Data Sharing & Access Policy

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Table of Contents

1 Introduction 3
2 Acronyms 3
3 Request Procedure 3
4 Regulatory Issues 4
5 Appeal Process 4
6 Revision History 5
7 Signature 5

1 Introduction

The Canadian Clinical Trials Group recognizes that the individual patient data (IPD) from its trials represent a rich resource and is committed to supporting their use for purposes that extend beyond the purposes defined in trial protocols. Consequently, when CCTG led studies are published, a statement that IPD data will be shared when feasible after formal application is made. Currently, IPD from trials led by CCTG supported by the Cancer Therapy Evaluation Program of the National Cancer Institute are posted at the NCI and accessible there. However, the databases for the large majority of CCTG led trials are housed at CCTG. This policy applies to the latter studies.

Investigators external to the CCTG operations and statistical office can use CCTG IPD for research projects via two mechanisms: 1. Undertaking an analysis of data that remains at CCTG via collaborative project with CCTG faculty; 2. Requesting that trial data be released for analysis at the investigator's institution. This policy applies to both mechanisms. It describes the process for making a request, as well how requests are evaluated,which are the same in both cases.The additional steps required when data is to be released are also described.

2 Acronyms

CCTG	Canadian Cancer Trials Group
ICMJE	International Committee of Medical Journal Editors
NCI	National Cancer Institute
CTEP	Cancer Therapies Evaluation Program
IPD	Individual Patient Data
SOP	Standard Operating Procedure

3 Request Procedure

An investigator who wishes to use IPD from one or more of the CCTG's studies must make a formal request to the CCTG. The CCTG will review the request as described below.Requests for data will only be considered once the primary study analyses have been published. If the investigator wishes to discuss the request before filing a formal application, they should contact the relevant study senior investigator or, for a multiple study request XXXXX.

CCTG has developed a platform for submitting, processing, evaluating, and tracking data use requests.

CCTG will conduct a review of the merit and feasibility of the proposal, including whether there are sufficient available data to provide adequate information for analysis., The initial review will be conducted by the relevant study statistician(s) and senior investigator(s). If they have concerns about the scientific merit or feasibility of the proposal, additional faculty and members of the appropriate Disease Site Committee(s) may be consulted for further input on required scientific content or feasibility. In addition, Senior Managers will be consulted if the proposal represents additional workload or other feasibility concerns. Once a proposal is approved on scientific grounds, the budget and logistic issues will be considered.Investigators will be notified of the CCTG's decisions in writing by the Senior Investigator and/or Senior Biostatistician. 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 below. This information will also be tracked.

Data ReleaseIn circumstances where, for whatever reason, it is decided that data should be released rather than analyzed “in house,”the release of data is subject, but not limited, 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 cite the trial identifier and source of data, and agree to keep the IPD 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 below must be met.
4. A fee may be charged, using a cost recovery model, to support the internal infrastructure required to assemble the requested datasets.
5. CCTG policies will apply to the use and transfer of data including but not limited to CCTG policies for Privacy and Confidentiality (CTG-POL-0009), Clinical Data Transfers (DBS-SOP-0116), and Informed Consent (ERG-SOP-0069). 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 and will be included in the data sharing agreement
6. A contract between CCTG and the relevant parties regarding the release of data will be executed. This will be completed acknowledging that 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.

4 Regulatory Issues

This policy aligns with CCTG policies for Privacy and Confidentiality (CTG-POL-0009), Clinical Data Transfers (DBS-SOP-0116), and Informed Consent (ERG-SOP-0069) and is in accordance with applicable regulations and guidelines. The working assumption of this policy is that the analyses described will be conducted using de-identified data. CCTG will assess the need for REB approval and re-consent where applicable. This assessment takes into account TCPS 2 which states that “consent is not required for research that relies exclusively on secondary use of non-identifiable information.”

5 Appeal 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.

6 Revision History

Version Number	Version Date	Brief Description of Revision(s)
V001	March 25, 2016	Draft
V002	July 20, 2016	Initial Release
V003	March 5th, 2017	Updated to clarify that this is now the CCTG Policy for Data Sharing and Access. CTG-POL-0008 Data Sharing is now obsolete.
V004	November 30, 2020	Updated to reflect new process via DASH system.

7 Signature

Signature of Responsible Group Leader:	Dr. Janet Dancey	On file	2021Jan04
	Name	Signature	Date