CancerCare Manitoba
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GOVERNING DOCUMENTS

Policy and Procedure

Title:	**Event and Critical Incident Reporting (ECIR)**	
Policy Number:	02.024	Section: Clinical Administration
Effective Date:	November 20, 2015	
Revised Date:	May 9, 2019	
Approving Body:	President and CEO	
Authority:	CancerCare Manitoba Act	
Responsible Officer:	President and CEO	
Delegate:	Director, Quality, Patient Safety and Risk Department	
Contact:	Quality, Patient Safety and Risk Department	
Applicable to:	All CCMB Staff and Physicians	

1.0 **BACKGROUND:**
Not Applicable

2.0 **PURPOSE:**

2.1 To provide direction regarding the reporting and management of events.

2.1.1 To promote and support a culture of open communication that recognizes that all CCMB staff and affiliated staff play an important role in improving safety and quality of care.

2.1.2 To provide a standard and integrated system for reporting, recording, tracking, analyzing, trending, learning and recommending improvements from reported events that impact on the quality of patient care or safety of patients, staff, or affiliates.

2.1.3 To provide a means of recording events, either unusual or unexpected, such as property damage, theft, confidentiality breaches, and other perceived risks to the organization.

2.1.4 To provide a means of recording employee injury or other employee events that may occur.

2.2 To provide direction to CCMB staff and physicians with respect to critical incident reporting, reviewing, documenting and submitting to Manitoba Health in accordance with the responsibilities outlined in The Regional Health Authorities Act, specifically:

2.2.1 Ensure timely, comprehensive and factual reporting and review of critical incidents (CI's) in order to promote learning, enhance patient safety and reduce organizational risk through the implementation of system improvements.

2.2.2 Ensure that the lessons learned from the critical incident reviews are shared with all relevant stakeholders so that sustainable improvements in the health care system and patient safety are achieved.

2.3 To reduce the risk of patient harm by reporting on and learning from these events.

3.0 **DEFINITIONS:**

3.1 **ECIR:** the Event and Critical Incident Reporting system – The occurrence recording (Events & CI's) database available on every CCMB computer desktop.

3.2 **Critical Incident (CI):** An unintended Event that occurs when health services are provided to an individual and results in a consequence to him or her that: is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay and:

- does not result from the individual's underlying health condition or from a risk inherent in providing the health services.
- requires a safety review which is carried out by a Critical Incident Review Committee (CIRC).

3.2.1 **CIRC:** an individual or group whose responsibility is to carry out a safety review of a Critical Incident.

3.2.2 **Safety Review:** the act of reviewing and documenting what transpired by means of reconstructing the sequence of events and consulting with those involved or those who have knowledge of the processes associated with the incident all which have been identified by the CIRC.

3.3 **Potential Critical Incident (PCI):** An event that:

- Is being investigated to determine if it meets the criteria of a CI.
- Had been investigated to determine if it met the criteria of a CI but did not meet the criteria.
- Is to be investigated and reported internally to management in the same manner as a CI without the need to report to government or CI notification email.

3.4 **Event :** An unintended occurrence that takes place when health services are provided which:

- is not "best practice" involving patients, visitors, volunteers, employees or affiliates, property or equipment
- is identified as a potential risk to the quality and or safety of:
    - a patient
    - an employee
    - the work environment
- involves staff injuries

3.5 **Patient:** all persons receiving or registered to receive health care services.

3.6 **Family:** a patient, relative, life partner or children borne/adopted by the patient.

3.7 **CCMB Staff:** includes all employees, associate employees and volunteers who work at CCMB.

3.8 **QPSR:** Quality Patient Safety and Risk department.

3.9 **Alert Recipient:** a Manager Review, Manager Close or Admin in the ECIR who is

emailed a notification that an event was submitted in the ECIR.

3.10 **Initiator:** is an individual who submits an Event in the ECIR.

