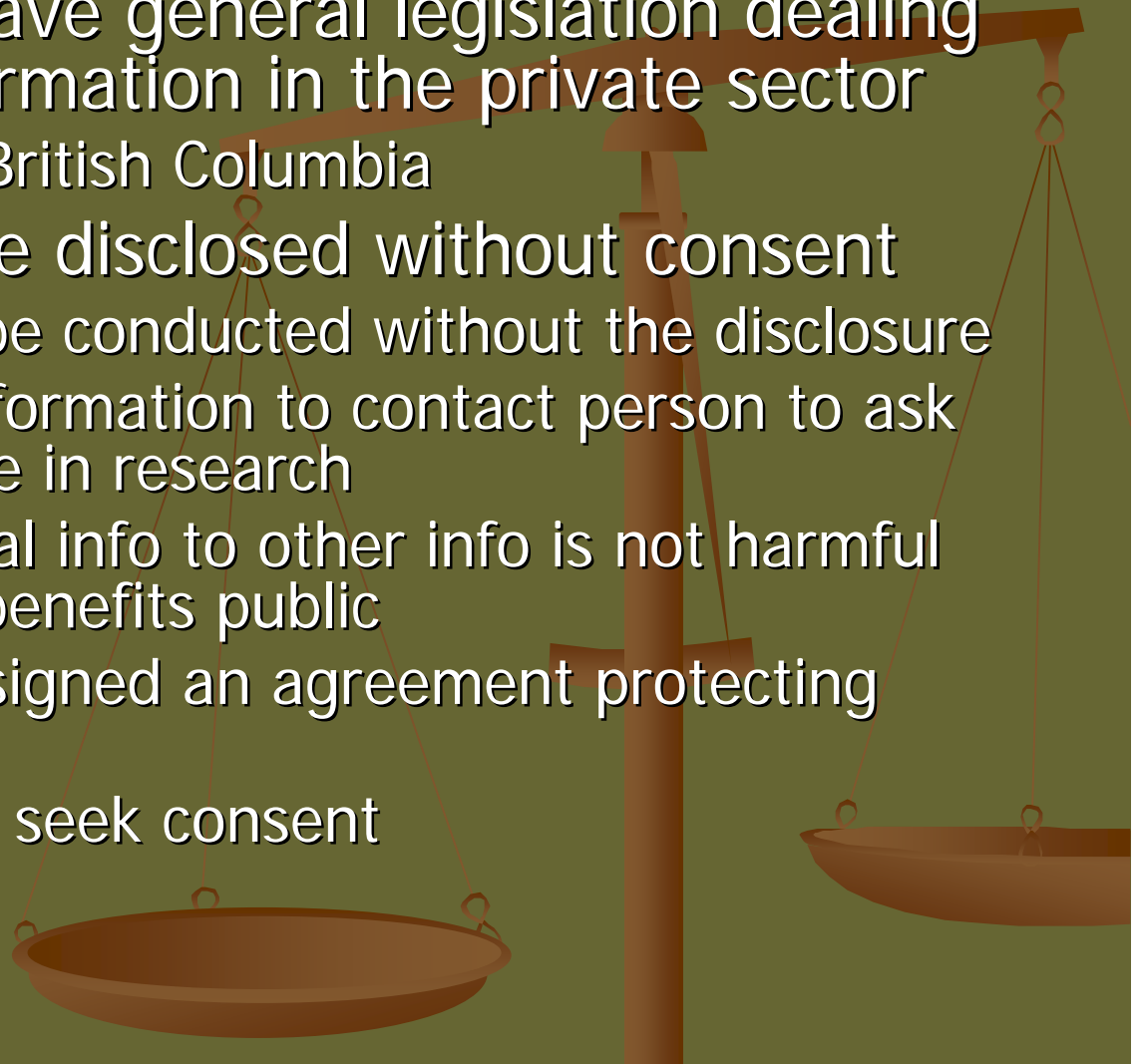


# Public Sector Legislation

- When personal information can be released without consent for research (NS *FOIPOP*)
    - Research cannot be accomplished unless information “is provided in individually identifiable form”
    - There is no harm to the individual and it is in the public interest
    - Adequate security measures are in place to ensure confidentiality
- 

# Private Sector Legislation

- Some provinces have general legislation dealing with personal information in the private sector
  - Alberta, Quebec, British Columbia
- Information can be disclosed without consent
  - Research cannot be conducted without the disclosure
  - Cannot use the information to contact person to ask them to participate in research
  - Linkage of personal info to other info is not harmful to individual and benefits public
  - Organization has signed an agreement protecting information
  - It is impractical to seek consent



# Health Specific Legislation



- Passed in four provinces
  - Alberta, Manitoba, Ontario, Saskatchewan
- Manitoba
  - Health Information Privacy Committee reviews requests for access to health information held by government bodies or agencies
- Ontario
  - Health information custodian and researcher agree on conditions and restrictions on use, security, disclosure, etc. of information

