Canadian Cancer Trials Group

Privacy and Confidentiality

V006 July 30, 2021

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1 Policy Description

It is Canadian Cancer Trials Group (CCTG) policy to ensure compliance with applicable privacy legislation related to clinical trial conduct in Canada. This includes clinical trials led by CCTG as well as clinical trials done in partnership with others (e.g. pharmaceutical partner, NCI US NCTN collaboration, International Cooperative Group partner).

2 Introduction and Scope

This policy outlines the procedures for ensuring compliance with applicable privacy legislation and procedures for addressing non-compliance. It applies to the collection, storage, use, and disclosure of information obtained from clinical trial participants for CCTG trials. Agreements, including but not limited to Participating Centre Agreements and vendor specific agreements (e.g. QARC), detail requirements with respect to privacy.

3 Definitions

3.1 Terms

Agent: In relation to a health information custodian, means a person that, with the authorization of the custodian, acts for or on behalf of the custodian in respect of personal health information for the purposes of the custodian, and not the agent's own purposes, whether or not the agent has the authority to bind the custodian, whether or not the agent is employed by the custodian and whether or not the agent is being remunerated. (1)

Centre Code: A four letter code is given to each participating centre by CCTG. For example, Princess Margaret Hospital has a centre code of CAMP.

Central Office: CCTG Central Operations and Statistics Office location in Kingston, Ontario at Queens University.

Covered Entity: A health plan, a health care clearinghouse or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard. (2)

Data Use Agreement: An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected. (3)

De-Identified: Refers to records (including those containing personal health information (PHI)) that cannot be directly linked to the participant and are linked to participants via coded identifiers only.

Health Information Custodian: A person or organization who has custody or control of PHI as a result of or in connection with performing the person's or organization's powers, duties or work, as described below:

a) A health care practitioner or a person who operates a group practice of health care practitioners.
b) A service provider within the meaning of the Home Care and Community Services Act, 1994 who provides a community service to which that Act applies.
c) A community care access corporation within the meaning of the Community Care Access Corporations Act, 2001.
d) A person who operates one of the following facilities, programs or services:
    - A hospital within the meaning of the Public Hospitals Act, a private hospital within the meaning of the Private Hospitals Act, a psychiatric facility within the meaning

of the Mental Health Act or an independent health facility within the meaning of the Independent Health Facilities Act.
- A long-term care home within the meaning of the Long-Term Care Homes Act, 2007, a placement co-ordinator described in subsection 40 (1) of that Act, or a care home within the meaning of the Residential Tenancies Act, 2006.
- A pharmacy within the meaning of Part VI of the Drug and Pharmacies Regulation Act.
- A laboratory or a specimen collection centre as defined in section 5 of the Laboratory and Specimen Collection Centre Licensing Act.
- An ambulance service within the meaning of the Ambulance Act.
- A home for special care within the meaning of the Homes for Special Care Act.
- A centre, program or service for community health or mental health whose primary purpose is the provision of health care.

e) An evaluator within the meaning of the Health Care Consent Act, 1996 or an assessor within the meaning of the Substitute Decisions Act, 1992.
f) A medical officer of health of a board of health within the meaning of the Health Protection and Promotion Act.
g) The Minister, together with the Ministry of the Minister if the context so requires.
h) Any other person prescribed as a health information custodian if the person has custody or control of personal health information as a result of or in connection with performing prescribed powers, duties or work or any prescribed class of such persons. (1)

Health Information: Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. (2)

Human subject: Refers to a living individual about whom an investigator (whether professional or student) conducting research obtains:

a) Data through intervention or interaction with the individual, or
b) Identifiable private information. (4)

Identifying Information: Information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual (1)

Individually Identifiable Health Information: Information that is a subset of health information, including demographic information collected from an individual, and:

a) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
b) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
    i. That identifies the individual; or
    ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (2)

Limited Data Set: Refers to protected health information that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement. (3)

CCTG Patient Serial Number: A coded identifier generated by CCTG that consists of the participant's centre and enrolment number. For example, CAMP0001 would be the CCTG patient serial number for the first participant enrolled in a given trial at Princess Margaret Hospital.

