BRITISH COLUMBIA | Ministry of Health

Health Data Request (HDR) Manual

Last revised: March 2015

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The Health Data Request application form (HDR) has been developed and approved by Ministry of Health (MOH). It is intended to be used to request only data administered by MOH as well as for data requests that involve linkage between MOH administrative data and external data under other public bodies' stewardship. The HDR form is meant to stand alone. It should contain all the information required to support an application as well as a complete description of the project.

All requests for MOH administrative health data are adjudicated by MOH which, in turn, is bound by BC's Freedom of Information and Protection of Privacy Act (FIPPA) and other relevant laws and regulations of the Province, and ethical guidelines. MOH staff works with Applicants to facilitate the process. However, a complete and detailed application package makes the administrative process much easier to undertake and considerably shortens the approval and data provisioning time. The HDR Manual is intended to educate and help potential applicants develop good applications that require little review and clarification.

The majority of applications processed by MOH are submitted by Health Authorities (HAs) and the agencies of Provincial Health Services Authority (PHSA). All these requests are adjudicated and agreements (Information Sharing Plans – ISP) are developed under the umbrella of the General Health Information Sharing Agreement (GHISA) established between MOH and HAs as equal parties. With other public bodies requesting administrative health data, MOH will develop Information Sharing Agreements (ISA).

Academic research requests or other research requests not associated with HAs are currently processed by Population Data BC, which is an MOH service provider. Please visit Population Data BC website for more information.

PLANNING AND COMPLETING A DATA ACCESS REQUEST

Why is an HDR form needed?

The MOH and other Data Stewards from which external data might be requested require detailed information about your project in order to adjudicate it. MOH staff will also need this information in order to prepare the data, once an HDR has been approved and an administrative agreement entered into. The HDR is designed to collect and present this information in the most efficient manner possible for adjudication and for ultimate data provisioning.

There could also be circumstances when the request is not necessarily for access to specific data extracts for specific study populations but rather refers to systems access and systems connectivity. In this case the HDR should also be used but the information requested on the form would not be needed, as it will not be relevant to this category of request

The HDR was originally designed to serve Applicants from other organizations requesting MOH administrative health data. However, the potential scenarios for which the HDR could be used are:

- External Applicants requesting MOH administrative health data only.
- External Applicants requesting MOH administrative health data as well as external MOH data that will be linked with MOH data.
    - In this case the HDR form is only for the MOH administrative data. The request for external data is usually for data from the Applicant's parent organization and the Applicant would need to request those data following the processes required by the organization providing the data.

- MOH Applicants requesting External data to be linked with MOH administrative data.
    - As for the previous case, the request for external data by MOH staff will need to follow the process established by the organization from which external data is being requested.

The HDR form is not designed for MOH employees that need access to MOH administrative data. MOH employees would need to complete the HLTH 7076 - DSAM Database Access Request form in order to access to MOH data.

Unfortunately, at this time, there is no common platform for processing health data requests between MOH and HAs.

A summary of the HDR process

The data access request process is dependent on, but separate from, funding and ethics. For applications that involve research rather than program evaluations, Applicants will need to have funding in place (or Organizational Support documentation) and an approved ethics certificate. Data access approval is not automatic and must be taken as seriously as an application for funding or ethical review. Completing a HDR takes time, planning, and attention to detail, as the document is reviewed thoroughly.

The application process requires that the Applicant:

- Become familiar with all material outlining access requirements, data holdings, study population definitions, and privacy considerations, as presented on the MOH website.
- Ensure that the project objectives are in alignment with the relevant legal authorities (FIPPA) that permit disclosure; consult with your organization's Privacy Branch to determine the appropriate legal authority under which information will be collected, used, and disclosed will be used.
- Where relevant, ensure that the ethics requirements of MOH and other Data Steward(s) have been met.
- Ensure that the appropriate application, approvals and Administrative Agreements are sought, (including linkage requirements) if external data is to be used.
- Submit a fully completed HDR to MOH, including ALL required attachments.
- Where relevant, work with MOH and other Data Steward(s),to complete the Study Population description and discuss linkages.

Please visit MOH's website for more information. Questions about the application process or any part of the application are to be directed to the staff in MOH's Information Management and Knowledge Services Branch (IMKS) at: HealthDataHA@gov.bc.ca for Health Authorities Applicants or HealthDataISA@gov.bc.ca for other public organizations.

Once the HDR form has been reviewed and all necessary details have been clarified and confirmed (including MOH data variable checklists), an Information Sharing Plan or an Information Sharing Agreement will be approved and signed by the MOH Chief Data Steward (the Executive Director of IMKS) as well as the applicable authority of Applicant's parent organization and/or any other relevant Data Steward(s). This is a legal agreement between MOH and the public bodies representing the Applicants. The variables checklists associated with the HDR form will become an appendix to the Administrative Agreement. This is not the case for agreements concerning system access or systems' connectivity.

How to complete the form

The HDR form is available as a PDF 'form-fill' application with the document text being protected from inadvertent changes. Checkboxes may be checked by clicking with a mouse or using the space bar.

PROJECT TITLE

It is preferable that the project title is succinct and that it captures the main objective of the project, whether it is a program evaluation, program monitoring, surveillance, research, or system access request.

RELATIONSHIP TO PREVIOUS AGREEMENT(S) / PREVIOUS REQUESTS

Information provided in this section is useful for two main reasons: it speeds the administrative approval process as well as leveraging any pre-existing cohorts, linkages, extracts, programming codes, etc., facilitating faster data provisioning.

Proposed End Date of Project

This information is useful for establishing the length of the agreement to be entered into by MOH and Applicant's parent organization.

