Reproductive Care Program of Nova Scotia

Protocol for Linking Chart Review Data to Data from the Nova Scotia Atlee Perinatal Database

Step	Rationale/Additional Information
1. The investigator will consult with RCP about the format for an electronic data entry file (e.g. spreadsheet) and/or a hard copy data entry record. Since RCP will create the file and the investigator will enter data extracted from charts, both parties must be involved in the discussion about file format.	Consultation will ensure that the investigator is comfortable with the file format and that the chart review data file and the Nova Scotia Atlee Perinatal Database file will be compatible.
2. RCP will extract the names, birth dates, and unit numbers for the study population. A hard copy of the list can be hand delivered to the IWK Health Records Department or RCP can send the list using *eSEND*, a secure file transfer mechanism, to any facility in Nova Scotia. The investigator will be notified when the chart list has been delivered to the Health Records Department.	Personal identifiers must be delivered to Health Records using a secure method for information transfer. If the review will take place at a facility outside of the IWK, a secure method of information transfer must be negotiated.
3. The investigator will obtain an encrypted password-protected USB Flash Memory Drive (USB-FMD) from the IWK IT Department, and arrange delivery of the USB-FMD to RCP.	The USB Flash Memory Drives available from the IWK IT Department have the security features required by the JDAC. In 2014 the cost for an 8GB USB-FMD from the IWK is $25.01.
4. The investigator will work with the Health Records Department to arrange details for records review (e.g. chart pulling schedule and space to carry out data entry).	Health Records staff need lead time to pull charts. There may be a fee levied for chart retrieval if that is the Departmental policy.
5. RCP will list the chart numbers and a link ID to each record on the USB-FMD in the format determined in Step 1. The researcher will personally pick up the USB-FMD from RCP.	Chart numbers are considered personal identifiers in the context of the health care system and must be appropriately protected. If the investigator will not be reviewing charts at the IWK, a secure method for transferring the USB-FMD to the investigator must be negotiated.
6. The investigator will extract (*list variables*) from the records reviewed. All data obtained from the chart review must be saved only to the USB-FMD. Ideally, the investigator will use the USB-FMD with his/her laptop computer, not connected to the Internet. If the investigator does not have access to a laptop computer, a hard copy data collection record may be used and the data entered from a desk top computer into a spreadsheet on the USB-FMD. It is the responsibility of the investigator to maintain the security and integrity of the USB-FMD, and the hard copy data entry sheet if used, between chart review sessions. Please describe the procedures that will be followed. (e.g. store in a locked cabinet in an office with restricted access).	Limiting storage of the chart review data to the USB-FMD ensures that the personal health information collected will not be inadvertently accessed from a shared drive.

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7. At the end of the chart review exercise, the investigator will deliver the USB-FMD in person to RCP. RCP will: a. transfer the chart review data to a temporary file, b. link these data to the pertinent Atlee Database records, c. add the clinical variables approved, and d. remove all identifiers including the link ID and assign a Unique Study Number to each case to create the "data analysis file". *(Note: Infants will be given the mother's study number. Twins will be given the mother's study number with an extra digit: A for "Twin A", B for "Twin B", etc.).*	The Study ID de-identifies the list of cases and serves as the link to cases in the Nova Scotia Atlee Perinatal Database. *Note: A set of unique study IDs is created for every project that requires person-level data to ensure that data sets for different projects cannot be linked.* The *Personal Health Information Act* (PHIA) allows the Minister of Health/Nova Scotia Department of Health & Wellness (DHW) to collect, use and discloses personal health information without consent for purposes described in the legislation. There are specific provisions related to research in PHIA. As a provincial program of the Department of Health & Wellness, RCP is subject to the requirements outlined in the legislation and also adheres to the Program's Data Management Principles and Privacy Policy.
8. The data analysis file comprised of the Study ID, variables collected from the chart review, and variables from the Nova Scotia Atlee Perinatal Database, will be placed on the assigned restricted drive on the IWK IT Server for access by the investigator.	If the investigator must work from outside of Halifax, alternate arrangements may be considered but must be negotiated with the JDAC, the DHW and RCP. The RCP Data Use Agreement outlines the responsibilities of the investigators and any restrictions placed on the use of the data file. At the end of the project, the investigator must return the data file to RCP or destroy it. RCP will sequester analysis files for researchers on request.
9. a) RCP will purge the chart review data from the USB-FMD and return it to the researcher. b) RCP will delete the chart review data from the temporary location in RCP, unless other arrangements have been requested by the researcher.	The USB-FMD has volatile memory thus the chart review data will be gone and cannot be recovered. RCP does not have the authority to retain information that is not part of the established variable list for the NSAPD. However, upon request RCP will hold a copy of the chart review data in a secure location to assist researchers with meeting requirements for record retention.