Non Compliance - Privacy Breach: A privacy breach occurs when personal information is collected, retained, used, or disclosed in a manner that is not in accordance with the acts and regulations. Privacy breaches generally include the unauthorized disclosure of personal information for example by a file being lost, misplaced, or stolen, or by inadvertently disclosing through human error (e.g. mail/email sent to wrong individual).

Personal Health Information (PHI): With respect to an individual, whether living or deceased, means

a) Information concerning the physical or mental health of the individual;
b) Information concerning any health service provided to the individual;
c) Information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;
d) Information that is collected in the course of providing health services to the individual; or
e) Information that is collected incidentally to the provision of health services to the individual. (5)

Personal Information (PI): Recorded information about an identifiable individual, including,

a) Information relating to the race, national or ethnic origin, colour, religion, age, sex, sexual orientation or marital or family status of the individual,
b) Information relating to the education or the medical, psychiatric, psychological, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,
c) Any identifying number, symbol or other particular assigned to the individual,
d) The address, telephone number, fingerprints or blood type of the individual,
e) The personal opinions or views of the individual except where they relate to another individual,
f) Correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,
g) The views or opinions of another individual about the individual, and
h) The individual's name where it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual. (6)

Protected Health Information: Protected health information is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. Protected health information excludes education records covered by the Family Educational Rights and Privacy Act, as amended 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer. (2)

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research. (2,4)

3.2 Acronyms

EDC	Electronic data capture
ETL	Ethics Team Leader

EU	European Union
GDPR	General Data Protection Regulation
IT	Information Technology
NCI US	National Cancer Institute of the United States
OCO	Office of Compliance and Oversight
PHI	Personal Health Information
PI	Personal Information
REB	Research Ethics Board

4 Collection of Personal Information/Personal Health Information by CCTG

CCTG collects both personal information (PI) and personal health information (PHI), as defined above, from participants who have provided written consent to participate in a clinical trial. Information is collected for trial purposes only, or as required by the regulations. The PI/PHI collected is detailed prospectively via the clinical trial protocol, case report forms/electronic data capture forms (mocks), and via the informed consent form. Participating centres should document the PI/PHI required for each clinical trial in the local Research Ethics Board (REB) application per local policy.

This information may be communicated to CCTG via paper-based or electronic data capture (EDC) forms. PI/PHI communicated in paper format may additionally be retained electronically.

Examples of PI/PHI that may be collected as needed on a trial-specific basis are presented in Table 1. If local policy prohibits the collection of data required as specified for the trial, the centre must promptly notify the Ethics Team Leader (ETL) or designated back-up (Manager, Office of Compliance and Oversight (OCO)). The ETL and OCO Manager will assess to determine an appropriate course of action in association with the REB/institution as appropriate and will advise other groups internally including the trial Senior Investigator and Study Coordinator.

Table 1. Personal Information/Personal Health Information Collection and Rationale

Information collected	PI/ PHI	Rationale for collecting
Race/ethnicity	PI	Collected to facilitate assessment of demographic information relevant to the study question and eligibility criteria as applicable. For NIH/NCI US affiliated trials collection of this is a condition of funding.
Gender/Sex	PI	For the purposes of stratification, statistics, and confirmation of eligibility, as applicable.
Date of birth (DOB) (Either year/month/date or year/month are acceptable)	PI	Required for eligibility purposes, statistical information, and to assess safety reports. If not permitted by local REB/institution, partial DOB (year/month only) is acceptable. CCTG Electronic Data Capture (EDC) system will accept either full or

		partial DOB. NCI US CDUS requires submission of partial date of birth only (year/month).
Pathology Accession Number (PAN)	PI	Required for correlative studies/tumour banking, as outlined in the protocol and informed consent form. CCTG collects PAN to ensure the correct sample is received and returned to institution, when required. While PAN is collected internally, upon arrival at the Tumour Bank this is de-identified and provided a Tumour Bank Identification Number (TBID) per TMG-SOP-0083 Correlative Science and Tissue Banking to ensure privacy and confidentiality.
Test dates/results, adverse events, medical history, concomitant medications, radiological reports/ images, pathology reports, and other supporting documents as applicable to the trial	PI/ PHI	For the purposes of the research as outlined in the protocol and informed consent form.
Participant initials OR a unique two or three letter code assigned by hospital	NA	Requested to confirm information received is for the correct participant. Based on REB/institution policy, the code can be participant initials, scrambled initials, or other local coding process as long as the identifier is unique to the participant. CCTG will accept any two (or three) letter code (See Table 2). The process should be in accordance with local Standard Operating Procedure and may be reviewed during on-site visits.
Other	PI/PHI	If other PI/PHI is planned for collection in the trial this should be prospectively indicated in the trial protocol, consent, and case report forms/electronic data capture (mock forms) for centre and institution/REB review.

