Addendum to the Canadian Organ Replacement Register Privacy Impact Assessment (2010): Access to Kidney Transplantation Feasibility Project, July 2012

Standards and Data Submission

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Institut canadien d'information sur la santé

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Addendum to the 2010 Canadian Organ Replacement Register Privacy Impact Assessment:
Access to Kidney Transplantation Feasibility Project

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Background

The Canadian Organ Replacement Register (CORR), maintained by the Canadian Institute for Health Information (CIHI), is Canada's national registry for patients with end-stage organ failure. CORR contains patient-level data on all end-stage kidney failure patients from the time they begin chronic dialysis treatment, as well as on kidney and other solid-organ transplant recipients from the date of transplantation. However, at present, CORR contains very limited patient-level data to understand the subset of chronic dialysis patients who are also wait-listed for a kidney transplant.

In 2009, the CORR Board and the Canadian Society of Transplantation's Kidney Working Group identified a broader need to determine access to kidney transplantation among all patients with end-stage kidney failure and thus provide a more accurate assessment of the unmet need for transplantation than is currently available from CORR. The CORR Board approached CIHI to carry out data collection activities for the Access to Kidney Transplantation Feasibility Project (also known as CORR WAVE) to collect patient-level information on a cohort of end-stage renal disease patients who present to Canadian transplant centres, with follow-up on those referred to the deceased-donor waiting list. Patients are enrolled into the project over a three-year period and followed up as part of a five-year feasibility project. Data collection activities are carried out by CIHI on behalf of the CORR Board. CIHI manages the collection, use, disclosure and retention of this data in the same way as for other CIHI databases.

This additional data collection stream, considered to be an extension of CORR, will help quantify and explore movements on and off waiting lists and access patterns to waiting lists across the country, including calculation of wait times in the system. At the end of this project, discussions will take place regarding the value of the information collected and options will be proposed for maintaining this data collection stream on a permanent basis.

A privacy impact assessment (PIA) of CORR was finalized and published on CIHI's website in 2010. This foundational PIA examined the privacy, confidentiality and security risks associated with CORR. The purpose of this addendum is to describe the privacy and security aspects particular to CORR WAVE that are not already addressed in the foundational CORR PIA.

Statement of Purpose

The objectives of CORR WAVE are to

- Determine the incidence of chronic dialysis patients activated onto the deceased-donor kidney transplant waiting list;
- Collect information to calculate wait times in the system (for example, time from referral to deceased-donor waiting list, time to transplantation from any donor source);
- Quantify movements off the waiting list and their reasons;
- Provide national baseline data on waiting list activations (registrations) for deceased-donor kidney transplants;

- Assess the feasibility of collecting this additional data for ongoing operations; and
- Assess the feasibility of collecting this type of data for other organs.

The project commenced on January 1, 2010, and is governed by a steering committee that includes a CORR Board executive sponsor and a CIHI executive sponsor.

The target population for this project is end-stage renal disease patients who have been referred for transplantation. Currently, 16 out of 18 transplant centres that receive adult patients across seven provinces are participating in the project.

From a cost and technological perspective, it was decided that the most practical solution for this feasibility project was to design, develop and implement an electronic file processing application and a stand-alone database, separate and apart from CIHI's CORR database and applications. CIHI considers CORR and CORR WAVE to be a single data holding.

Personal Health Information Collected

The data collected at the time of a patient's initial evaluation (see Appendix A) includes the following:

- Transplant program identification (that is, program name, city);
- Patient identification and demographic information (for example, name, gender, date of birth, health card number and province or territory of issue);
- Other patient information (that is, city and province/territory of residence, postal code, race);
- Transplant referral information (for example, date of referral, date of initial dialysis treatment);
- Consultation and final disposition (for example, date of first visit with surgeon, death before wait-listing, whether patient is currently on chronic dialysis, date of initial dialysis treatment); and
- Clinical information (for example, serum creatinine level).

Additional data (see Appendix B) is collected when patients are removed from or reactivated back on to the waiting list, including the following:

- Transplant program identification (that is, program name, city);
- Patient identification and demographic information (for example, name, date of birth, health card number and province or territory of issue);
- Removal from waiting list information (that is, date of removal, reason for removal, whether removal is permanent); and
- Date patient is reactivated to waiting list.