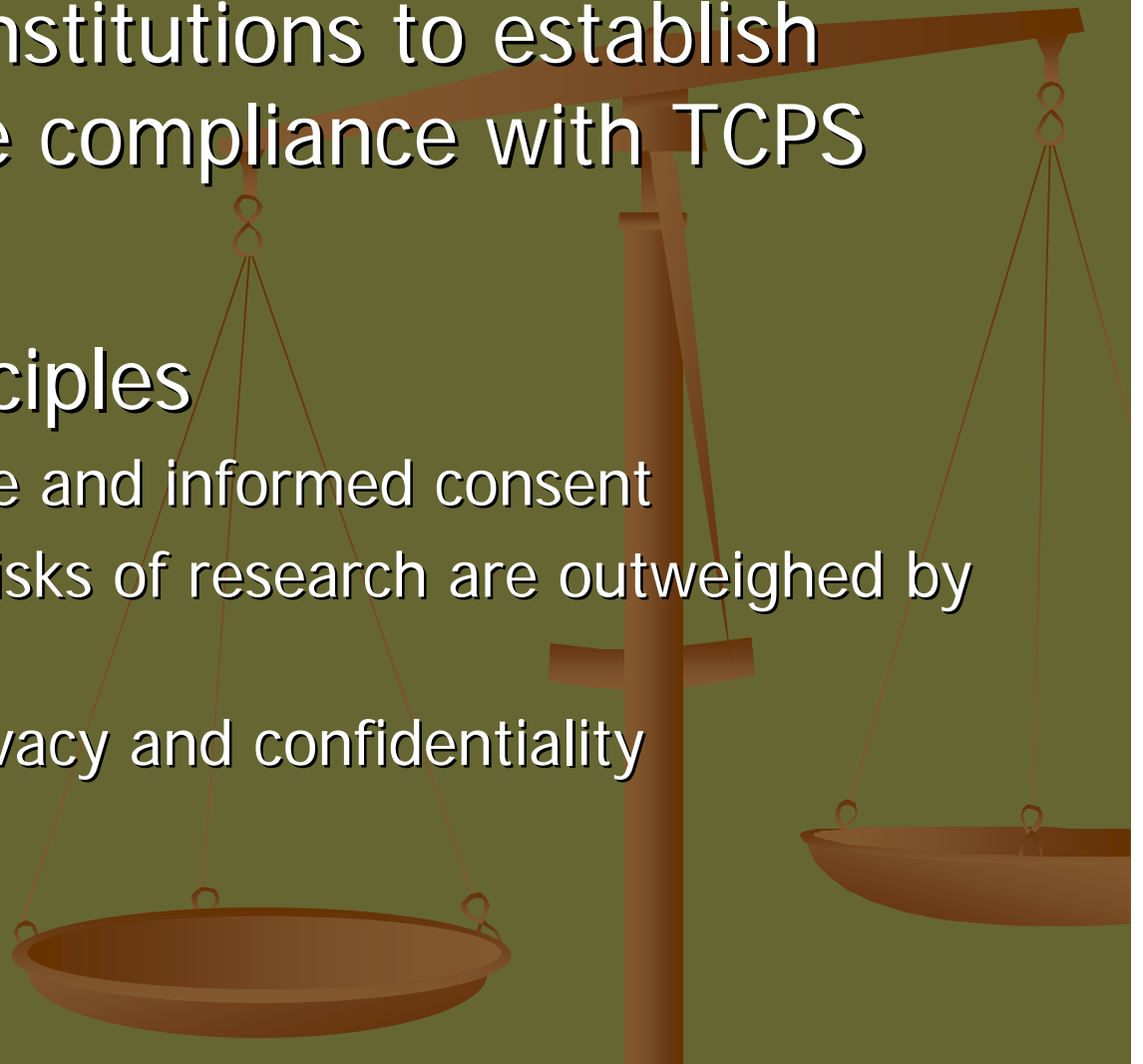
# Standards & Guidelines



- Tri-Council Policy Statement
  - Not strictly a legal document though it could be used as evidence of the legal standard of care
- CIHR Best Practices
  - Grounded in the Model Code – a schedule to PIPEDA
  - Used to interpret TCPS

# Tri-Council Policy Statement

- TCPS requires institutions to establish REBs to oversee compliance with TCPS
- Key ethical principles
  - Respect for free and informed consent
  - Ensuring that risks of research are outweighed by benefits
  - Respect for privacy and confidentiality