3.11 **Manager Review:** an individual's role in the ECIR who has the ability to:
- create and submit Events
- view, modify and add follow-up to all files for which access rights are granted
- create/respond to Tasks
- generate reports
- sign off on Events when completed

3.12 **Manager Close:** an individual's role in the ECIR who has the ability to:
- create and submit Event files
- view, modify and add follow-up to all files for which access rights are granted
- create/respond to Tasks
- resolve or close Events
- generate reports

3.13 **Admin:** an individual who has the ability to:
- create and submit Events
- view, modify and add follow-up to all Events
- resolve or close Events
- view, modify and/or delete incomplete files
- create, schedule and generate reports that include data for all files using the Report Editor and Designer
- post reports to the shared reports folder for managers to access
- create/ respond to Tasks
- create Alerts
- delete or cancel files from the system
- customize and configure the system as required

3.14 **Severity Levels:** A multi-tiered selection of event severity. Selection of a severity level of High or Highest signifies that the Event is a PCI. The severity levels include the following:
- Negligible; Unsafe condition (non-event)
- Negligible; Event did not reach patient – near miss
- Low – Moderate; Event reached patient with no harm
- Low – Moderate; Event reached patient with minimal harm
- High – Temporary Harm; Event reached patient and intervention needed
- High – Temporary Harm; Event reached patient and hospitalization needed
- High – Permanent Harm
- Highest – Death

3.15 **Alert:** An e-mailed notification that an Event has been submitted from the ECIR.

4.0 **POLICY:**

4.1 The Director of Quality, Patient Safety and Risk is responsible for the development

and management of the Event & Critical Incident Reporting (ECIR) system (see Appendices I, II, III).

4.2 Staff members are protected from assignment of blame and punitive action for submitting an Event.

4.2.1 At any time when a staff member or medical staff has demonstrated deliberate disregard for patient safety, CCMB reserves the right to address such instances in an appropriate manner in accordance with applicable policies or processes, collective agreements or Medical Staff By-Laws, even when such a staff member or medical staff is involved in a CI.

4.2.2 In the spirit of establishing a just and fair learning culture, CCMB shall not dismiss, suspend, demote, discipline, harass or otherwise disadvantage any staff member involved in events leading to a CI and/or because the other person has complied with the requirement to provide information, documents or records under *The Regional Health Authorities Act* except as outlined in Item 4.2.

4.2.3 **The ECIR Submissions are not to be used for the purpose of the reporter's performance review.**

4.3 All CCMB staff and Physicians are responsible for reporting events that impact on patient safety, quality of care and overall safety within the organization. CCMB Staff and Physicians who witness or are involved in an Event will enter it promptly in the ECIR System.

4.4 The QPSR department at CCMB shall ensure that all CI's are thoroughly reviewed (including debriefing of appropriate staff, patients and family whenever possible) in order to promote system-wide learning through the appointment of a Critical Incident Review Committee (CIRC), as described in *The Regional Health Authorities Act* and as detailed in the Standards of Practice, Event and Critical Incident Reporting (J:\ Drive Quality Folder).

4.5 All documentation must be complete; factual; clear; concise; stated without conjecture or subjective language or contain language that is self-incriminating to the corporation and/or staff.

4.6 Actual information about patient management as a result of an Event would be specified in the chart and <u>not</u> in the ECIR system.

- Reporting an Event is not to be documented in the patient's health record

4.7 Modification to Event in the ECIR can be made only by communicating the correction to the Manager of the Site and/or Area in which the Event occurred or the systems Admin keeping in mind that there is a permanent record of original entry in the system.

4.8 Events with potential ramifications associated with breaches of legislation must be captured in the system.

4.9 Immediately after an event occurs, CCMB Staff and Physicians are to take whatever action within their scope of duties or responsibilities is required to correct the situation and ensure that safeguards are put in place should a person be affected.

4.10 The immediate supervisor or designate shall:

4.10.1 Take or initiate any additional remedial action within his/her scope of duties or responsibilities required to correct the situation.