SUPPORTING DOCUMENTATION

Several documents might be needed to support a request for administrative data. The form offers multiple choices such as:

- Funding Agreement
- Privacy Impact Assessment (PIA)
- Security and Threats Risk Assessment (STRA)
- Transfer Under Agreements (or other project-related contracts)
- General Services Agreement
- Ethics Certificate
- Other (specify)

Requests from HAs or other public organizations involving only MOH administrative health data that are not intended for research purposes, do not require any additional documentation. However, requests from HAs that involve linkage between MOH data and HA(s)'s or other public organizations' data might require a Privacy Impact Assessment (PIA). In these instances MOH will not require the PIA. However the Privacy Branch of the organization providing the external data that will be linked to MOH data, or Applicant's Privacy Branch parent organization (if they are not the same) will need to be consulted in order to identify whether a PIA is needed or not.

Requests submitted by MOH employees for external data that will be linked with MOH administrative data will need to consult with MOH Health Information, Privacy, Security, and Legislation Branch (HIPSL) in order to identify whether a PIA is required and if necessary to obtain the support for completing a PIA.

Funding Agreements or General Service Agreements are usually needed when the party requesting the information is conducting research or program evaluation acting as a service provider to the public body that will be the signatory party to the administrative agreement. These funding agreements also certify the legal position of the party that will have access to data.

Ethics certificates are required for all research projects. It is advisable when considering such a project, that the ethics application and the administrative application (HDR form and additional materials) are completed in parallel, since they require similar information. This avoids duplication of effort and ensures consistency between the two documents. It should be noted that many Health Authorities data requests have the blue print of a program evaluation, monitoring, or surveillance but the applicants intend to publish their findings and in parallel obtain ethics approvals. If this is the case, please submit the ethics request and approval at the same time as the HDR package even though the original objectives of the study are not for research purposes.

A Security and Threats Risk Assessment might be required when the request is for data that will be stored for a longer period of time (e.g. a databank, registry) and an assessment of the infrastructure used is then needed.

Other documents that might be required are those that certify that the project is being supported by the parent organization, especially for research projects (e.g. Letter of Authorization to Conduct Research such as those issued by Fraser Health Authority or approvals following a VCH Operational Review Application for a New Research Project). These types of approvals are generally available only when the Applicant is also using external data. For instances when the Applicant is pursuing research using only MOH administrative health data, an official letter from the parent organization will be required instead.

When the affiliation of the applicant with the public body is not evident, for instance an academic researcher who is also providing services in some official capacity to the public body but there is no funding agreement in place, a formal document confirming this relationship will be required (e.g. Vancouver Coastal Health Research Institute letter attesting the Affiliated Investigator Status).

Research requests from public bodies that also involve industry funding need to be properly disclosed. In view of its obligations under FIPPA, MOH has instituted a policy that MOH will provide data to researchers under contract to industry only when:

(a) the research is conducted at arm's length from the sponsor;
(b) no sponsor's employees, contractors, or agents are part of the project team;
(c) the sponsor has no influence on study direction or analysis; and
(d) the sponsor has no access to data, other than final published results.

SECTION I: REQUESTOR INFORMATION

REQUESTOR/APPLICANT

This section will provide information about the person who is assuming responsibility for the project and particularly for the data being requested.

INSTITUTION ADDRESS

This section needs to be filled only if the address provided for applicant differs from the parent organization address.

SIGNATORY TO AGREEMENT

This section provides information concerning the party (administrative authority) that will be accountable for enforcing the terms and conditions of the administrative agreement.

PROJECT MANAGER

If different from requestor, this will be the primary contact for correspondence.

PERSON WHO WILL RECEIVE THE DATA

This could be the same person as the requestor or project manager or one of the persons who will have access to the data being requested. This information is necessary for the establishment of the Secure Access Transfer Protocol (SFTP) folders by the MOH IT department.

PERSONS WHO WILL HAVE ACCESS TO THE DATA

Please identify ALL individuals who will have access to the requested data at any time. Please include requestor, signatory and/or project manager on this section if they will be accessing data. The checkbox specifying the access for linkage purposes or analyses will serve to indicate whether the person will in fact have access to identifiable information or not.

This information will be used to populate Section 4[1] of the ISP template developed under the GHISA umbrella for HAs and MOH only. Information Sharing Agreements (ISAs) with other organizations will contain this information under other specific sections. It is MOH policy that for ISPs in particular, only the roles and positions of the personnel that will have access to data will be described, rather than specific names. This policy was instituted in order to reduce the administrative burden of having to amend agreements for every change in personnel.

The actual names will be kept as a note to file in the project documentation (the case management file). For addition or removal of team members from the project roster, after project approval, a Notification Form for Addition & Removal of Team Members will have to be submitted to IMKS at: HealthDataHA@gov.bc.ca for Health Authorities projects (for ISPs) or HealthDataISA@gov.bc.ca for other public organizations. This form will be available on MOH website and can also be requested from IMKS.

Although FIPPA governs the collection, use, and disclosure of identifiable information, **it is MOH policy to disclose data in de-identified format or to insure that analyses are performed on de-identified data.** As a consequence only some of the project team members should have access to identifiable information and **only** for linkage purposes. When only MOH data will be used in the project, the data extract will always be de-identified and IMKS personnel will maintain the cohort crosswalk (personal identifiers and MOH generated Study IDs) which can then be used in case of subsequent amendment requests for additional data (additional datasets or data refreshes).

When linkage between MOH data and the Applicant's parent organization is involved, the project team might not be necessarily involved in the linkage, but rather personnel from the parent organization's Decision Support Team. This needs to be identified prior to HDR form submission and detailed in the HDR form.

[1] Specify the categories of individuals within each Party who are authorized to access the information, including whether access to Personal Information is permitted, and the reasons for their access.