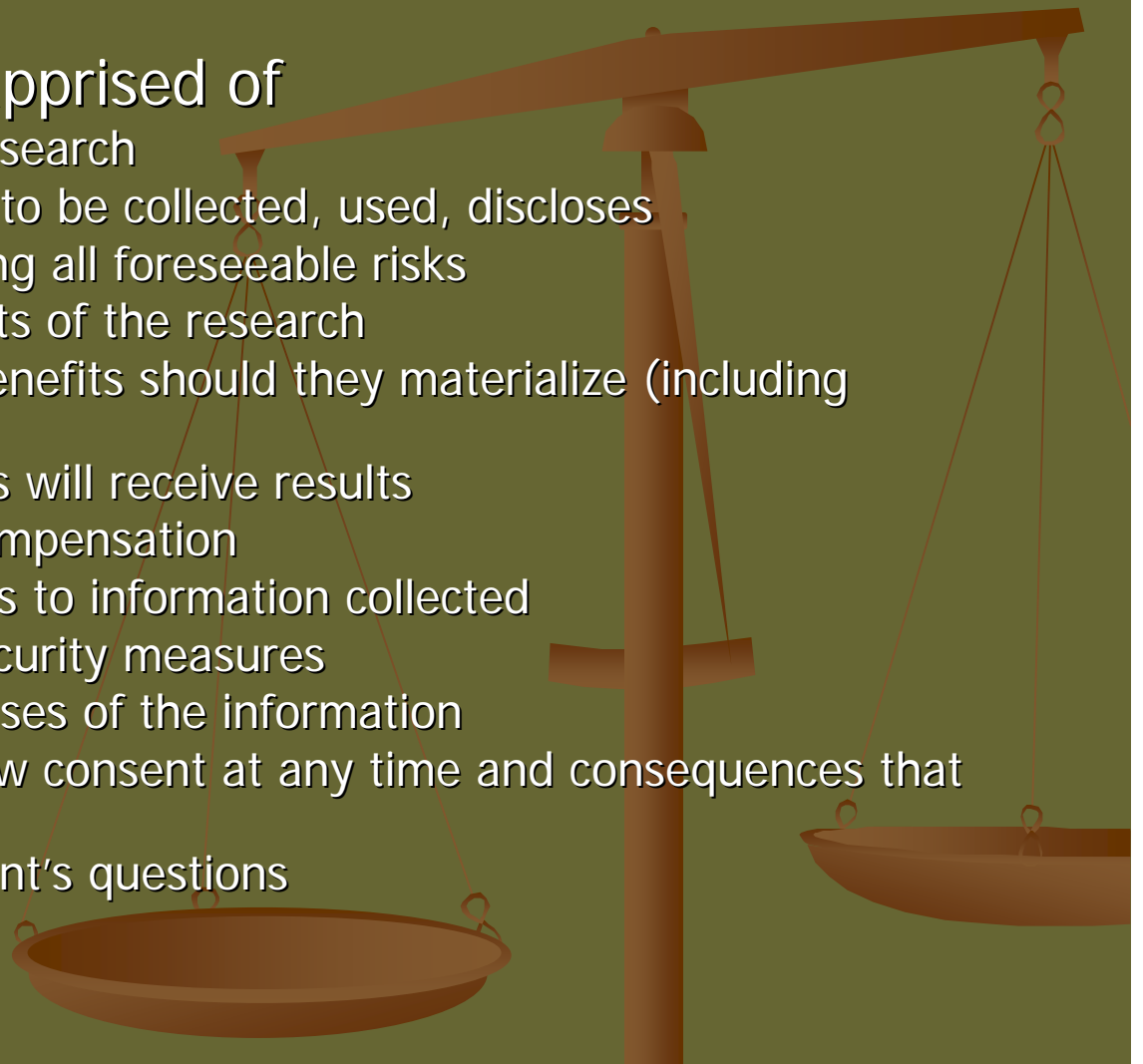
# TCPS - Consent

- Voluntary and Informed Consent
  - Research participants must freely consent to participate in research
    - No coercion or undue influence
  - In the case of incompetent persons, consent may be given by a third party

