BC CANCER Biobanking and Biospecimen Research Services
Provincial Health Services Authority

`

Date: September 29, 2021

Re: Proposed changes to TCPS 2 (2018) Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials

To: The Secretariat and Panel experts

We appreciate the effort by the Panel to include information in TCPS about broad consent for the storage and use of data and human biological materials.

There are two overall areas of concern with respect to governance and the shared responsibility to protect participants in new research outside of Canada and in institutions/research parties not under the auspices of TCPS.

Governance (p.1 Introduction)

- The text in the proposed guidance related to inclusion of information about governance in a broad consent is contradictory. Information about governance is acknowledged to be important for some participants (line 37-38) but later it is stated on line 125 that for broad consent to be informed it must include information about 'the repository and its governance (if known)'. We think it is critical for a repository to adopt known governance and in the context of asking for broad consent it is essential to include information about the nature and governance of the registry/repository.
- We also recommend that either the website of the registry/repository or its registration on a national public locator (see below) be included in the broad consent so participants can get current information related to its nature and governance now and in the future.
- It would also be helpful from an institutional and funder governance oversight perspective if the registry/repository was registered on a public locator. This could be accomplished by the requirement for registration in the well-established Canadian Tissue Repository Network biobank certification program which was designed by Canadian ethicists, funders, researchers and biobankers to address issues of governance and quality in biobanking https://biobanking.org/webs/certification.

The shared responsibility to protect participants (p.2)

- The proposed approach to ensuring ongoing protection for participants when data or human biological material collected and stored under broad consent is used for research in countries outside of Canada and in institutions that are not eligible to manage Agency funds is insufficient in our view.
- In our view it is not acceptable that there is no requirement for third party review of the research in the future in order to ensure the research to be conducted under the terms of the broad consent meets the terms of the broad consent and so participants consent continues to be respected and participant welfare continues to be protected throughout the research life cycle.
- The third-party review of the broad consent could be conducted by the institution hosting the research, the registry/repository, or an ethics committee.
- The onus for this review/oversight could be delegated from the REB to registry/repository in the case the repository is an institutional biobank with appropriate governance.

There are a few other specific points and areas needing clarification:

- Line 19-21 currently reads 'Now, however, there is general approval for seeking broad consent for the use of stored data and human biological materials for l**ess or** un- specified research. We suggest the words 'less or' should be removed as the meaning is unclear and does not add to the term 'un-specified'. We suggest the sentence be revised to read '*there is general approval for seeking broad consent for the use of stored data and human biological materials for un- specified research*.'

- Line 47-51 currently reads 'When the stored data and human biological materials are used for new research, the researcher associated with the new project takes on the same responsibilities.' We suggest that since other stakeholders (e.g., the repository) continues to have responsibilities, the sentence be revised to read, '*When the stored data and human biological materials are used for new research, the researcher associated with the new project* ***also*** *takes on the same responsibilities*…"

- Line 62-63 currently reads, 'Alternatively, if the researcher is unable to make such an assurance, they must make that clear to participants during in the consent process.' In our opinion, if the researcher cannot assure third party review of research conducted under the broad consent, then this type of consent is inappropriate and specific consent should be sought. Seeking broad consent without a mechanism to protect participants in the future is not appropriate.

- Line 80-85 content does not match the section title (line 79) 'Free of coercion and undue influence' and first sentence (line 80) 'Consent must be free of coercion and undue influence.'

- Line 129 currently reads 'Description of what data and human biological materials will be stored for research' and we suggest this be revised to read '*Description of what data and human biological materials will be* ***collected and*** *stored for research*.'

- Line 138 under the section title 'What is being collected and stored for unspecified research and why'
    - we believe that it is also important to inform participants providing broad consent for collection and storage and future use of their biospecimens that these biospecimens may not be used eventually for research. This may for example occur because of degradation over time, or because the biospecimen is not selected for use in a specific study. We suggest addition of a statement that indicates this along with the duration that samples will be stored. The text could read, '*The samples will be stored securely and indefinitely until they have been entirely used up or are no longer of scientific value.'*

- Line 139 under the section title 'What is being collected and stored for unspecified research and why'
    - we suggest the following text be expanded to include details or deleted: 'whether the human biological materials will be converted to information' as the HBM used for research are always converted into information.

- Line 167-190. This section is intended to provide more detailed description of the repository and its governance information requirements for broad consent. However, the bullet points do not include specific details on;
    - who is responsible for governance
    - what biobanking standards the repository will operate under

- Line 118, 198. In the context of broad consent, it is very important to provide the opportunity to participants to participate in ongoing consent by asking about preferences for future contact. This is not included in the subsequent bullets. Also Line 198, under the section titled 'Ongoing broad consent,' currently reads 'Researchers must respect the wishes of participants who do not want to be re-contacted.' We suggest that this should be revised to read '*Researchers **must ask participants if they want to be re-contacted in the future** and respect the wishes of participants who do not want to be re-contacted'.*

Thank you for considering this feedback.

We would welcome an opportunity to have a direct discussion with the TCPS Secretariat and Panel experts. Thank you for considering this request.

Sincerely,

Dr. Peter Watson
Director Biospecimen and Biobanking Research Services
BC Cancer, Provincial Health Services Authority

Cc Sheila O'Donoghue (BBRS Biobank leader), Jodi Leblanc (BBRS consent nurse)