SECTION II: PROJECT DESCRIPTION

BACKGROUND

The Applicant must provide a brief description of the project including its purpose and background. This should include an introduction to the project and its relationship to any other study program of research.

The Applicant must provide details of any relationship to other on-going studies. A general description of a broad area of investigation such as "to create a database on the health of health care workers" is not acceptable.

Please note that FIPPA requires that Data Steward(s) approve access to data on a "need to know" basis for specific purposes only. As such, the project's objective(s) will always be measured against the specific data requested.

As stipulated in FIPPA, the MOH will assess projects with a focus on public interest value, and relevant legislation.

PROJECT PURPOSE

Applicants must list ALL anticipated study objectives and questions, and should be as specific as possible. MOH assesses project objectives in accordance with current provincial and national laws, regulations, and ethical standards. Under FIPPA section 33 to 35, MOH is permitted to release only those data that are necessary to achieve a specific research objective. It is the responsibility of the Applicant to accurately describe this connection.

As mentioned before, please consult with your parent organization's Privacy Branch to properly identify the legal authorities under which the data will be collected, used and disclosed in order to align your project's objectives with the legal authority. This will especially be helpful in filling Section 2[2] of the ISP template.

Research questions are reviewed for public interest value and compliance with legislation and policy, particularly the BC Freedom of Information and Protection of Privacy Act (FIPPA), and the Tri-Council Policy Statement (TCPS2) for guidelines involving ethical research on humans.

Please note that upon approval and receipt of data, all analyses **must** be restricted to those required to answer these previously-stipulated research questions. Any change in direction or scope of the project must to be brought back for MOH review and approval, and may constitute a new project (requiring a new application and new data extract.)

Applicants must summarize the study design and methodology. Please outline the techniques and the methodologies that will be employed and provide clear rationales for the appropriateness of the study design and methods, where appropriate.

It is also necessary to identify each data file being requested (see section V: DATA REQUEST), including external data files, and describe why each file is necessary to achieve the project objectives.

[2] Authorities for Collection, Use and Disclosure under FIPPA and other Applicable Laws

SMALL CELL SIZE

It is necessary to describe measures that will be taken to protect confidentiality (i.e. potential re-identification of an individual) during analysis and in any publication or distribution of results when dealing with small cell size. Please be sure to describe protective measures that will be taken during analysis as well as in publication of results.

Examples of measures to be taken during analysis:

- Secure storage of the data on your organization's secure servers which involves controlled access for only individuals as specified in the HDR.
- Request for de-identified data, no identifiers will be retained for analysis.

Examples of measures to be taken during publication:

- Only aggregate results will be reported.
- Cell size of less than five individuals will not be reported.

SECTION III: PROJECT SPONSOR (IF APPLICABLE)

Please indicate direct or indirect sources – e.g. grant funding agency, Ministry sponsored, operational, etc. For research requests that are not funded, please include documentation (as indicated in SUPPORTING DOCUMENTATION section) confirming your parent organization administrative support and approval for your research project.

If the project is receiving industry funding, please include any contract or grant related with your project in order to allow MOH personnel to evaluate whether the parameters of your financial agreement will align with MOH policy concerning disclosure of data to research funded by industry.

SECTION IV: DATA SECURITY AND ACCESS

The first step of this section is to check whether the Applicant's Privacy, Security and Legislation department(s) has been contacted and can confirm whether reasonable security measures will be in place to protect the data.

As was mentioned in PROJECT PURPOSE subsection of SECTION II: PROJECT DESCRIPTION, we highly recommend that the applicant consults with the organization's Privacy team in order to align the project objectives with the legal authorities for collection, use and disclosure of personal information.

DATA TRANSFER

MOH preferred transfer option is via Secure Transfer Protocol (SFTP) which will be set-up by the MOH IT personnel on MOH servers. However, in order to properly establish the SFTP project folder, the Applicant must provide contact details of one of their organization's IT personnel who will be able to assist MOH IT department in setting up the folder. This IT person must be able to assist in gathering the network information (e.g. IP address) and coordinate software installation necessary for managing SFTP data transfers.

There is a checkbox available for "Other" data transfer options. Other options would be via VPN, through which applicants would gain access directly in MOH data warehouse and would be able to move the approved the data extract on their own. This is an option currently being implemented by MOH for transferring very large datasets.

PHYSICAL LOCATION

Please indicate the physical location(s) where APPROVED data will be used or accessed, including sites where data will be analysed as well as storage sites (if different). Indicate all general physical security measures in place at each location. Include measures taken to protect workstations, hard copy and source media.

NETWORK SECURITY AND BACKUPS

If data will be stored on a network or system to which individuals other than identified project personnel have access, or on a system connected to a public network (the Internet), please indicate, and if appropriate describe the network security measures in place.

PERSONAL COMPUTER SECURITY AND BACKUPS

If data will be accessed or stored on the hard drive of a personal computer, identify all security measures taken to protect data residing on the PC.

NOTE: Access and storage of record level data on laptop, notebook, handheld devices and other portable devices (e.g. external memory) will not be permitted.

SECTION V: DATA REQUEST

COHORT DEFINITION / POPULATION OF INTEREST

The study population comprises the group of subjects that an Applicant wants to include in their analyses. The study population may include multiple cohorts as well as one or more comparison group(s).

In order to clarify what is meant by 'study population', the table below provides a few examples of study populations, and how these relate to cohort(s), comparison group(s) and the data extract that might be requested for analyses.