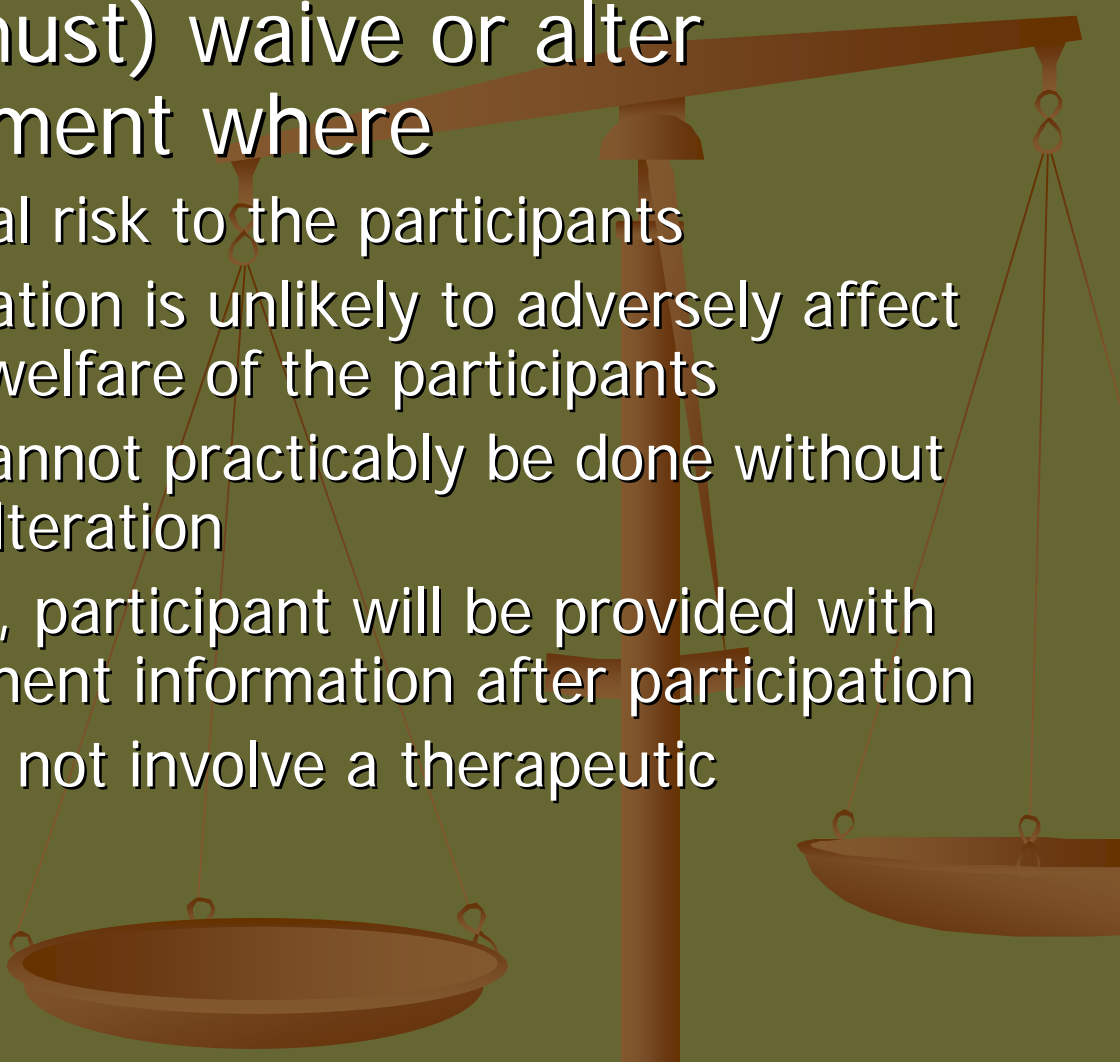


# TCPS - Consent

- Informed consent
- Participant must be apprised of
  - The nature of the research
  - What information is to be collected, used, disclosed
  - Information regarding all foreseeable risks
  - The intended benefits of the research
  - Who will reap the benefits should they materialize (including commercial aspects)
  - Whether participants will receive results
  - Details regarding compensation
  - Who will have access to information collected
  - Details regarding security measures
  - Any planned other uses of the information
  - The right to withdraw consent at any time and consequences that follow
  - Answers to participant's questions

