Research Ethics Board Guidelines for Unique Study Identifiers, Key Files and Access Logs

Sunnybrook Health Sciences Centre Research Ethics Board			
Guideline Title	Unique Study Identifiers, Key Files and Access Logs	**Version Date:**	June 30, 2009; May 3, 2011, November 18, 2013; January 20, 2016
Issued By:	Clinical Studies Resource Centre (CSRC), Research Ethics Office (REO)		
Approved By:	Director CSRC; REB Chair		

The Sunnybrook REO web page version of this document is considered the most current.
Please ensure that you have reviewed all linked documents and other referenced material within this guideline.

1.0 PURPOSE

These guidelines direct the creation, use, and storage of unique study identifiers, key files and access logs to ensure the confidentiality and privacy of research participants. These guidelines are issued by the Sunnybrook Research Ethics Board (REB) and are associated with the Sunnybrook REB-SOP-X.01 Use and Disclosure of Personal Health Information and the Network of Network (N2) Standard Operating Procedure (SOP) N2 SOP19 Confidentiality and Privacy adopted by Sunnybrook for the conduct of clinical research. It is the expectation of the Sunnybrook REB that these guidelines will be followed.

2.0 POLICY STATEMENT SUPPORTING THIS GUIDELINE

As per the N2 SOP19, “A participant who authorizes access to his/her data must be reasonably assured that the Sponsor or Sponsor/Investigator, Qualified Investigator (QI)/Investigator, their authorized representatives, Research Ethics Board (REB), and regulatory inspectors of the regulatory authorities will take precautions to ensure that verified and collected data remain confidential.”

The creation, use, and storage of unique study identifiers, associated key file and access log is vital to ensure the confidentiality and privacy of a study participant.

3.0 DEFINITIONS

See also Glossary of Terms

Access Log: a document that records the names and signatures of those accessing the identifying information of the research participant, and the date at which this occurred.

De-identification: means to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.

Designated person: the Sponsor/Investigator, Qualified Investigator (QI), Principal Investigator (PI) or an appropriately trained member of the research team who has been designated by the Sponsor/Investigator, QI or PI to handle data and privacy protection for a specific research study.

Identifiable information: means 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.

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Key File: a document that links the unique study identifier with the identifying information of the research participant.

Task Delegation Log: a document that lists the delegation of trial specific duties by the Principal Investigator to other research personnel in the team.

Unique Study Identifier: a unique number or unique combination of letter, numbers and/or symbols used to identify a research participant. Also known as a unique study code.

4.0 RESPONSIBILITY

The Sponsor, Sponsor/Investigator, QI or PI is responsible for ensuring data and privacy protection. This includes both physical (premises and equipment) and logical (access control) security of research data. Data safeguarding procedures may be delegated in writing on a study task delegation log to appropriately trained research team members, however, the ultimate responsibility for ensuring data confidentiality rests with the Sponsor, Sponsor/Investigator, QI or PI.

5.0 GUIDELINES

5.1 Unique Study Identifier: use & storage

Unique Study Identifiers must not include Personal Health Information (PHI) of research participants, such as name, initials, full date of birth (DOB), and hospital file number.

Note: As per the N2 SOP 19, use of a unique study number/code only as the unique identifier is considered best practice. The Sunnybrook REB, however, may exercise the right to consider the use of other identifiers (i.e. partial DOB with month and year) whereby potential harms of using additional identifiers are well understood in relation to the risks of not using them. When this is the case, the collection, use, transfer and storage of PHI must be disclosed in the ICF.

1. A unique study identifier (e.g. unique study number/code) should be used to collect and store data (electronic or hard copy) pertaining to research participants.
2. Any information leaving Sunnybrook (case report forms, data collection forms, other study documents), including electronically captured data, should only be identified with a unique study identifier.
3. Videotapes, photographs, and other identifying images of research participants must be securely stored in locked cabinets or on a secure server separate from the research participants' study data.
4. Electronic data files with unique study identifiers must be stored on a secure server. If this is not possible, data are to be encrypted (i.e. laptop, USB key) and where applicable, hard copy data files with unique study identifiers securely stored in locked cabinets.

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5.2 Key File: use & storage

A ***key file***, including the research participant's name, date of birth, hospital file number (if applicable), and unique study identifier must be created. See sample key file below:

No.	Research Participant's Name	Date of Birth dd/mmm/yyyy	Hospital File Number	Unique Study Identifier	Initials (if applicable)
1	Jack Be Nimble	16OCT1971	774344	AAAA	JBN
2	Little Miss Muffet	07FEB1966	n/a	AAAB	LMM
3	Peter Peter Pumpkin Eater	24JUL1998	452212	OJKF	PPPE

1. Only designated person(s) identified on the study task delegation log is allowed to access the key file and assign unique study identifiers to research participants.
2. Regardless of the data medium used, the key file must be securely stored separate from the research participants' study data.
3. Except for long-term secure record retention (i.e. Iron Mountain), the key file, and the information contained therein, must not leave Sunnybrook or be shared with anyone not identified on the study task delegation log without the written approval of the Sunnybrook Research Ethics Board.

5.3 General Data Security (physical & logical)

Authentication of person(s) that access study data is a key element of data security.

1. Designated persons may grant authorized personnel permission to access identifiable data on behalf of the designated person(s) via a ***study task delegation log***. All authorized persons accessing identifiable data that would not be listed on the task delegation log, e.g. monitors and auditors, must sign a **study specific access log**. An access log should contain the information illustrated in the sample below:

STUDY ACCESS LOG			
Date (dd/mmm/yyyy)	Printed Name of person accessing identifiable data	Signature	Unique Study Identifier
01JAN2008	James Bond	*James Bond*	AAAA

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2. The designated person will be responsible and accountable for any missing identifiable data;

3. Cancel access of research team members who leave the study and update the study task delegation log accordingly.

5.4 Transmitting identifiable information

1. Sending identifiable PHI off-site (i.e. to a sponsor) is not permitted unless it is a) de-identified; or b) the REB has approved and participants have consented to the disclosure, unless the REB has approved a waiver of consent.
2. To send de-identified data: black out all identifiers (such as patient name, HFN, signature) on consent forms, case reports forms and other study documents.

6.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014) Chapter 5.
2. International Conference on Harmonization (ICH) Guidance E6: Good Clinical Practice (GCP): Consolidated Guideline (1997).
3. Ontario's Personal Health Information Protection Act (PHIPA).
4. Canadian Institute of Health Research (CIHR) Best Practices for Protecting Privacy in Health Research, September 2005.
5. Network of Networks Standard Operating Procedure: N2 SOP19.