

Updated December 04 2006, Updated Sept 25 2007

### **Protection for Intellectual Freedom and Publication Rights**

University and hospitals are committed to the concept that review by scholarly peers is the cornerstone of excellence in research, and that researchers should have the right to publish or otherwise disseminate the results of their research.

University and hospitals agree that they will not enter agreements that allow research sponsors to suppress or censor research results.

University and hospitals agree that they will not enter research agreements that do not allow researchers to retain a copy of data gathered at their site pursuant to a sponsored study.

University and hospitals agree that researchers must retain the right to publish or present their findings as they interpret them. In agreements with sponsors of health-related research, it is acceptable to agree to provide the sponsor with a manuscript or presentation for review prior to publication or presentation. Strenuous efforts should be made to limit the sponsor's delay of such publication or presentation to a maximum of 60 days, and in no case shall the allowable delay be more than 4 months from submission of the publication or presentation to the sponsor, after which time, the researchers must be free to proceed with the publication or presentation.

For large multi-site studies, a Toronto participating site might not be directly involved in the preparation and submission of a manuscript for publication, and therefore the interchanges with study sponsors might not be fully disclosed. To safeguard against the unlikely possibility that the study steering committee could be impeded in submitting a manuscript by a sponsor, the participating site in Toronto should retain the right to publish single-site results or make a single-site presentation and to submit such single-site publication or presentation to a sponsor within a maximum of 18 months after study completion. After submission to the sponsor, the review time-lines in the preceding paragraph apply. If the trial is sponsored solely by a public granting agency (or public granting agencies), a Toronto participating site may decide not to retain the right to publish single-site results or make single-site presentations under certain conditions. These conditions include there being a Steering Committee (and if relevant a Publication Committee) that retains the right to publish and which cannot be impeded from doing so by the sponsor.

University and hospitals agree that agreements with sponsors for research involving human subjects must permit the disclosure of research results to study subjects and/or their lawful representatives, sponsors, study steering committee, Research Ethics Boards (REBs) at the site and at other participating study sites, and regulators, if and when the investigator, institution and/or REB deem disclosure necessary to protect the health of study participants. Provision for disclosure to study subjects and/or their lawful representatives must also be made so as to obtain and maintain informed consent.

University and hospitals agree that no contract with sponsors shall contain provisions for binding arbitration of disagreements between the sponsor and the researcher on matters related to patient safety. University and hospitals agree that agreements with sponsors for research involving human subjects must set out that all parties will comply with all applicable laws and government regulatory requirements governing research, with Good Clinical Practices as set out in guidelines promulgated by regulators, and with the customary principles of ethical research.