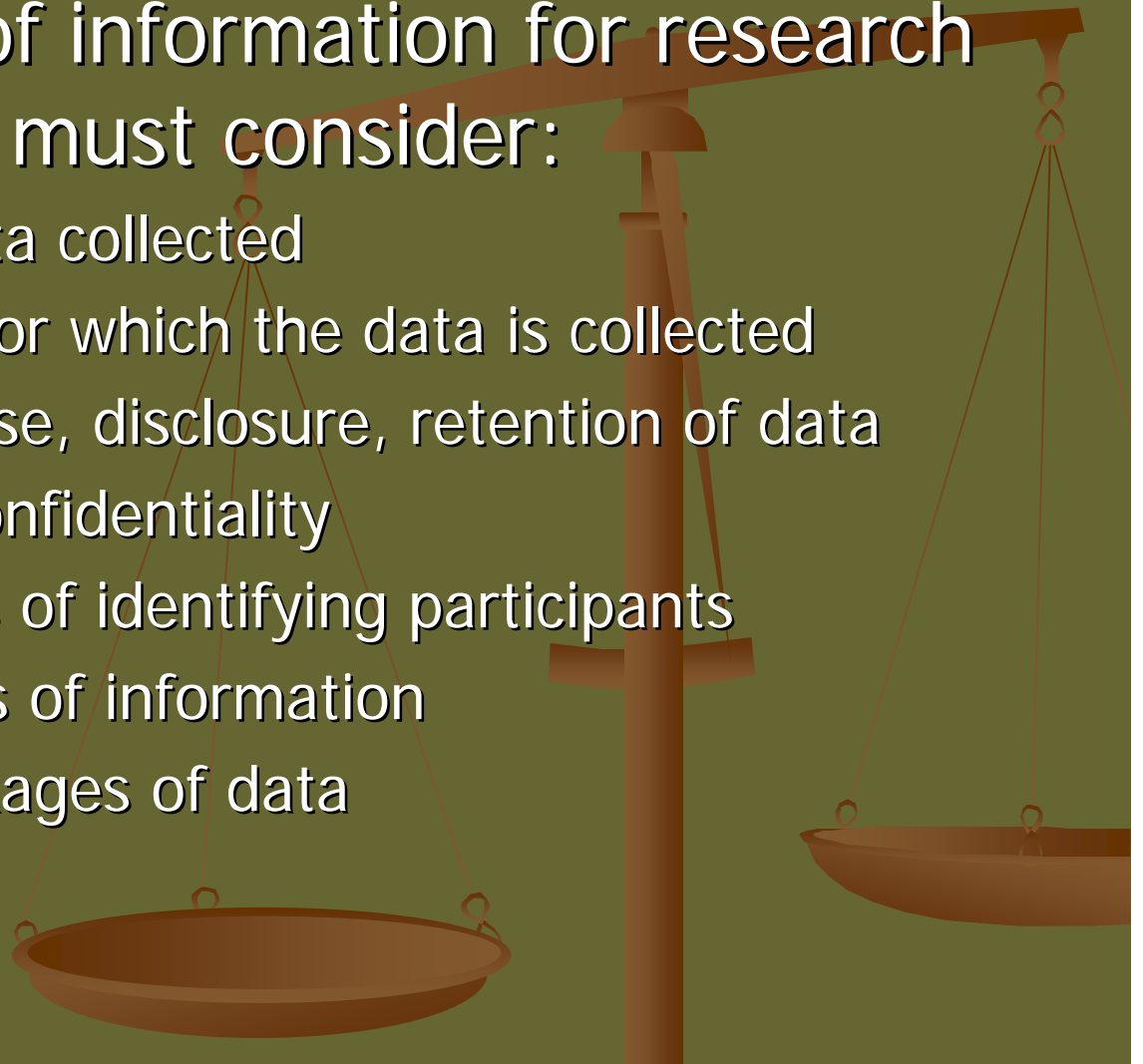


# TCPS - Consent

- REB may (not must) waive or alter consent requirement where
    - There is minimal risk to the participants
    - Waiver or alteration is unlikely to adversely affect the rights and welfare of the participants
    - The research cannot practicably be done without the waiver or alteration
    - Where possible, participant will be provided with additional pertinent information after participation
    - The study does not involve a therapeutic intervention
