Canadian Cancer Trials Group

Policies for the Sharing of Data

Policy Date: October 27, 2008
1.0 Introduction

This document describes Data Sharing Policy of the Canadian Cancer Trials Group (CCTG) and includes the policies and processes for provision of individual patient data to investigators for use in research projects. The CCTG is a cooperative group that conducts clinical trials in cancer research. The Group receives its funding support from multiple sources, which include the The Canadian Cancer Society Research Institute (CCSRI), the U.S. National Cancer Institute / Cancer Therapy Evaluation Program (NCI/CTEP), other peer-review granting agencies, including the Canadian Institutes of Health Research (CIHR) and from collaborations with industry. The Data Sharing Policy of the CCTG therefore includes compliance with, and accountabilities to, these various funding sources. Each trial that is led by CCTG has a formal protocol document, which includes a statement of the objectives of the study. Patient consent and authorization are obtained to collect the individual patient data required for addressing the study objectives. These data are sent from the treating or enrolling institution to Central Office of the CCTG, where the data are reviewed, processed and entered on an electronic database. These data may be submitted using paper-based Case Report Forms or through an electronic data capture (EDC) system; it is the intent of the CCTG to utilize EDC for all newly developed trials. Not all information submitted becomes part of the electronic database. The electronic database is used as the basis for the analysis of the CCTG studies, with the analyses performed by the faculty and staff of the CCTG Central Office.

The procedures described here do not cover requests for information from the Health Canada, the NCI, the U.S. Food and Drug Administration or other agencies that require information according to Canadian or U.S. federal regulations or by the terms of the Group’s grant awards. Such requests will be honored as expeditiously as possible. The data requested by an investigator may include data generated from laboratory correlative studies. However, this document only covers requests for existing data, not requests for use of tissue or for collection of additional data.

CCTG Data Sharing Policy is compliant with any policies developed by CCSRI, those that exist for NCI/CTEP and are available at http://ctep.cancer.gov/protocolDevelopment/docs/data_sharing_policy.pdf, and with the principles of CIHR as indicated at http://www.cihr-irsc.gc.ca/e/33925.html. If the policies of these organizations are amended, the CCTG will apply these new policies to any new applications for data sharing that are received. In complying with policies of NCI/CTEP and CIHR, reporting of studies that utilize data from CCTG trials must be compliant with the public access policies of these bodies. These include posting of published manuscripts on PubMed Central, which is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (see: http://www.pubmedcentral.nih.gov).
2.0 Request Procedure

While most analyses of the CCTG’s studies are performed at its Central Office, the Group also makes research data available to other investigators, including as required by the policies of the U.S. National Institutes of Health. An investigator who wishes to use individual patient data from one or more of the CCTG’s studies must make a formal request to the CCTG. The CCTG will review the scientific merits and feasibility of the request, as discussed in the following section. Requests for data will only be considered once the primary study analyses have been published.

A brief proposal must be submitted for review using the Request for Data Proposal Form, which is available from the website of the CCTG at http://www.ctg.queensu.ca/. This proposal should include a brief rationale, study objectives, eligibility criteria, outcome measures and analysis plan.

The CCTG will conduct a review of the merit and feasibility of the proposal, including whether there are sufficient data to provide adequate information for analysis and the availability of the required data. Reviewers will include faculty from the CCTG Central Office and members of the appropriate Disease Site Committee. If approved on scientific grounds, budgetary implications will be determined. Investigators will be notified of the CCTG’s decisions in writing. If a request is denied, the CCTG will, in the written decision, state the reasons the request was denied and inform the investigators that a denied request may be appealed as outlined in Section 6.0. Release of the data is subject to the conditions stated in Section 5.0.

3.0 Data Abstractions

While the CCTG is moving to an electronic data capture system, data from previous trials have been reported in paper form; some of these data may not be coded into a data base. In this case, the data will need to be abstracted from the paper-based Case Report Forms. Data abstractions can only be performed if adequate funding is available. Even if funding is available, the CCTG may not have sufficient staff available to perform the abstraction. Data received through EDC systems may also require transfer to an electronic data base; similar principles for transfer of these data will apply. Pending the nature of the data, the CCTG may be willing to have the investigators or their representatives or contractors come to the CCTG’s Central Office to perform the abstraction. Funding for clerical support will be required.

