Current Issues and Initiatives: What's going on at the Secretariat

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UBC REB Retreat
Vancouver, BC
October 21, 2015

PANEL ON RESEARCH ETHICS
Navigating the ethics of human research

Overview of presentation

Evolution activities:

- Evolution of Chapter 11- Clinical Trials
- Enhanced guidance on PPH research
- Material incidental findings
- Cell lines and REB review
- Mandatory consent

Overview of presentation (cont'd)

Strategic planning:

- REB survey
- Consideration of U.S. NPRM
- Possible initiative on consent

Education activities:

- New public interpretations
- New tutorial modules
- Material aimed at research participants

Evolution – Chapter 11 (Clinical Trials)

- Proposals put forward by working committee
- Main changes:
  - expanded scope
  - additional guidance specific to CTs, e.g.
- Next step: consultation

Population and Public Health Research

- Sub-committee proposals approved by PRE in June
- Recommendation: no new chapter required
- Additional examples, guidance proposed that relate specifically to PPH research, integrated within existing guidance

Material incidental findings

- Can TCPS 2 provide better guidance?
- Clarifying criteria for defining what incidental findings are material
- Clarify roles and responsibilities for informing participants about m.i.f.

REB review of cell line research

SRCR interpretation requires REB review if cell lines not anonymous

- Does this interpretation serve a useful purpose?
- If so, could it serve this purpose in a less onerous way?

Mandatory consent

- Possible considerations:
  - Undue influence (depending on vulnerability of participant in the circumstances)
  - Undermining of autonomy
  - Risk of re-identification

  vs.

  - Reduced burden on participants
  - Greater return on scarce research resources

Strategic planning - REB Survey

Goal of Queen's assessment and evaluation team:

- determine what training REB members receive
- to what extent do REB members use TCPS 2

Our interest:

- how can TCPS 2 be improved?
- identify gaps, areas requiring clarification…

Strategic planning - NPRM

- Issues of interest
  - More meaningful and transparent consent process
  - Proportionate review
  - Consent for secondary use research with biospecimens
  - Broader scope of coverage (all CTs, regardless of funding source)

NPRM (cont'd)

- Avoid imposing burdens that don't enhance protections
- Adding categories of research exempt from IRB review
- Single IRB review for multi-site research within U.S.
- Limits on continuing review

Towards greater divergence from or harmonization with TCPS 2?

Strategic planning - Consent

Contemplating broad initiative on consent

- recurring theme in many issues
- broad vs specific
- mandatory vs voluntary
- one-time vs ongoing
- informed??????????

Best practices?

Creative/alternative approaches?

Education activities

- New batch of public interpretations
  - Issues of REB review, governance, researcher responsibilities, scope of application of TCPS 2…
  - Also revisions to two existing interpretations

Education activities (cont'd)

- Release of additional tutorial modules
  - FNIM
  - multi-jurisdictional research

- Developing materials aimed at research participants

Comments? Questions?

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