- 

# TCPS - Consent

- Regarding use of information for research purposes, REBs must consider:
  - The type of data collected
  - The purposes for which the data is collected
  - Limits on the use, disclosure, retention of data
  - Security and confidentiality
  - Possible means of identifying participants
  - Secondary uses of information
  - Anticipated linkages of data



# TCPS – Consent

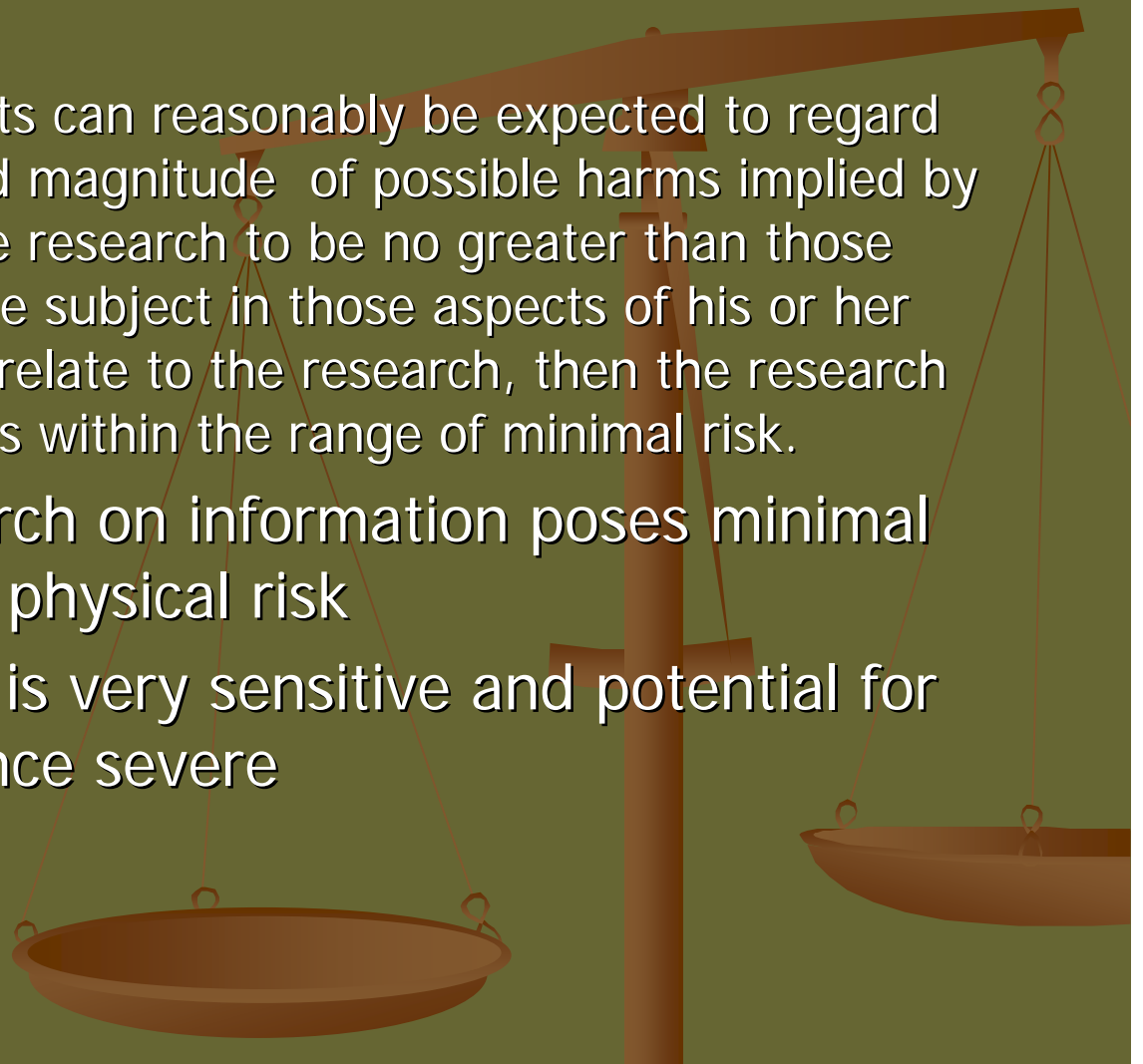
- Opt-in & Opt-out
- Documentation
- Right to Withdraw
- Notification
- Contact