However, there will be circumstances in which a particular request does not rely on a cohort / study population. In this case the request would consist only of a particular data extract, e.g. "All DAD encounters in BC between 2006 and 2014, where the ICD10 codes where … and the CCI codes where…". In this situation, there will be no study population to start with. *i.e.* the study cohort will be created during the extract process

Nevertheless, if the applicants need to link the subjects of the extract with their organization's data, then MOH will have to identify all the PHNs, create a crosswalk with PHNs and Study IDs, transmit the crosswalk to the applicant, wait for the applicant to apply the Study IDs to her/his data, remove the PHNs and destroy the crosswalk file, and confirm that to MOH. Only then MOH will release the extract. This indicates that in such situations the study cohort was created post hoc. Even if there is no data linkage involved, MOH will still create the study cohort file, de-identify the PHNs and maintain a crosswalk – the default assumption is that the data extract is released in a de-identified form as a privacy protection feature. Only when the data extract is to be provided in an identifiable form this post hoc cohort creation step will not be pursued.

Study Population	Cohort	Comparison group(s)	Data Extract
All women who gave birth in a BC hospital between 1993 and 2000, and their babies	Women who gave birth between 1993 and 2000 who are residents of Greater Vancouver	Women who gave birth between 1993 and 2000 who are residents of other parts of BC	All MSP Services, hospital separations and deaths data for mothers, from one year before to two years after birth. Births data for the babies, plus all MSP Services, hospital separations and deaths data for two years after birth.
All individuals aged 65 and over who spent at least one night in a residential care facility between 1 April 1998 and 31 March 2008, plus a 10% random sample of other individuals aged 65 and over.	Individuals 65 and over who spent at least one night in a residential care facility between 1 April 1998 and 31 March 2008.	A 10% random sample of individuals who did not spend a night in a residential care facility but who were 65+ and resident in BC at some point between 1 April 1998 and 31 March 2008.	Home and Community Care, MSP Services, and Hospital Separations data for 1998/99 to 2007/08.

1. Who is creating the study population?
The cohort(s) or comparison group(s) for the study may be defined by data from MOH and/or by external data (from Applicant's parent organization, from another organization or Applicant-collected data). Please indicate the details of this in the checkboxes provided. This provides the MOH and, if the case, Applicant's parent organization Decision Support team with a quick context for their review of the study population section.

2. Text description
Applicants must define their study population in text providing a comprehensive description. Details should include information that will assist MOH and Applicant's Decision Support team in creating the study population. At this point, full descriptions of the cohort(s) (including inclusion and exclusion criteria and comparison group(s)) are helpful.

If the study population(s) are defined using external data or a combination of MOH data and data external to MOH, this will involve the exchange of personal identifiable information as well as health information between the MOH and Applicant's parent organization or the organization on which the study population(s) is based in order to help define the study population(s). (e.g. cohort defined by Cardiac Services and MOH consisting of patients 19 years and older that had open heart surgery between 2009 and 2014 and that have taken statins for at least two years prior to the surgery date)

MINISTRY OF HEALTH DATA

Please indicate the MOH database(s) relevant to this data request by checking the appropriate checkbox(es) in this section. The database Checklists for any of the listed databases are available on MOH website with their accompanying dictionaries. In most cases the Checklists will include a

variable field name which provides a generic description of the field, and which will be used by the analysts when producing the data extracts. These will also assist the Applicant in correctly identifying the required variables for the extracts and will preclude the need of additional layout files.

There is an additional column in the checklist for the Applicant to provide a rationale aligned with the study objective for requesting the respective variable. This is done in order to comply with the ISP template which requires that the agreement specifies not only the categories of information being collected, used and shared, but also the reasons why each data element needs to be collected, used and shared for purposes of the particular Information Sharing Situation.

The checklists do not include an exhaustive listing of the data elements within a database. In general only the most commonly requested data fields have been included. However, if an Applicant requires additional data elements for their proposed project, a blank checklist will be available for requesting these additional data elements.

Applicants must download and complete the appropriate data file checklist(s) and select the fields to be used for analysis. Applicants need to request the data for their extract and not the data required to construct a study population when filling out the data file checklists.

All checklists have the same fields that need to be filled:
Project Title:
Applies to cohort(s):
Date Range (from - to):
Other Date Range and Filtering Criteria:
Other filtering criteria might include beside the desired data range of the extract, particular diagnostic codes or intervention codes or particular drugs dispensed.

Applicants are encouraged to use all available resources, such as information provided on the MOH website, discussions with MOH staff or their organization's Decision Support staff, and consultations with other successful Applicants. Neither the MOH nor parent organization's approving authority will be held responsible for data selection oversights. The onus is on the Applicant to identify the data holdings pertinent to their project prior to submitting an application for data.

Applicants are required to fill in the tables in the HDR form specifying with a check mark each data file they wish to request. In the associated checklists it is necessary to state the time period (start and end date) for which the data are being requested. Applicants are encouraged to define a start and end date at the beginning/end of **either the fiscal or calendar year**. This is relevant because some of the data files are organized either by fiscal or calendar year. Although it is possible to restrict them to either fiscal or calendar year, it is not possible to appropriately filter the files to start at the beginning of a calendar year and end at the end of the fiscal year without the Applicant losing a few months of data.

Please indicate whether all cohorts will require the same data. If <u>not</u>, please use a separate checklist for each cohort. An example of this would include a study with two cohorts, each requiring very different fields from MSP. A study could have a cohort of mothers and a cohort of babies and is it possible that PharmaNet data is being requested for the mothers, but no PharmaNet data is being requested for the babies.

Applicants are required to provide information on each external data file they will be using for their study. Using the available blank checklist, please specify the data file name and data source in the space provided. It is also necessary to state the time period (start and end date) for which the external data is being requested, the cohort for which will be used, and other date range and filtering criteria.

