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October 26, 2011

Dear Sponsor,

By way of this letter we would like to inform you that the UHN REB has a new Unanticipated Problem Reporting Framework., which significantly changes the reporting requirements for adverse events, protocol deviations and other unanticipated events for UHN sites.

The new framework was pilot tested with several UHN sites earlier this year, prior to a soft launch on August 11th, until the date of this letter when the framework has become mandatory.

Our new requirements are based on the guidance document issued by our national REB organization, the Canadian Association of Research Ethics Boards (CAREB). Both CAREB and we anticipate that other REBs across the country will adopt similar reporting requirements for unanticipated problems based on this national guidance document. If you would like to read further about the guidance, please visit the CAREB website (<http://careb-accr.ca/?q=node/240>)

These changes impact Sponsors directly for the reporting of external adverse events. If these events are to be reported to the REB, they must be accompanied by all of the information outlined in Section 5.2 of our guidance document (“External (Non-Local) Adverse Events”), which is based directly on the CAREB requirements.

There are also different requirements for the submission of SUSAR or periodic safety reports to the UHN REB, as well as updated investigational product documentation (investigator brochures, product monographs, device manuals, etc.). In summary, if the updated information does not affected the risk/benefit ratio to participants and necessitate amendments to the study, it need not be submitted to the REB.

All Unanticipated Problem Report forms not accompanied by the required documentation will be returned to the sites as of the date of this letter.

During the soft launch period it has been left to the discretion of the individual sites and sponsors as to whether to follow the new framework, or to report on the previous REB reporting forms for external adverse events, local adverse events and protocol deviations.

However, any reports completed on the new Unanticipated Problem Reporting Form will be evaluated according to the new requirements, and returned to the sites if the event does not meet the 3 criteria to constitute an “unanticipated problem”.

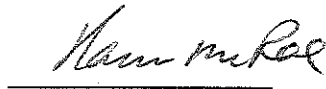
Until November 30th, the UHN REB will be accepting reports on the previous reporting forms for events that occurred prior to the issue of this letter, though it is our preference that sites follow the new reporting requirements even for events that occurred in the past.

Should you have any concerns about these changes, please contact the undersigned Co-Chairs, or CAREB directly.


Best Regards,

UHN REB Co-Chairs

Dr. Karen McRae

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Dr. Jack Holland

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Dr. Anna Gagliardi

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Dr. Paul Oh

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