4.10.2 Take or initiate other measures to reduce injury/risk/loss as necessary in the circumstances.

4.10.3 Take or initiate other measures to put process improvements in place to mitigate the potential for the reoccurrence of similar event.

4.11 The CIRC Lead will present recommendations resulting from a CI Safety Review to the appropriate member of the Leadership Team to identify ownership of the implementation and the expected dates of completion.

4.11.1 The Quality, Patient Safety & Risk Program will monitor recommendation completion status and submit progress reports to Manitoba Health.

4.11.2 Lessons learned shall be shared with all appropriate individuals and organizations as detailed in the Procedure section below.

4.12 Disclosure of a CI shall occur in accordance with the CCMB Critical Incident Disclosure Policy 02.004 and as described in The Regional Health Authorities Act including an apology in accordance with The Apology Act of Manitoba.

4.13 No record or information, including an opinion or advice, prepared solely for the use of a CIRC, or collected, compiled or prepared by a CIRC for the sole purpose of carrying out its duties, may be produced in any legal proceeding.

4.14 Even though a CIRC is conducting its safety review of a Critical Incident, CCMB and other bodies such as the Chief Medical Examiner and regulatory bodies have the right to review the facts giving rise to a CI. Such review(s) shall be independent of the CIRC and may include meeting with and interviewing some of the same individuals involved in a safety review by the CIRC. Individuals shall not answer questions about the CIRC proceedings during these other investigations or in any legal proceeding, but may answer questions about the facts that gave rise to the CI.

4.15 Various reports based on non-CI Events are created by the QPSR and provided to:

- CancerCare Board of Directors
- CancerCare Leadership Team
- Quality Systems Team
- DSG Chairs
- CCMB Staff and Physicians

- Other relevant committees (e.g.: CCMB Standards Committee, Workplace Safety & Health, etc.)

4.16 An ECIR submission may be classified as an "error" if the event is a duplicate entry or the submission is deemed a non-event, substantiated by both the reporter and their manager.

4.17 Event submissions which predate implementation of the CCMB electronic reporting systems have been retained in accordance with Policy 06.013, Retention of Non-Medical Records.

4.18 Inquiries from the media regarding CI's or any other CCMB sensitive information is to be directed to CCMB Communications at 204-787-1878.

5.0 PROCEDURE:

5.1 Manual Reporting (See Appendix IV)

If the ECIR is not available on line:

- print and complete the Manual Reporting Forms, utilizing the Event Information Selections document (J:\ Drive Quality Folder).
- transcribe the manual report into the ECIR once it is available

6.0 REFERENCES:

6.1 WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, From Information to Action (2005). World Health Organization. Available at: http://osp.od.nih.gov/sites/default/files/resources/Reporting_Guidelines.pdf

6.2 The Regional Health Authorities Act
https://web2.gov.mb.ca/laws/statutes/ccsm/r034e.php

6.3 Section 9 of The Manitoba Evidence Act
https://web2.gov.mb.ca/laws/statutes/ccsm/e150e.php

6.4 The Apology Act of Manitoba
https://web2.gov.mb.ca/laws/statutes/2007/c02507e.php

7.0 RELATED POLICIES:

7.1 CCMB "Critical Incident, Reporting and Management" (December 2011), Policy #02.003 has been incorporated into this policy. Policy #02.003 has been archived.

7.2 CCMB "Critical Incident Disclosure", Policy #02.004 remains as a policy related to Disclosure of a Critical Incident.

7.3 Event and Critical Incident Reporting, Standards of Practice document (J:\ Drive Quality Folder).

Policy Contact: All enquiries relating to this policy should be directed to:	
Name:	
Title/Position:	Director, Quality, Patient Safety and Risk Department
Phone:	
E-mail:	

DOCUMENTATION	
Policy Location: This policy is located (hard and e-copy formats):	
1.	The original signed and approved policy is on file in the Executive Office, CCMB
2.	The e-copy is on file in the CCMB Governing Documents Library, SharePoint
3.	