If the external data consists of Applicant-collected data, on the blank form please be sure to include the source of the data, the purpose of collection and the data collection type (survey, questionnaire, focus group, interview, etc.). Please also list the data files included in the data source to facilitate an understanding of the information provided in the table on this page. Please also include any other pertinent details that will give the MOH and parent organization a better understanding of the data source.

In the blank checklist, enter the name of the data file, describe the data collection type (i.e. survey, questionnaire etc.) and the date range for which the data are available.

It is necessary to provide a plain language list of fields that are available in the Applicant collected data file. If applicable, please identify those fields that will be used for linkage only and fields that will be retained for analysis.

If Applicant-collected data or another external data source is to be linked to MOH data, subject consent may be required (e.g. when the external data is a survey data set collected by the Applicant). MOH reserves the right to request informed consent of research participants as a requirement under applicable law and/or government policy and procedure. In cases where it is required, the consent form must be included in the application package, and must specifically provide consent to link data for the specified study objective. This should be the same consent approved by the Research Ethics Board.

If requesting linkage of data from MOH to Applicant -collected data, the Applicant will be required to provide written informed consent to use and link the collected data for the specified study purpose(s). Consent documents should explicitly identify proposed linkages and the data involved.

Requests for Health System Utilization Matrix ("Blue Matrix") will be handled differently from all other requests. Firstly, there is no actual checklist available for the Blue Matrix, but rather an information package. There will be a standard package offered at individual level of data which will be described in the information package. For all other Blue Matrix requests, please contact Martha Burd, Director of Health System Analytics at Martha.Burd@gov.bc.ca for more details.

DATA LINKAGE

Data linkage refers only to situations where MOH data extracts will be linked with external data for the purpose of accomplishing study objectives. The potential stages in cohort creation that might involve MOH and external databases do not represent linkages for the purpose of this subsection. For instance, a study population defined using only external data or a combination of external data and MOH data that does not require any external data to fulfill the study objective does not involve data linkage.

Please check whether a data linkage will be involved and if so, provide lists with the external databases and variables that will be used for linkage and continue with Section VI of the HDR form.

DATA TRANSFER FREQUENCY

Data transfer frequency refers to the number of times a data extract needs to be provisioned. Most commonly only one data extract is required for a project. However, there might be circumstances, given the nature of the study, that several updates are necessary in order to provide applicants updated data. The updates could be annual, bi-annual, or quarterly.

The table below can serve as an example for a study requiring annual refreshes for the study cohort as well as for the data extracts.

Year of Update	Study Cohort	DAD Request	PharmaNet request
2014	Jan 1, 2007 to Dec 31, 2012	April 1, 2006 to March 31, 2013	January 1, 2009 to December 31, 2013
2015	Jan 1, 2008 to Dec 31, 2013	April 1, 2007 to March 31, 2014	January 1, 2010 to December 31, 2014
2016	Jan 1, 2009 to Dec 31, 2014	April 1, 2008 to March 31, 2015	January 1, 2011 to December 31, 2015
2017	Jan 1, 2010 to Dec 31, 2015	April 1, 2009 to March 31, 2016	January 1, 2012 to December 31, 2016
2018	Jan 1, 2011 to Dec 31, 2016	April 1, 2010 to March 31, 2017	January 1, 2013 to December 31, 2017

SECTION VI: LINKAGE TO EXTERNAL DATA SOURCE

This section is for Applicants who intend to link MOH data to their organization and/or another organization's data.

PART 1 – LINKAGE KEY TABLE

Table 1 identifies all external data sources described in previous section and their respective Identifier fields to be used for linkage. Please note these will be removed from the final extract unless identified as required to be retained for analysis. If retention is required, a strong rationale for doing so is necessary.

Please use the table to identify the data source and the availability of a PHN for linkage. Please also indicate whether it is necessary to retain this field for analysis .Use this table to identify all identifiers, besides PHN, that are available to be used for linkage. State the source of the data, the field name (Name, Date of Birth, Postal Code, Sex, etc.) and state whether the field is to be retained for analysis. With a strong rationale, an Applicant may request some identifier fields to be retained.

PART 2 – LINKAGE STRATEGY

As was mentioned previously, for the purposes of this manual, data linkage is considered only when MOH data will be linked with external data via one or more linkage keys with PHN being one of the keys. However, the ISP or any other agreement that will be entered by the parties will have to depict the data flows in their entirety, including the actual step when the data linkage occurs. Please note that applicants are responsible for PHN quality submitted while MOH takes no responsibility with data cleansing when poor quality PHNs are provided for linkage

Also, it needs mentioning that as a policy, MOH provides only de-identified data extracts, unless there is a compelling need for personally identifiable information. For projects involving de-

identified extracts, the MOH will create and maintain the crosswalk containing the PHNs and the corresponding project Study IDs, regardless of the fact that there is a linkage involved or not.

Given that the study cohort can be generated only in three ways: (1) by MOH; (2) by the external party(ies); (3) MOH and external party(ies) and that (a) there will be linkage between MOH data and external party(ies) or (b) not - there is a limited set of options as to how the data flows could go. An additional factor concerning the study population is when there is only an extract involved, with the study population developed post-hoc as described in Section V.

For the purposes of this manual, the study cohort(s) refer to the unique list of PHNs that satisfies certain pre-defined study criteria. A data extract will consist of an extract from particular datasets for the defined study cohort(s) for a specific date range and/or other filtering criteria. However, certain requests might not require the development of an initial cohort but might comprise only an extract for a particular date range and filtering criteria. In this case, a cohort will be created post-hoc for the purpose of maintaining an internal MOH crosswalk.