4.0 Regulatory Considerations

As described in section 1.0, support for CCTG activities comes from a number of sources. All trials are conducted in compliance with the International Harmonization Conference on Good Clinical Practice. Trials that utilize drugs are conducted according to the regulations of Health Canada, including where appropriate, according to the specific regulations associated with a Clinical Trials Application. Trials performed in
collaboration with, or through the support of, NCI/CTEP require that all research use of data collected on human subjects from these studies be subject to applicable U.S. Office of Human Research Protections (OHRP) regulations and to applicable U.S. regulations of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPPA). Generally, patients have only consented to have their health information used for the objectives of the clinical trial in which they participated. Use of the data for other research projects is allowed only if a Research Ethics Board has determined that use of the data in the project meets the minimal risk criteria for conducting the research without the patients' consent, if the use of the data in the project is exempt from consent requirements, or if the project does not constitute human subjects research. The required level of review or approval will generally depend on the degree to which the data have been rendered fully anonymous, de-identified, or coded. Guidance on these matters can be found in the OHRP document “Guidance on Research Involving Coded Private Information or Biological Specimens” (http://www.hhs.gov/ohrp/policy/cdebiol.html) and at the NIH HIPAA Privacy Rule Information for Researchers site (http://privacyruleandresearch.nih.gov/clin_research.asp).

The criteria for de-identification of data under HIPAA are given in the Code of Federal Regulations, Part 46, Section 164.514. It should be possible to conduct most projects using coded data (as described in the OHRP Guidance) that meet the criteria for a limited data set that can be released under a data use agreement (as described in Part 46 of the CFR, Section 164.512 and in the NIH HIPAA guidance documents), without obtaining additional patient consent or authorization.

5.0 Release Conditions

Release of data for research purposes is subject to the following conditions. A formal data use agreement covering the relevant conditions will be required.

1. Investigators must agree to use the data only for the approved research project. If the investigator later wishes to use the data in a new project, a new proposal must be submitted.

2) Investigators must agree to keep the individual patient data confidential. The data may only be shared within the team conducting the analysis project. Requests from other individuals for access to the data should be referred to the CCTG.

3) The regulatory requirements discussed in Section 4.0 must be met.

4) In situations where a complex data set is required, a fee may be charged.

5) Copies of all abstracts and manuscripts arising from the project must be sent to the CCTG with an opportunity for the CCTG to provide commentary prior to abstract / manuscript submission. Approval of the manuscript is not a condition for use of the data. For studies funded by the NCI/CTEP that are not subject to a
binding collaborative agreement, copies of abstracts and manuscripts only need to be sent to CCTG concurrent with their submission for publication.

6) Other relevant CCTG policies will apply to the use of data. Particularly, policies relating to authorship and review of abstracts and manuscripts will apply. The authorship policy of the CCTG is available on the CCTG website at http://www.ctg.queensu.ca/public/publications/PublicationPolicy-Authorship.pdf. If data are being provided for an independent project, then there may be no expectation for the CCTG to have representation on the authorship; where CCTG members have made substantial contributions to the project, authorship will be expected. Details of authorship must be negotiated prior to CCTG release of data.

7) Release of data collected in a clinical trial conducted under a binding collaborative agreement between the CCTG and NCI/CTEP must be in compliance with the terms of the collaborative agreement between CCTG and NCI/CTEP. Release of data collected in a clinical trial conducted under a binding collaborative agreement between the CCTG and a pharmaceutical / biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by CCTG and the company. Release of the data is also subject to the terms of any contracts between the CCTG and other entities, which cover any of the requested data.

8) In releasing the data, the CCTG makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the data will not infringe any patent, copyright, trademark, or other proprietary rights. No indemnification for any loss, claim, damage, or liability will be intended or provided.

6.0 Appeals Process

If a request for data is denied the applicant may appeal the decision. The appeal will be reviewed by the Director of the CCTG in conjunction with an ad hoc committee of the CCTG’s Clinical Trials Committee. Where applicable, the appeal review process will also include the NCI’s program officer and an outside statistician. The statistician will be named jointly by the CCTG Director and the program officer.