NA – Not Applicable

4.1 Identification of documents sent to CCTG

CCTG requires that copies of protocol-mandated supporting documents that are sent to central office be identified, as shown in Table 2, with the participant's trial code, CCTG patient serial number, and participant initials or a two/three letter code assigned by the centre only. These are required for quality assurance purposes only, to ensure that the documents received are associated with the correct participant for review. The initials or two/three letter code provided is required to remain the same throughout the course of the trial.

Table 2: CCTG Identifier Requirement Example

Identifier Name	Example
Trial Code	MA.32

Patient serial number	CAMP0001
Participant initials OR two/three letter code	AB

Centres are required to locally obscure all directly identifying information or participant identifiers such as, name, address, telephone number, hospital number and health card number from copies of any supporting documents submitted to CCTG. All identifiers should be obscured by the centre prior to submitting to CCTG. Any participant identifiers that are not permitted by local policies should also be obscured by the centre. The centre is responsible for ensuring that the information sent to CCTG is in compliance with local regulations and policies.

If issues of non-compliance are noted, refer to section 7.0.

5 Access and Provision of PI/PHI Retained by CCTG

All CCTG central office staff are required to sign a confidentiality agreement (CTG-FRM-0004 Undertaking of Confidentiality – CCTG Internal). This is filed in the GAO Group Administration files. In addition, visitors to central office are required to sign a confidentiality agreement (CTG-FRM-0003 Undertaking of Confidentiality – External Visitors) before accessing participant records. Further, access can only be granted if it has been agreed to by the participant via the informed consent process.

5.1 Obtaining informed consent

CCTG requires that informed consent be appropriately obtained from each participant in a clinical trial in accordance with ERG-SOP-0069 Informed Consent.

5.2 Withdrawal of consent

Personal information/personal health information obtained prior to the withdrawal of consent will be collected/retained. Date of death may be obtained from public sources (e.g. newspaper obituaries or public registries) following withdrawal of consent. Local REB approval may be required. No further information is to be collected following the withdrawal of consent. (TMG-WKI-0154 Withdrawal of Consent)

5.3 Data reports / data sharing

CCTG will share data in accordance with CTG-POL-0043 Data Sharing and Access and in compliance with Canadian, US, and EU privacy requirements. Formal data agreements cover relevant conditions including confidentiality of individual participant data. Further, clinical data transfers will be conducted according to DBS-SOP-0116 Clinical Data Transfers.

CCTG collects limited redacted source data in an EDC portal in order to verify eligibility / outcomes. Source data/documents are not released from the central office.

5.4 Data storage, destruction/archiving, and retention storage

All paper records at CCTG are stored behind locked doors with controlled access according to TMG-SOP-0254 Trial Master File. Once archived, paper records off-site are stored at a secure facility per TMG-WKI-0134 Off-Site Storage.

Electronic records within the CCTG computing system are protected by security measures, as described in DBS-POL-0106 General Computing and Network Security Policies.

Destruction/Archiving

Destruction of paper documents must be conducted in a manner appropriate to the confidential nature of the document. Any material considered to be in the public domain can be recycled or disposed of through general garbage disposal; examples include:

- Any material posted on our external, non-password protected website
- Journal articles, reports and abstracts, once published
- Any information found in public clinical trial registries
- Any publically available pharmaceutical information, such as product monographs

In order to protect the privacy of individuals, material not in the public domain, should be shredded (if not required to be kept on file). Particular attention should be given to patient data, regulatory and proprietary information; examples include:

- All patient chart materials, including verification printouts, correspondence, supporting documents, forms
- Protocols, trial-related guidebooks
- Data listings, including patient data, site data (CPI, monitoring reports), accrual
- Regulatory documents, including Investigator's Brochures
- Meeting materials, including agenda and minutes
- Information obtained from non-CCTG sources that may be considered confidential (e.g. non-public CTSU or cooperative group material)

Electronic records containing personal information/personal health information will be archived in a secure manner. Audit trails for data changes will be maintained.

