HREBA | Health Research Ethics Board of Alberta

1500, 10104 - 103 Avenue
Edmonton, Alberta, T5J 0H8

Phone: 780-423-5727
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Guidelines for Principal Investigator Conflict of Interest

If the PI has an actual or perceived conflict of interest (COI) on a study, it is important to determine if it is disclosed and managed. Actual and perceived conflicts of interest arise when a PI has, or appears to have, a personal interest that may jeopardize the PI's independence, impartiality, or objectivity.

Where a COI exists a conflict assessment and management plan should be provided. The goal of a conflict assessment and management plan is to disclose the COI, explain how the study will be monitored to identify any conflicts that may arise, and to explain to the potential participants how the study is designed to avoid conflicts and/or deal with any conflicts that do arise. For example, if an Investigator is being paid for successful recruitment – then someone else who is objective should manage recruitment to avoid coercion and undue influence. If positive data analyses are required to support ongoing funding from a sponsor, or to provide evidence to support drug or device approval – then someone who is objective should provide an independent review of the study data.

In COI cases, the following process is to be followed:

- In IRISS, the conflict must be stated on the Conflict-of-Interest page.
- If not already provided under Section 11.0 on the documentation page, PI must provide a conflict assessment and management plan. Please see TCPS2 2022, Chapter 7: Conflict of Interest, for a discussion on identifying, disclosing, and managing conflicts of interest.
- The conflict of interest must be disclosed in the ICF using the following standard wording (modified as necessary to fit the particular circumstances in the study). This wording should be added in the appropriate section in the ICF. Instructions in red.

  "Dr. <add last name> [examples follow as guidelines, choose the wording which applies or create similar wording to accurately disclose the conflict in the current study] occasionally acts as a consultant for the sponsor and has received payments from the sponsor for these services. For example, Dr. <add last name> has <*Note services provided to Sponsor*, e.g. presentations re: at scientific conferences, sits on advisory panels/board, and/or provides consultation as an expert in meetings with the sponsor]>.

  and/or

  Dr. <add last name> <use wording that discloses things such as whether the Investigator has shares in/owns patent in/etc. the drug company/device/etc.>

  Because Dr. <add last name> has a personal interest in the outcome of the study, it is considered to be a conflict of interest (or possible conflict of interest) by the Health Research Ethics Board of Alberta – <committee name (HREBA.XX)> and requires the study doctor let you know about this in case you have any questions or concerns. In addition to letting you and HREBA-<XX> know about this conflict of interest (or possible conflict of interest), Dr. <add last

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name> has provided a management plan to address any concerns that might arise during the research.

Additionally, Dr. <add last name>_ will not push you to take part in this study over other studies or over standard treatment for your condition and will not prevent you from withdrawing from the study at any time should you so choose. If you ever have concerns about this, you should talk to Dr. <add last name> or contact HREBA-<XXX> Toll-Free: 1-877-423-5727."

If you have any questions regarding this procedure, please email the appropriate committee:

Cancer Committee: cancer@hreba.ca

Clinical Trials Committee: clinicaltrials@hreba.ca

Community Health Committee: communityhealth@hreba.ca

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[1] TCPS2022 – Chapter 7

[2] SOP – 105B.003