Data Collection and Submission, Storage and Access; Verification, Processing and Dissemination

Data Collection and Submission, Storage and Access

Data is collected from patients by staff in the transplant centres. There are two methods of data collection: paper forms and electronic files. Collection occurs at the time of specific events, such as the time of referral, the patient's evaluation and activation on to the waiting list, and removal from or re-activation back on to the waiting list. See Appendix C for an overview of the data flow.

For transplant centres that choose to submit by paper, the submission process involves the capture of relevant information on the CORR WAVE paper form by staff in the transplant centres.

Following the completion of these forms, staff in the transplant centres package and double-wrap the forms and courier them to CIHI, where data is manually entered by CORR WAVE staff into a data entry application specifically developed for this project. From this application, files are generated, processed and loaded into the CORR WAVE database.

Of the 16 transplant centres participating in the project, 5 currently submit data to CIHI by paper (3 in Quebec, 1 in Alberta and 1 in Manitoba). The transfer of personal health information on paper raises risks to the privacy of the individuals concerned compared with transfer by electronic means. CIHI's *Standard for Health Data Collection* stresses the importance of protecting health data while in transit from data providers through to CIHI's receipt and does not include the collection of personal health information on paper. CIHI is working closely with its data providers to eliminate the remaining transfer of paper-based personal health information to CORR WAVE, while recognizing that if this option were to be eliminated, some clinicians would not submit data electronically to a voluntary registry. Nonetheless, CORR is encouraging data providers to explore other options for transmitting the data electronically (such as by sending encrypted scans of paper forms). It is CORR WAVE's objective to receive all submissions electronically within the next year.

For transplant centres that choose to submit data electronically, the submission process involves the capture of relevant patient information by staff in the transplant centres using the data entry application specifically developed for CORR WAVE. Once entered, data is manually exported on a monthly or quarterly basis and sent to CIHI via CIHI's secure electronic Data Submission Service. Submitted data is then processed and loaded into the CORR WAVE database.

Both the manually entered data from paper forms and the data submitted electronically are stored on CIHI's secure network and are accessed on a need-to-know basis by authorized CIHI staff.

Currently, CIHI's practice prohibits the dissemination by CIHI of paper records containing personal health information. This restriction applies in all jurisdictions.

Verification, Processing and Data Dissemination

Following submission of the data collected by transplant centres, CIHI undertakes its data verification and processing activities, where reports (for example, error/correction reports, submission reports, annual reconciliation reports) are produced. These reports are returned to individual transplant centres using one of CIHI's preferred methods of dissemination, as set out in CIHI's *Privacy Policy Procedures, 2010* (for example, CIHI's or the client's secure web-based application, emailing of encrypted files with facility authorization). Once received, staff in transplant centres make the necessary corrections and subsequently resubmit data using one of the methods described above.

Use—Data Linkage

To achieve the general objectives of CORR WAVE, as described earlier in this document, CIHI needs to link CORR WAVE data to CORR data. This linkage is subject to Section 18 of CIHI's *Privacy Policy, 2010* (which refers to data linkage within a single data holding for CIHI's own purposes) and does not require formal approval. Any linkage of CORR/CORR WAVE data to other CIHI data holdings is subject to Section 19 of CIHI's *Privacy Policy, 2010* (which refers to data linkage across data holdings) and requires formal review and approval internally within CIHI.

Disclosures

Publication

CIHI will use CORR WAVE data to produce publicly available reports containing aggregated findings, such as an annual report, special analytical products and various data tables. Due to the nature of the material being reported by CORR, there may be instances when cells with fewer than five observations are reported. CORR and CIHI recognize that there is a small risk of re-identification from reporting small cell sizes if they were to be matched with other external sources of information. Cases where small cells are published are reviewed with CIHI's statisticians to ensure that the risk of re-identification is minimized, as set out in CIHI's *Privacy Policy, 2010*. Small cells are typically reported at a provincial or national level to reduce the risk of re-identification and residual disclosure. These practices are consistent with those of CIHI's CORR database.

Third-Party Data Requests

Customized record-level, de-identified data and aggregate information from CORR and CORR WAVE may be requested from time to time, for example, by researchers. CIHI administers a third-party data request program, which contains and ensures privacy and security controls within the recipient organization.

As set out in sections 45 to 47 of CIHI's *Privacy Policy, 2010*, CIHI's data disclosures are made at the highest degree of anonymity possible while still meeting the research and/or analytical purposes of the requester. This means that, whenever possible, data is aggregated. Where aggregate data is not sufficiently detailed for the intended purpose, record-level data that has been de-identified may be disclosed to the recipient on a case-by-case basis and where the recipient has entered into a data protection agreement or other legally binding instrument with CIHI. Only those data elements necessary to meet the intended purpose may be disclosed.