Retention

Records will be maintained according to ERG-SOP-0073 Records Retention.

Participant Charts – Out of Office

Participant charts (paper) may be taken out of the office by authorized staff for working on at home only under the following conditions:

- Manager/supervisor approval is obtained prior to removing charts from the office.
- Charts are taken out only by staff members directly involved in the conduct of the trial (e.g., study coordinator, monitor or senior investigator for the trial).
- None of the charts are for local (Kingston area) patients.
- Charts are only out for brief period of time, either overnight or the weekend.
- The location of the chart is known to other central office staff.
- During transportation participant charts are carried in a closed case or carrying bag and are not left unattended during transport at any time.
- While at home charts are not left where non-staff members may have access to them.

Electronic participant information exists in CCTG files and databases that are restricted to staff. All CCTG staff have signed a form, indicating that they will maintain absolute confidentiality of information (CTG-FRM-0004, Undertaking of Confidentiality – CCTG Internal). While electronic information may be accessed by authorized staff from any location with internet access, such as from home or from personal cellular phones, this should only be done under the following conditions:

- Access outside of the office is for the purposes of work
- Care is taken by staff member that non-staff members may not view or access this information

6 Requests from Participants to Access Information about them Retained by CCTG

Requests from participants to access information about them held by CCTG must be directed to the ETL and OCO Manager for further assessment. When GDPR is applicable to a trial, participants have the right to review, correct, obtain and limit their person data. GDPR includes allowances for restricting these rights in scenarios such as scientific research where removing data could impact the integrity of the trial and/or safety and well-being of other participants.

7 Non-Compliance

Issues of non-compliance with privacy requirements resulting in privacy breaches may be identified by a centre, CCTG, or other source. Issues should be directed to the ETL or designated back-up (OCO Manager). The ETL and OCO Manager, in consultation with other groups internally including trial Senior Investigator and Study Coordinator, will assess to determine an appropriate course of action.

Retrospective approval for information provided from the local REB/institution may be possible in certain cases and will be obtained where possible. Implementation of corrective action with respect to related data systems will be reviewed by the Chief Information Officer in consultation with the Systems Administrator.

The assessment and corrective action plan will be documented and will include but is not limited to identification of the scope of the potential breach and steps to contain the breach. Local centre/REB policy will consider identification of those individuals whose privacy was breached and notify those individuals accordingly.

Further, if issues of non-compliance with privacy requirements constitute a significant finding, this will be addressed as a significant finding according to AMG-SOP-0027 Significant Findings and Research Misconduct.

8 US Privacy Legislation

Title 45 CFR Part 45: The Common Rule; FDA Title 21 CFR Part 50, 56

As a recipient of US Federal funds to conduct research, CCTG ensures compliance with the HHS Protection of Human Subjects Regulations Title 45 CFR Part 46 (or the Common Rule), and the FDA Protection of Human Subjects Regulations Title 21 CFR Part 50, 56. (4,7) This includes but is not limited to, Informed Consent Form (ICF) required elements for privacy and confidentiality, Research Ethics Board (REB) or Institutional Review Board approval of ICF, collection of REB membership, as well as review of participant signed ICF for compliance (central and on-site). CCTG policies facilitate compliance with US privacy legislation.

For trials where CCTG participates in US Cooperative Group studies, US Cooperative Group policy/US federal regulations regarding privacy will be followed.

Health Insurance Portability and Accountability Act: The Privacy Rule

The Administrative Simplification standards - adopted by Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, otherwise known as the Privacy Rule - apply to any entity that is:

- A health care provider that conducts certain transactions in electronic form
- A health care clearinghouse
- A health plan.