Therefore, there are 8 possible combinations between the factor representing how a cohort is established (4 levels) and the factor indicating whether linkage between MOH data and external data will be involved (2 levels). These combinations, although different yield a smaller number of possible data flows. The following table represents the potential combinations and the resulting types of data flows, categorized function of their level of complexity. The DATA FLOWS subsection will describe the potential situation for each particular data flow category.

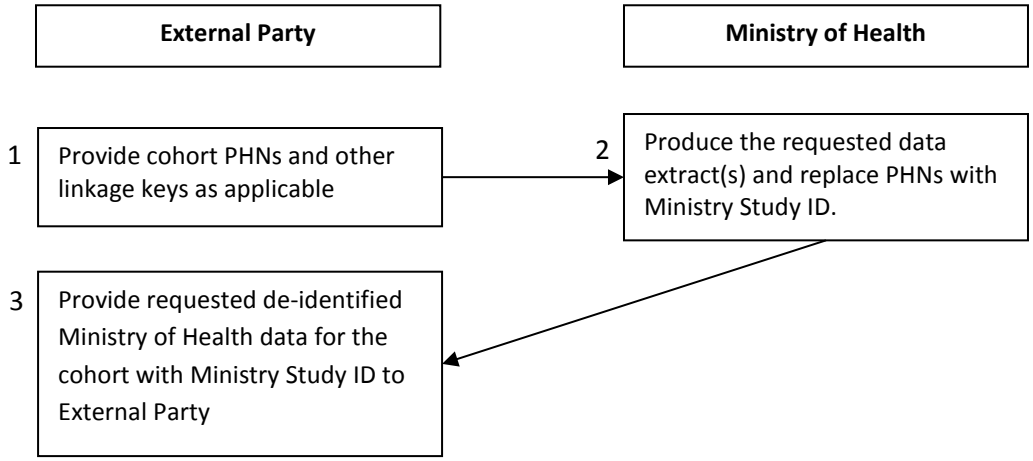
Cohort defined by	**Linkage btw MOH and External Data**	
	Yes	**No**
MOH	Category B	Category A
External	Category B	Category A
Both	Category C	Category C
Extract - No initial cohort	Category B	Category A

Data Flows: Category A - Simple; Category B - Medium; Category C - Complex

DATA FLOW CATEGORIES

Data Flow – Category A - Simple

Cohort defined using data source from External Party and no external variables for analysis



Step-by-Step:

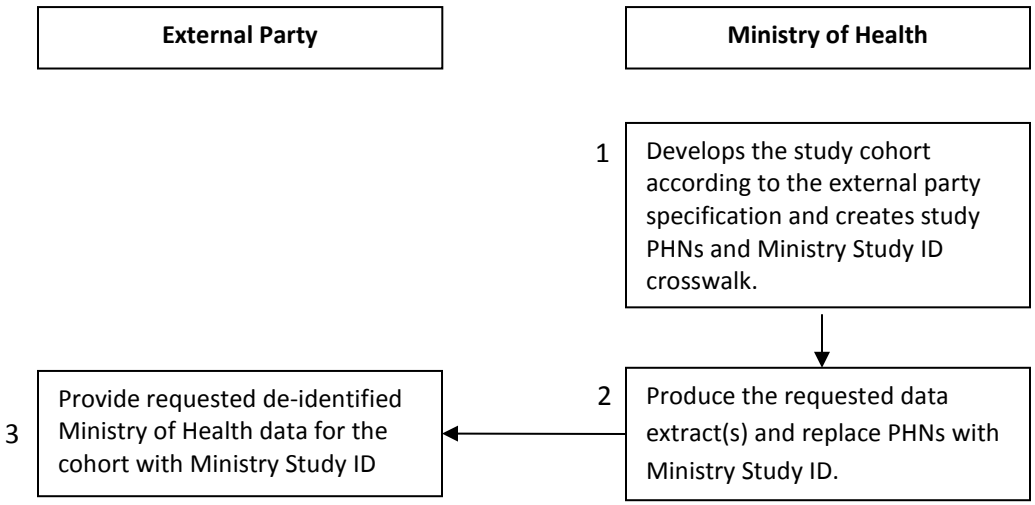
Step 1: External Party prepares and provides the Ministry of Health (the "Ministry") an electronic data file of cohort PHNs and other linkage keys as applicable for linkage purpose only.

Step 2: The Ministry produces the requested data extract(s) and replace PHNs with Ministry Study ID.

Step 3: The Ministry prepares and provides requested de-identified Ministry data for the cohort with Ministry study ID.

OR

Cohort defined using Ministry data and no external variables for analysis



Step-by-Step:

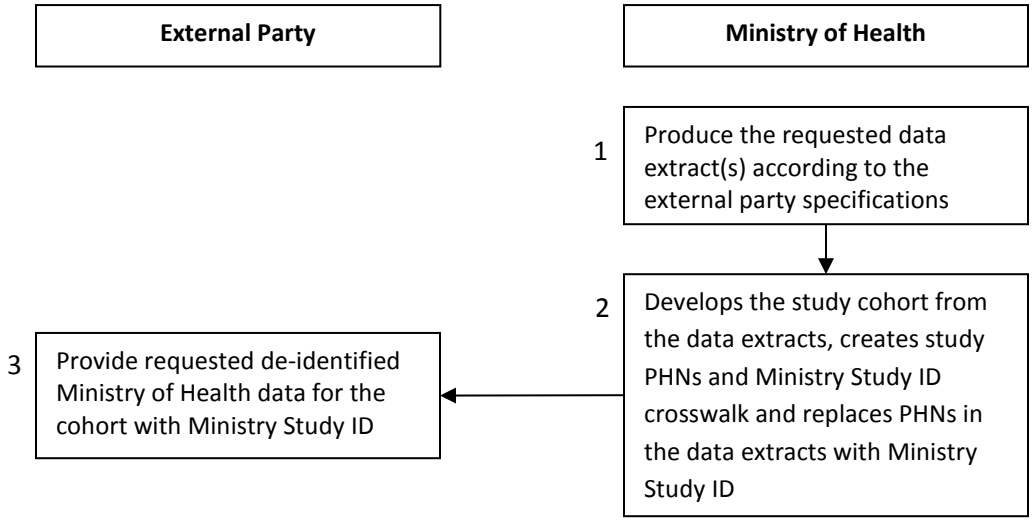
Step 1: Ministry of Health (the "Ministry") develops the study cohort(s) according to External Party specifications and creates a crosswalk with study PHNs and Ministry Study ID..