# TCPS – Risks & Benefits

- TCPS definition:

- If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk.
- Prima facie, research on information poses minimal risk as there is no physical risk
- Some information is very sensitive and potential for breach of confidence severe



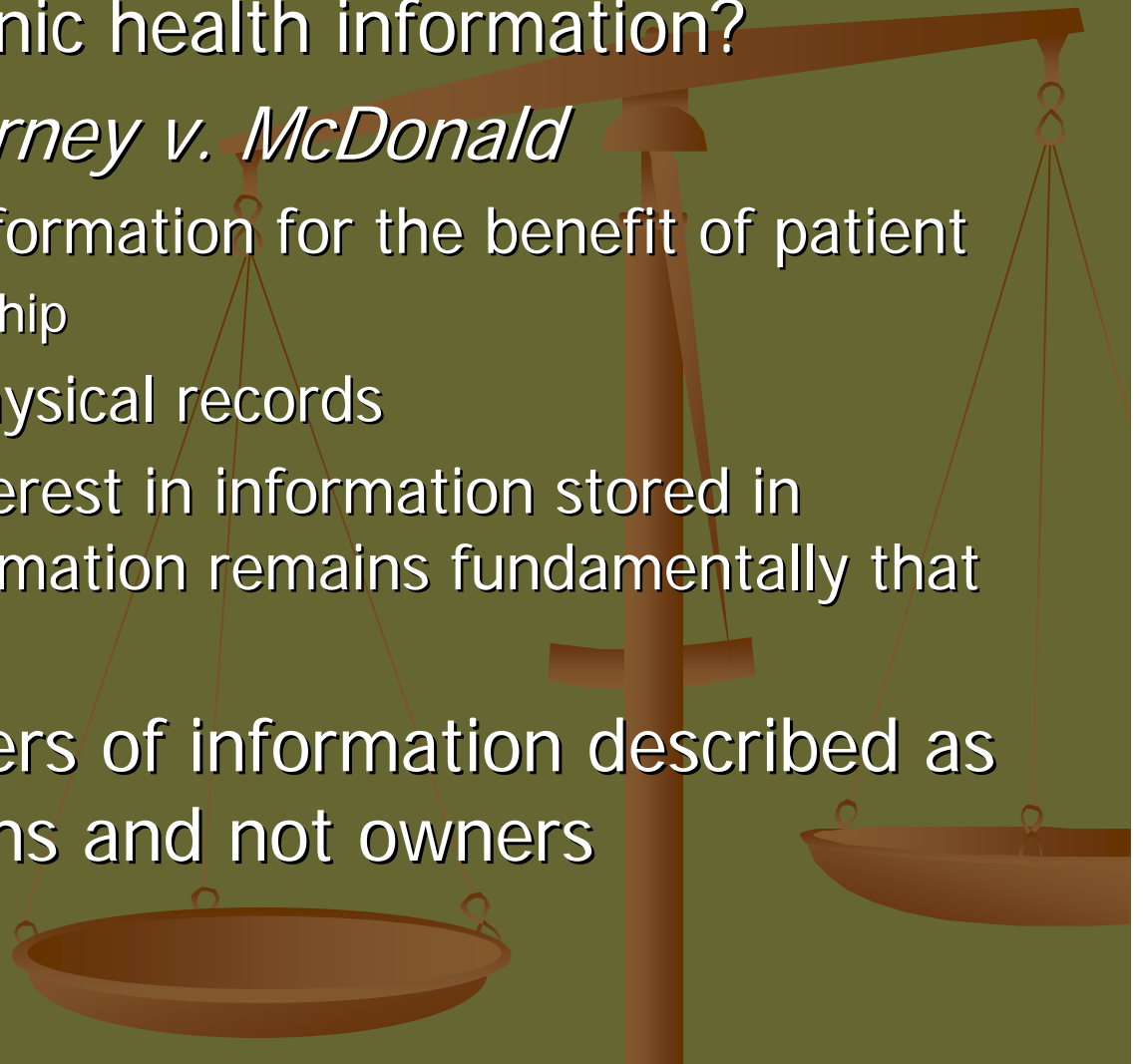
# TCPS – Privacy & Confidentiality

- Duties towards privacy and confidentiality may be heightened in research context



# Use of Databases in Research

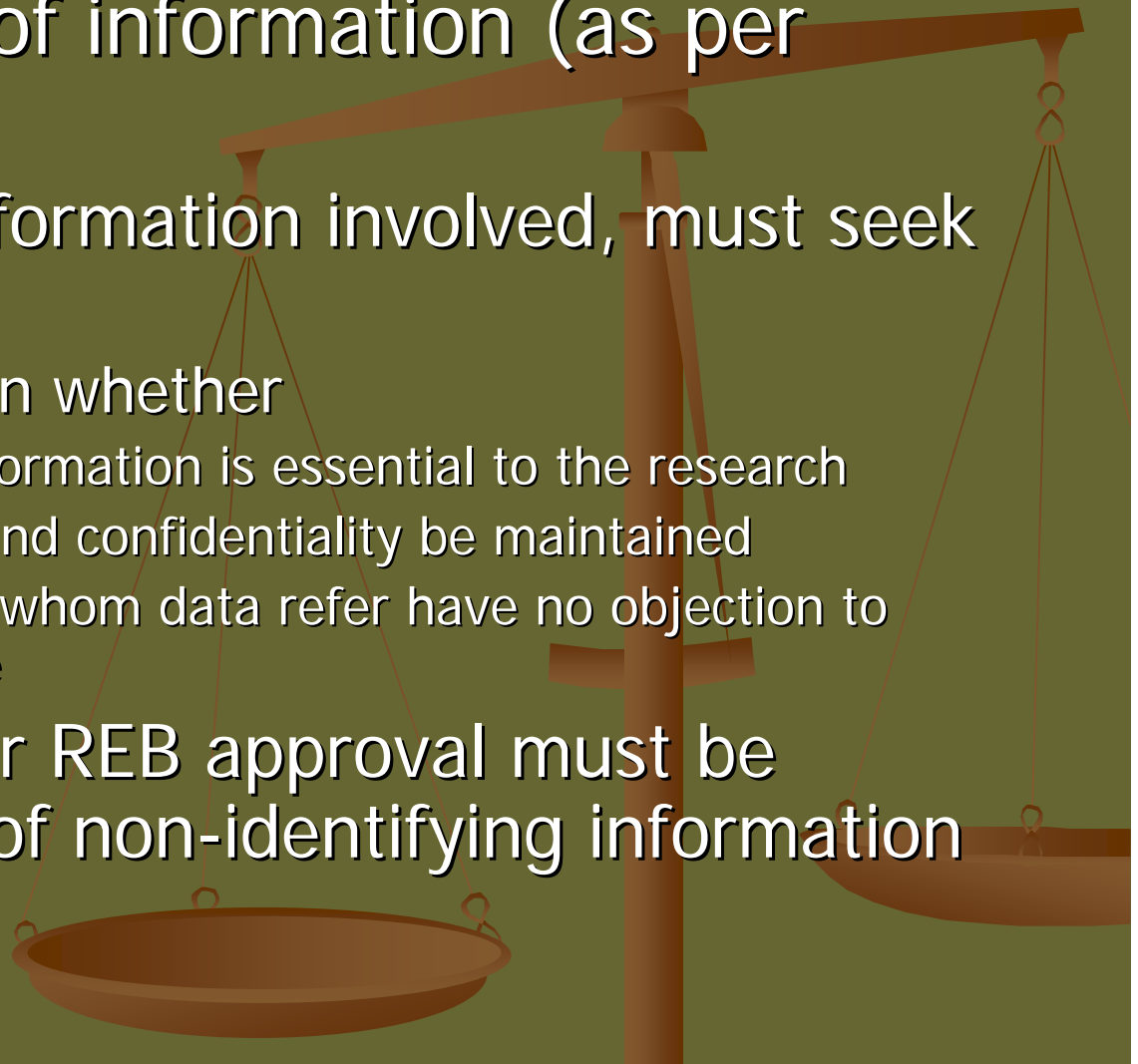
- Who owns electronic health information?
- Not clear – *McInerney v. McDonald*
  - Physician holds information for the benefit of patient
    - Fiduciary relationship
  - Physician owns physical records
  - Patient retains interest in information stored in records “The information remains fundamentally that of the patient”
- Legislation – holders of information described as trustees, custodians and not owners