An entity that is one or more of these types of entities is referred to as a "covered entity" in the Administrative Simplification regulations. HIPAA (or the Privacy Rule) applies to all “covered entities”. CCTG as a not-for-profit non-government cooperative group research sponsor is not a “covered entity”. However, as a cooperative group research sponsor CCTG is aware of the Privacy Rule as it establishes the conditions under which covered entities can use or disclose protected health information for many purposes including for researchers. As centres may be “covered entities” facilitating their compliance with HIPAA requirements is important.

Covered entities may use and disclose a limited data set for research activities conducted by itself, another covered entity, or a researcher who is not a covered entity if the disclosing covered entity and the limited data set recipient enter into a data use agreement. A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the protected health information in the data set only for specified purposes. CCTG utilizes Participant Centre Agreements as well as specific trial protocols, protocol signature pages, and protocol specific contracts (where appropriate), in combination to detail these agreements.

A limited data set should excludes direct identifiers, but that may include city, ZIP Code for US participants, elements of date (e.g. date of birth), and other numbers, characteristics, or codes that are not direct identifiers.

General Data Protection Regulation

The European Union General Data Protection Regulation (GDPR) came into effect 2018May25 for all European member states. GDPR was implemented to protect data subjects regarding the use, disclosure and transmission of personal data. The data subject is granted the right to review, correct, obtain and limit their personal data. However, GDPR includes allowances for restricting these rights in scenarios such as scientific research where removing data could impact the integrity of the trial and/or safety and wellbeing of other participants.

GDPR is relevant to CCTG in the following scenarios:

1) **CCTG trial with international participation:** If an EU organization is participating on a CCTG trial and acting as the sponsor in an EU member state, then GDPR applies as the data processor (i.e. the EU sponsor) is established in the EU. GDPR template language will be inserted into the EU sponsor consent template and it may also be applicable to CCTG/Canadian participants.
2) **Intergroup trial with CCTG/Canadian participants:** If the global sponsor (i.e. the data controller) is established within the EU, then they are bound by GDPR. The sponsor would be receiving data from CCTG/Canadian participants, therefore Canadians are protected by GDPR in this instance. GDPR template language will be inserted into the CCTG consent template for CCTG/Canadian participants.

9 Roles and Responsibilities

This policy applies to all CCTG staff involved in trial conduct at CCTG. This includes the following responsibilities:

Position/Title:	Responsibilities:
All CCTG Staff	Ensure compliance with privacy and confidentiality requirements. Notify the ETL and OCO Manager of issues of non-compliance as outlined in this policy

10 Appendix

None

11 References

1. Ontario. Personal Health Information Protection Act (PHIPA)
2. United States. Health Insurance Portability and Accountability Act (HIPAA): Privacy Rule
3. United States. HHS Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule
4. United States. HHS Protection of Human Subjects Regulations Title 45 CFR Part 46: The Common Rule
5. Canada. Personal Information Protection and Electronic Documents Act (PIPEDA)
6. Ontario. Freedom of Information and Protection of Privacy Act (FIPPA)
7. United States. FDA Protection of Human Subjects Regulations Title 21 CFR Part 50, 56 2.
8. General Data Protection Regulation.
9. United States. FDA Guidance Document. Guidance for Sponsors, Clinical Investigators, and IRBs Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.

12 Revision History

Version Number	Version Date	Brief Description of Revision(s)
V001	September 17, 2012	Initial Release
V002	December 10, 2012	Minor formatting errors corrected.
V003	October 1, 2015	Full review; incorporation of Shredding Policy (CTG-POL-0006) which is made obsolete; update titles of ERTL and SI; reformatting
V004	January 21, 2020	Full review. Updated title of ERTL, and relevant SOPs and forms. Addition of GDPR. Update to current template.
V005	May 29th 2020	Updated to re-insert data privacy language in section 5.3 regarding redaction of source documents where applicable. This was included in the original QAO-SOP-0115 (V1). Update to Data Sharing and Access Policy reflected.
V006	July 30th, 2021	Updated to insert provision to obtain date of death from public source following participant withdrawal of consent (5.2). Source data/document data sharing (5.3) edited for clarity. GDPR applicability for Canadian participants (8.0) update.

13 Signature

Signature of Responsible Group Leader:	Jessica Sleeth		2021Aug27
	Name	Signature	Date