Step 2: The Ministry prepares the requested de-identified Ministry data for the cohort with Ministry study ID.

Step 3. The Ministry provides the requested de-identified data to the External Party

OR

No initial Study Cohort and no external variables for analysis



Step-by-Step:

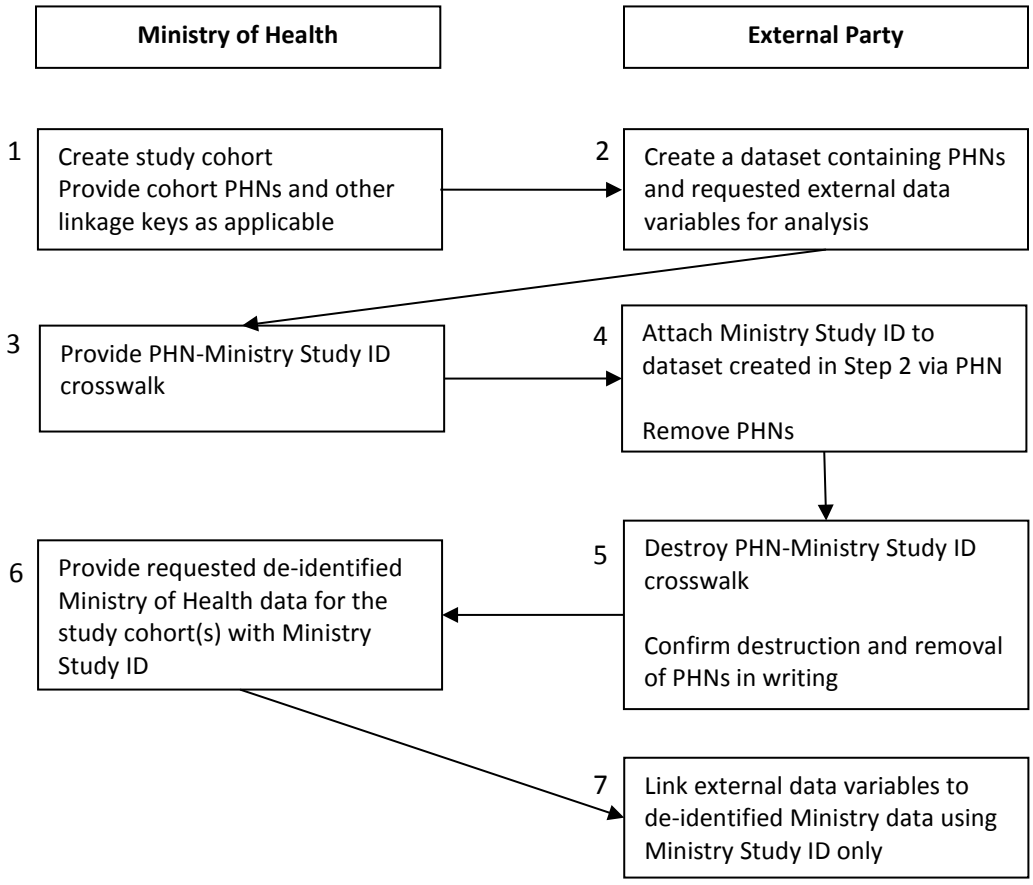
Step 1: Ministry of Health (the "Ministry") produces the data extract according to External Party specifications and creates a crosswalk with study PHNs and Ministry Study ID.

Step 2: The Ministry develops the study cohort from the data extracts, creates study PHNs and Ministry Study ID crosswalk and replaces PHNs in the data extracts with Ministry Study ID.

Step 3: The Ministry provides the requested de-identified data to the External Party

Data Flow – Category B – Medium

Cohort defined using Ministry of Health data (from cohort definition or just data extract) and external variables for analysis



Step-by-Step:

Step 1: The Ministry of Health (the "Ministry") prepares and provides External Party an electronic data file of cohort PHNs and other linkage keys as applicable for linkage purpose only.

Step 2: External Party prepares a version of the dataset to be used for the analysis of this project. This dataset should only contain the requested variables for analysis and the PHNs.

Step 3: The Ministry sends PHN-to-Ministry study ID crosswalk file to External Party.

Step 4: External Party assigns Ministry study ID to the dataset prepared in Step 2 and removes PHNs.