In 2009, CIHI adopted a complete lifecycle approach to data management. As part of that lifecycle, CIHI's Privacy and Legal Services (PLS) team developed and is responsible for the ongoing compliance monitoring process, whereby all record-level data sets that are disclosed to third-party data recipients are tracked and monitored for secure destruction at the end of their lifecycle. This requirement is consistent with Section 29 of CIHI's *Privacy Policy, 2010*, which requires linked data to be securely destroyed within the specified time period. Prior to disclosing data, third-party recipients sign CIHI's Non-Disclosure/Confidentiality Agreement (ND/CA) and agree to comply with the conditions and restrictions imposed by CIHI relating to the collection, purpose, use, security, disclosure and return or disposal of data. Moreover, CIHI imposes obligations on these third-party recipients, including

- CIHI's right to audit;
- Restrictions on the publication of cell sizes less than five; and
- The use of strong encryption technology that meets or exceeds CIHI's standards where mobile computing devices are used.

As of January 2011, in addition to the compliance monitoring process, PLS requires third-party data recipients to certify on an annual basis that they continue to comply with their obligations as set out in the Third-Party Data Request Form and ND/CA signed with CIHI. All disclosures of CORR/CORR WAVE data occur in a manner consistent with CIHI's preferred methods of dissemination, as set out in CIHI's *Privacy Policy Procedures, 2010*.

Return of Own Data

CORR WAVE data providers may request the data they provided to CIHI be returned. Return of this data occurs in a manner consistent with CIHI's preferred methods of dissemination, as set out in CIHI's *Privacy Policy Procedures, 2010*.

Conclusion

This PIA addendum summarizes CIHI's assessment of the privacy implications of CORR WAVE. No privacy risks were identified as a result of this assessment.

Appendix A—Initial Evaluation Form

Access to Kidney Transplantation Feasibility Project

INITIAL EVALUATION FORM

SECTION A1—PATIENT IDENTIFIERS

Transplant Program _____ (Name and City)

Patient ID _____

Last Name _____

First/Middle Name _____

Former Name _____

Sex ☐ Male ☐ Female ☐ Other

Date of Birth |__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

Health Card Number _____

Province or Territory of Health Card Number _____

Affix patient label, if available

SECTION A2—OTHER PATIENT INFORMATION

Race (**check one**):

☐ Caucasian ☐ Asian ☐ Black

☐ Indian (subcontinent) ☐ Pacific Islander ☐ Aboriginal

☐ Middle Eastern/Arabian ☐ Latin American ☐ Unknown

☐ Other/multiracial _____

City _____

Province or Territory _____

Postal Code _____

SECTION B—TRANSPLANT REFERRAL

Date of transplant referral:

|__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

Was the patient on chronic dialysis at the time of transplant referral?

☐ Yes ☐ No

If YES, date of initial dialysis treatment for end-stage renal disease:

|__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

If NO, most recent serum creatinine level: _____ µmol/L

Complete sections C and D once final disposition is known. Submit partial form with sections A and B completed if final disposition is not known at the time of submission to CIHI. Once disposition is known, submit remaining sections and Section A1—Patient Identifiers.

SECTION C—CONSULTATION AND FINAL DISPOSITION

Was the patient seen by a transplant nephrologist/surgeon? ☐ Yes ☐ No

If yes, date of first visit with transplant nephrologist/surgeon: |__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

☐ Patient died before wait-listing or final disposition

Date of final disposition regarding wait list activation: |__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

Is patient currently on chronic dialysis? ☐ Yes ☐ No

If YES, date of initial dialysis treatment: |__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

If NO, most recent serum creatinine level: _____ µmol/L

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Formulaire disponible en français.

Form IE2010 (reviewed 2011)

Appendix B—Waiting List Removal/ Reactivation Form

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WAITING LIST REMOVAL/REACTIVATION FORM

For removals lasting six months or longer. Do not complete for reasons of transplant or death as these outcomes are captured in CORR.

