



**CHILDREN'S & WOMEN'S HEALTH
CENTRE OF BRITISH COLUMBIA**

AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

**University of British Columbia – Children's & Women's Health Centre of BC
Research Ethics Board
(UBC C&W REB)**

UBC C & W Research Ethics Board

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As a result of the US OHRP audit of the UBC Clinical Research Ethics Board (CREB) this past year; all UBC ethics boards have had to implement changes to stay in compliance with US regulations. All studies that need to comply with FDA requirements (indicated by an affirmative answer to question 7.12 of the RISe application form) such as US sponsored clinical trials and any study that is funded by a US government agency (NIH, DHHS) must be reviewed by the full board regardless of risk to the subjects. In addition, all related amendments and annual renewals must also be reviewed at the full board meeting. The REB is aware of the delay that this creates and is working with the UBC Office of Research Services to find a solution. In the meantime, please take this into consideration when submitting post approval activities and be aware of meeting dates in relation to your study expiry dates. A full list of meeting dates and deadlines can be found on our website (http://www.cfri.ca/reb/meetings_deadlines.asp)

In addition to these changes, these types of studies also require the use of a checklist at the end of each full board review. The board reviews the checklist and if all answers cannot be marked "YES", the study is an automatic **DEFERRAL** and must come back to another full board meeting for subsequent review. The checklist is attached to this email - please take it into consideration when submitting US funded/sponsored studies for review.

It is also evident to the REB that there is much confusion surrounding a **DEFERRAL** and what that means for your submission.

When a study is approved with **PROVISOS** it is essentially approved if the requested changes are made. When you submit your proviso response back to the board, it is reviewed by the Chair and the Associate Chair outside of a full board meeting and providing they are satisfied with the response, an approval is issued.

When a study is **DEFERRED** it indicates that there are substantive issues still to be addressed that require the study to come back to the full board for review. A deferral response should be regarded as essentially a new submission and therefore must be submitted in accordance with REB submission deadlines in order to be reviewed at the next scheduled Full Board meeting.

Finally, please keep an eye out for the REB's 1 year report card and survey due out July 30th. Both the REB and PHSA are interested in your feedback and suggestions. The results of the survey will be reviewed in the early Fall and shared with the C&W community.

Please do not hesitate to contact the REB staff with your questions or comments regarding these changes.

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