

1) SAMPLE OF THE VERSION SENT TO THE INVESTIGATOR AND THE REB AFTER THE QI VISIT



Centre universitaire de santé McGill
McGill University Health Centre
Research Ethics Office - Quality Assurance and Education Program
QI Visit Report

Study Title: A Randomized Controlled Trial of Drug X for Condition Y

REB Study Code: REB-00-000

Date of On-Site Visit: 25-Sep-2008

Study Personnel Interviewed: Dr. Zed.

Current Study Status: Active.

Findings	Applicable Regulations and Comments	QA Recommendations	Investigator's Comments to REB
<p>1) Most consent forms were duly signed and dated by the participant and the designated member of the study team. However, the name and signature of participant AA were missing from the consent form on file for him/ her.</p>	<p>ICH GCP Guideline Article 4.8.8: "Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion." According to the Regulatory Framework in Health Research at the McGill University Health Centre, "failure to obtain consent/ assent from a subject" is a "Serious human subjects protection violation."</p>	<p>The participant should sign the consent form at his/ her next study visit, as well as a statement indicating that the study was fully explained to him/ her before his/ her participation.</p>	

Additional comments from the QA coordinator: None

Additional investigator comments: