Providence Research

Memorandum

To: Industry sponsors conducting clinical trials within Providence Health Care facilities

From: UBC Providence Health Care Research Ethics Board (REB)

Date: January 5, 2023

Re: **REB position on Informed Consent Forms (ICFs)**

The purpose of this memorandum is to communicate the PHC REB's requirements with regards to participant Informed Consent forms. It is hoped that the provision of clear and proactive direction to clinical trial sponsors will reduce the workload on all stakeholders and improve the timelines from submission to approval.

Consent forms for use at PHC sites must be prepared in accordance with the following:

1) The REB recommends no more than a grade 7 reading level be implemented for consent documents. Medical jargon must be explained in lay language.

2) Local consent templates must be adhered to. These can be found at: https://www.providenceresearch.ca/research-ethics/forms-guidance

3) Revisions to standard wording are not permitted **and will result in a delayed time to approval**. If there is additional language that the sponsor would like included, please have this added underneath the required wording (never edit or insert in standard wording) and keep the following in mind:

i. Additional language should be limited to what is deemed necessary
ii. It should be limited to new information (remove any redundancy)
iii. Under no circumstances can the language contradict standard wording. Note that in the event the sponsor's wording in any way conflicts with the standard REB statements, the REB statements govern.

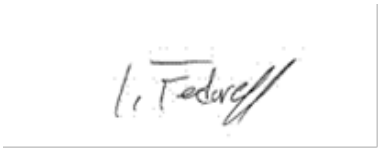
4) Informed consent forms are NOT legal documents. Contract-type language and anything limiting the sponsor's liability is not appropriate and will be required to be removed.

5) PHC is a Catholic Institution. As such, mention of contraception/birth control is not permitted in consent documents in use at this site. The local template includes alternative language which must be used instead.

6) If the study involves genetic sequencing, whether included in the main protocol or as a potential component of future research, the position of the REB is that this must be optional unless it is integral to the conduct of the study-at-hand. If the genetic testing is not integral to

the study at hand, a separate optional genetic consent document must be included for review. See Sections 39.6.1.1 - 39.6.1.3 at:
https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/tissue_collection_banking.pdf

Sincerely on behalf of the PHC REB Chairs,



Dr. Kuo-Hsing Kuo, Chair
Dr. Stephen Hoption Cann, Associate Chair
Dr. I. Fedoroff, Associate Chair