SECTION A—PATIENT IDENTIFIERS

Transplant Program _____
(Name and City)

Patient ID _____

Last Name _____

First/Middle Name _____

Former Name _____

Date of Birth |__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

Health Card Number _____

Province or Territory of Health Card Number _____

Affix patient label, if available

SECTION B—REMOVAL FROM WAITING LIST

Date patient was removed from waiting list:

|__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

Main reason patient was removed (**check one**):

- ☐ Identified living donor
- ☐ Acute myocardial infarction
- ☐ Stroke
- ☐ Other cardiovascular disease
- ☐ Investigation for cardiovascular disease
- ☐ Major cardiac surgery
- ☐ Major non-cardiac surgery (including vascular)
- ☐ Active malignancy
- ☐ Investigation for malignancy
- ☐ Active/untreated infection
- ☐ Patient preference
- ☐ Moved out of area and/or onto new waiting list
- ☐ Other reason (specify) _____

Was the removal from the waiting list permanent?

☐ Yes ☐ No ☐ Unknown

SECTION C—REACTIVATION TO WAITING LIST

Date patient was reactivated to the waiting list:

|__|__|/|__|__|__|/|__|__|__|__| (DD/MON/YYYY)

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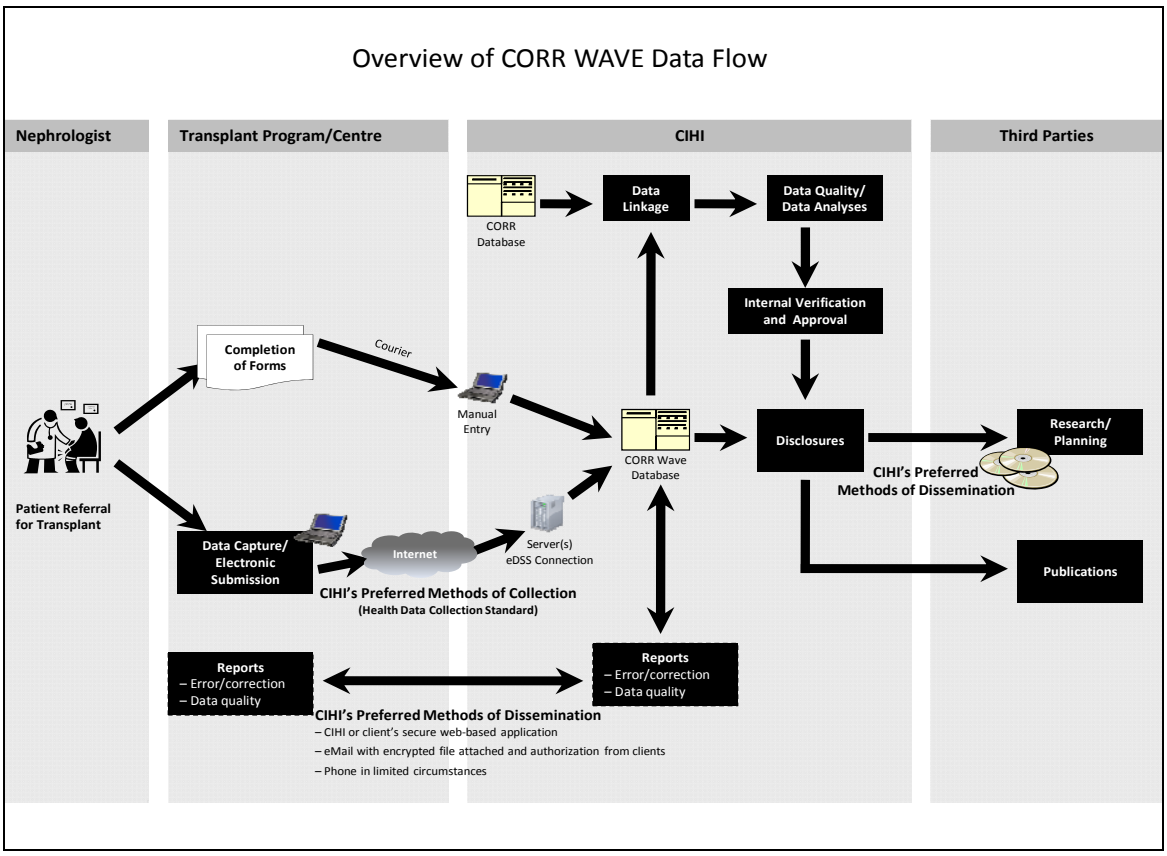
Formulaire disponible en français.

Form WLR2010 (reviewed 2011)

Appendix C—Overview of CORR WAVE Data Flow



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