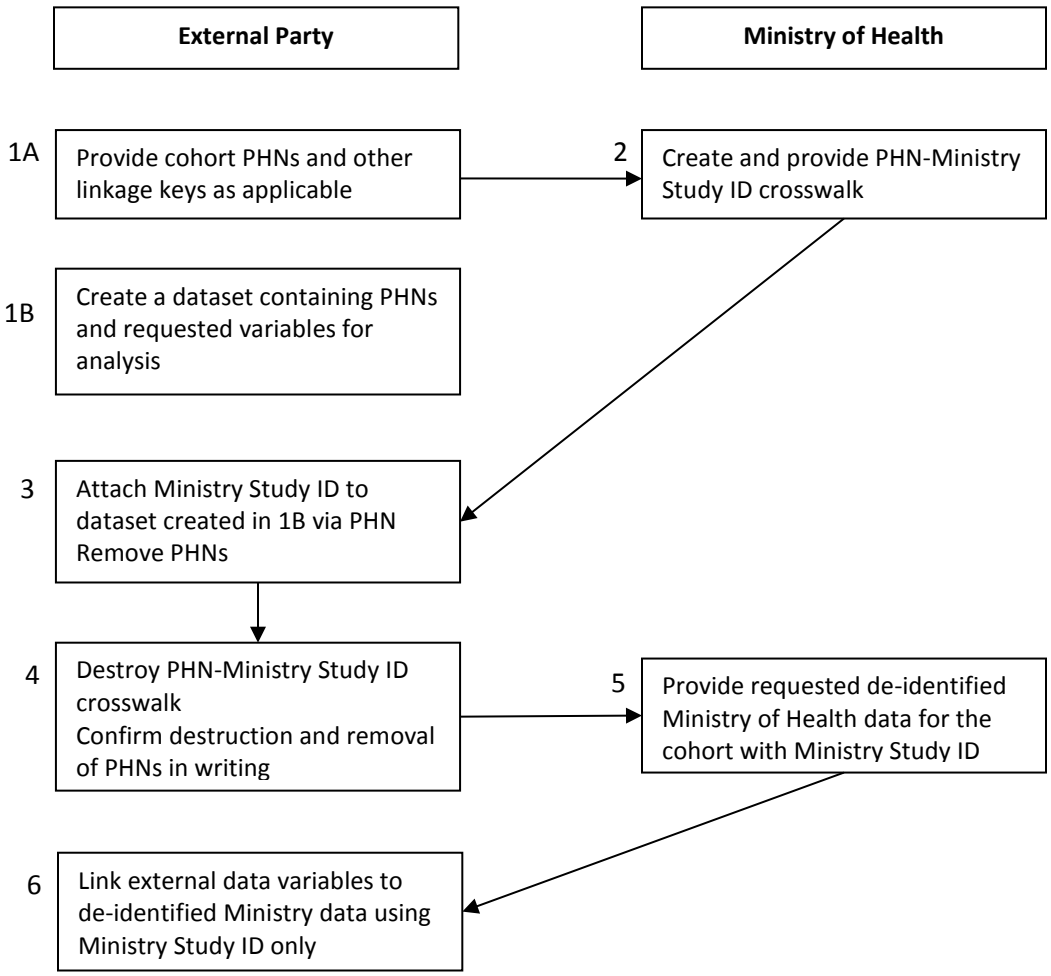
Step 5: External Party destroys PHN-to-Ministry study ID crosswalk file and confirms with the Ministry in writing the destruction of crosswalk file and removal of PHNs.

Step 6: The Ministry prepares and provides requested de-identified Ministry data for the study cohort(s) with Ministry study ID.

Step 7: External Party links files prepared in Step 4 and 6 via Ministry study ID only to carry out the analysis.

OR

Cohort defined using data source from External Party and using external variables for analysis



Step-by-Step:

Step 1A: External Party prepares and provides the Ministry of Health (the "Ministry") an electronic data file of cohort PHNs and other linkage keys as applicable for linkage purpose only.

Step 1B: External Party prepares a version of the dataset to be used for the analysis of this project. This dataset should only contain the requested variables for analysis and PHNs.

Step 2: The Ministry assigns Ministry study ID to the individuals in the cohort that are successfully matched. The Ministry sends PHN-to-Ministry study ID crosswalk file to External Party.

Step 3: External Party assigns Ministry study ID to the dataset prepared in Step 1B and removes PHNs.

Step 4: External Party destroys PHN-to-Ministry study ID crosswalk file and confirms with the Ministry in writing the destruction of crosswalk file and removal of PHNs.

Step 5: The Ministry prepares and provides requested de-identified Ministry data for the cohort with Ministry study ID.

Step 6: External Party links files prepared in Step 3 and 5 via Ministry study ID only to carry out the analysis.

Data Flow – Category C - Complex

This category includes situations when the cohort is defined using Ministry of Health and External data from one or multiple parties - from cohort definition or just initial MOH data extract – regardless of whether linkage with external variables will be involved.

Given the many potential linkage situations that could exist, there is no general data flow described here. The Applicant will have to describe in writing and/or with the help of diagrams the envisioned data flow corresponding to their actual project situation.

PRIVACY RISKS CONSIDERATION

Under the revised BC privacy legislation, some projects may require a completion of a Privacy Impact Assessment (PIA). As was indicated earlier in the manual, - please contact your parent organization's Privacy and Security branch to determine if a PIA is required for the project.

IN CLOSING

Project communications

Once the HDR package has been received by MOH, the project will be issued a project number for tracking purposes. The assignment of the tracking number does not necessarily mean the review process has been activated. While every HDR will receive a tracking number, not every HDR will be approved as submitted. Please use the title that appears on the HDR and the MOH-assigned project number on all future correspondence with MOH.

QUESTIONS AND HELP

MOH personnel are available to assist applicants with the HDR process. That said, staff time is a finite resource. Only complete applications will be reviewed by MOH staff. Applications received that are missing required documents, or do not meet a reasonable standard of consistency (e.g. consistency between the HDR and ethics application where applicable) will be returned to the Applicant and will not be processed until the application is re-submitted as a comprehensive and complete package.

MOH is working to move many of its support-related functions to the web in order to maintain high levels of support for applications. Prior to contacting the MOH, Applicants are urged to consult the MOH website for answers to their questions. If the Applicant cannot find the information needed on the MOH website, they should then contact the MOH directly.