



MEMORANDUM

TO: VCHRI

FROM: UBC Clinical Research Ethics Board Administration and Jean Ruiz, Director, UBC Office of Research Ethics

DATE: Oct. 21, 2024

RE: Clinical Trial Agreements, Sponsor-Researcher Contracts, and REB Review

Purpose

The UBC Clinical Research Ethics Board (CREB) has standardly required executed Clinical Trials Agreements (CTAs) and/or Sponsor-Researcher Contracts and Budget to be reviewed by the CREB manager and, if necessary, the CREB Chair before the certificate of approval is released and the researcher can commence their research. The CREB, following BC Cancers' lead (see [Memo dated May 27, 2024](#)), will stop requiring researchers to submit finalized contracts and subsequent contract amendments to the board for review. The contracts office at Vancouver Coastal Health Research Institute (VCHRI) cover the TCPS2 [6.24](#) requirements in their review.

TCPS2 Requirements

The TCPS2 does not require REB review of sponsor-researcher contracts, but rather the onus is on the institution to ensure the contract meets TCPS2 requirements. Moving forward, the UBC CREB will rely on Vancouver Coastal Health Research Institute (VCHRI) to ensure that the TCPS2 requirements for sponsor contracts are met. These items are part of their normal contract review and a submission to the CREB introduces unnecessary duplication of work. The research ethics boards will still request contracts as necessary as part of their reviews.

TCPS2, Chapter 6, Section E states "Institutions should ensure that sponsors' legitimate interest are reasonably balanced against researchers' ethical and legal obligations to participants and their duty to disseminate data and research findings." Article 6.24 further outlines specific elements that institutions need to ensure are outlined within the contract. The article is reproduced below for reference:

Article 6.24 TCPS2(2022)

It is the responsibility of institutions to review clauses in sponsor-researcher contracts related to confidentiality, publication, and access to data. They shall require that any clauses related to confidentiality and publication be consistent with the researchers' duties to:

- a. disclose new information that may affect participant welfare or consent to REBs and participants; and
- b. report research findings in a timely manner without undue restriction.

Institutions shall also ensure that sponsor-researcher contracts:

- a. stipulate that researchers, primarily the principal investigator, should assume the primary role and responsibility for the analysis, interpretation, and preparation of the findings for publication;
- b. permit principal investigators to access all study data;
- c. permit researchers to access all study data collected at their respective sites; and
- d. permit all researchers to access all study data in cases where no principal investigator is named.

To read all of section E, including the application section, please see the following link:

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter6-chapitre6.html#e

Conclusion

To reduce redundancy of review, the UBC CREB will not require researchers to submit Sponsor-Researcher Contracts to the REB. Review of contracts will lie within contracts office within VCHRI. Ethics questions or concerns about a contract can be referred to the CREB as needed. The CREB may request access to a contract as part of their review.