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From: John Williams
Sent: Mon, 27 Sep 2021 10:14:50
To: secretariat (SRCR/SCRR)
Cc: Ethics
Subject: TCPS 2 Consultation
Sensitivity: Normal

\f0Greetings,

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\f0Here are my comments:

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\f0(1) Review of Multi-Jurisdictional Research - no comments.

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\f0(2) Broad Consent in Research

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\f0- In the Introduction, references should be given for the statement, "there is general approval for seeking broad consent for the use of stored data and human biological materials for less or un- specified research that may be conducted in different and unspecified contexts, now or in the future."

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\f0- In section 3, this statement ("This guidance can be applied to other communities when appropriate (Article 2.11)") is too vague. The use of "may" and "when appropriate" weaken the statement to the point of uselessness.

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\f0- In section 5, this statement "The researcher should consider what information is meaningful to the participant's decision to participate at the time of consent, and what information might be more appropriate as an addendum, which may be of more interest to them later" seems to place an impossible burden on the researcher, especially where the research involves a large number of participants. Note the inconsistency between "the [individual] participant" and the entire participant population ("them").

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\f0- Also in section 5, there is an apparent inconsistency between "For broad consent to be informed, it must include information about..." and "The following is a more detailed description of these requirements that can be used...." How will researchers and REBs decide what information is actually required?

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\f0- In section 7, is this definition/description of broad consent ("Broad consent is used when data or human biological materials are collected for storage for unspecified research") meant to be comprehensive? It excludes other health-related and behavioural longitudinal studies of individuals and populations.

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\f0Review of Research Involving Cell Lines - no comments.

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\f0Research Involving Totipotent Stem Cells - no comments.

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