# Use of Databases in Research

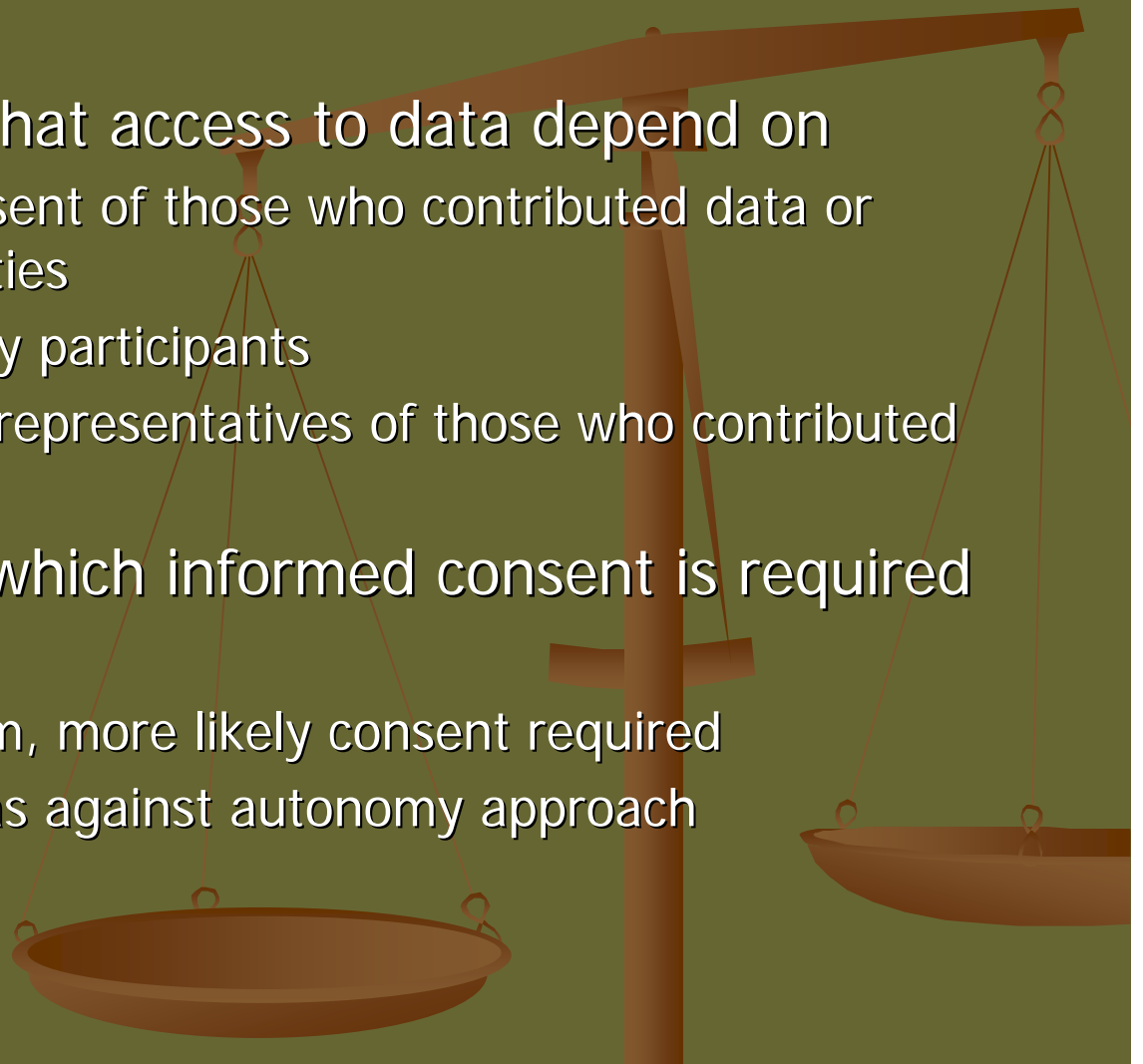
- Secondary Use of information (as per TCPS)
  - If identifying information involved, must seek REB approval
    - REB to ascertain whether
      - Identifying information is essential to the research
      - That privacy and confidentiality be maintained
      - Individuals to whom data refer have no objection to secondary use
  - Unclear whether REB approval must be sought for use of non-identifying information



# Use of Databases in Research

## ■ Consent

- REB may require that access to data depend on
  - The informed consent of those who contributed data or authorized 3<sup>rd</sup> parties
  - A strategy to notify participants
  - Consultation with representatives of those who contributed data
- Conditions under which informed consent is required are unclear
  - Higher risk of harm, more likely consent required
  - Harm vs. benefit as against autonomy approach



# Use of Databases in Research

## ■ Data Linkage

- Combined data sets of even de-identified information can lead to identification of individuals
- Sensitivity of data created
- Function creep

