DALHOUSIE UNIVERSITY Health Data Nova Scotia **Research Plan Policy**	**Author:** S.Kennedy	**Review Date:** 01.12.2017
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1. BACKGROUND & PURPOSE

1.1 Under the *Personal Health Information Act* (PHIA) prior to the disclosure of personal health information for research purposes, a researcher must submit a research plan.

1.2 This policy sets out (i) the information that is required to be included in a research plan and (ii) the process of submission to Health Data Nova Scotia (HDNS).

2. APPLICATION

2.1 This policy applies to all researchers who are requesting access to HDNS data.

3. DEFINITIONS

3.1 *Data Access Request (DAR) Form:* The request form completed by the researcher to request access to data for projects. It is reviewed for privacy, confidentiality, and security concerns by the HDNS Data Access Committee.

3.2 *Personal Health Information:* Identifying information about an individual, whether living or deceased, and in both recorded and unrecorded forms, if the information:

(i) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,

(ii) relates to the application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,

(iii) relates to payments or eligibility for health care in respect of the individual,

(iv) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance

(v) is the individual's registration information, including the individual's health-card number, or

(vi) identifies an individual's substitute decision-maker.

3.3 *Research:* A systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research.

3.4 *Research Ethics Board (REB):* An REB established and operating in conformity with the Tri-Council Policy Statement. A body of researchers, community members, and others with specific expertise (e.g. research ethics, or relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

4. POLICY STATEMENT

4.1 The requirements for the content of a research plan are set out in *PHIA* and must include the following information:

(a) a description of the research proposed to be conducted;

(b) a statement regarding the duration of the research;

(c) a description of the personal health information required and the potential sources of the information;

(d) a description as to how the personal information will be used in the research;

(e) where the personal health information will be linked to other information, a description of the other information as well as how the linkage will be conducted;

(f) where the researcher is conducting the research on behalf of or with the support of a person or organization, the name of the person or organization;

(g) the nature and objectives of the research and the public or scientific benefit anticipated as a result of the research;

(h) where consent is not being sought, an explanation as to why seeking consent is impracticable;

(i) an explanation as to why the research cannot reasonably be accomplished without the use of personal health information;

(j) where there is to be data matching, an explanation of why data matching is required;

(k) a description of the reasonably foreseeable risks arising from the use of personal health information and how those risks are to be mitigated;

(l) a statement that the personal health information is to be used in the most de-identified form possible for the conduct of the research;

(m) a description of all individuals who will have access to the information, and

(i) why their access is necessary,

(ii) their roles in relation to the research, and

(iii) their qualifications;

(n) a description of the safeguards that the researcher will impose to protect the confidentiality and security of the personal health information;

(o) information as to how and when the personal health information will be destroyed or returned to the custodian;

(p) the funding source of the research;

(q) whether the researcher has applied for the approval of another research ethics board and, if so, the response to or status of the application; and

(r) whether the researcher's interest in the disclosure of the personal health information or the conduct of the research would potentially result in an actual or perceived conflict of interest on the part of the researcher.

5. PROCEDURES

5.1 Research plans must be submitted as specified in the HDNS Feasibility and Cost Estimate Request and HDNS DAR Forms.

6. ADMINISTRATION

6.1 Accountability

6.1.1 The researcher requesting data access is to ensure that their Research Plan includes all the required information.

6.2 Monitoring, Auditing and Reporting

6.2.1 The HDNS Finance and Administrative Officer monitors the status of project files and reports back to the Manager.

7. RELATED POLICIES AND OTHER DOCUMENTS

7.1 HDNS Policies and Procedures

- HDNS Data Access Policy

7.2 HDNS Forms

- HDNS Data Access Request Form

7.3 Other Documents

- HDNS Guide to Using Our Services