Revision History:

Date	Version	Status	Author	Summary of Changes
dd/mm/yyyy	#	Initial, Draft Final Minor/Major revision		
20/11/2015	1	Initial	QPSR	New policy for CCMB
23/02/2018	1	Minor Revision	S.Friedenberger I Anderson	Reformatted into new template; update of minor details
09/05/2019	2	Revision	Quality Wkg Grp	Reviewed and updated policy and appendices to current processes.

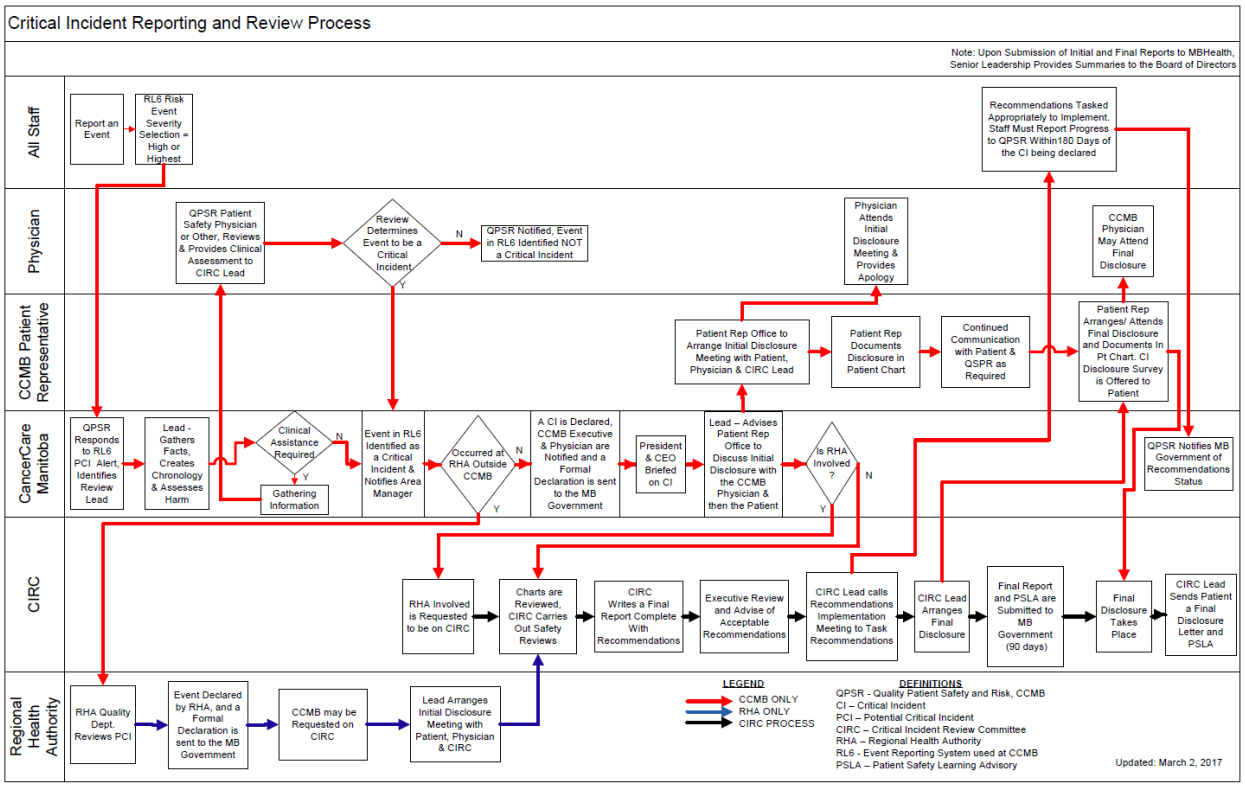
Approvals Record:
This Policy requires approval by:

Approval		
Date	**Name / Title**	**Signature**
	Not required.	

FINAL APPROVAL:

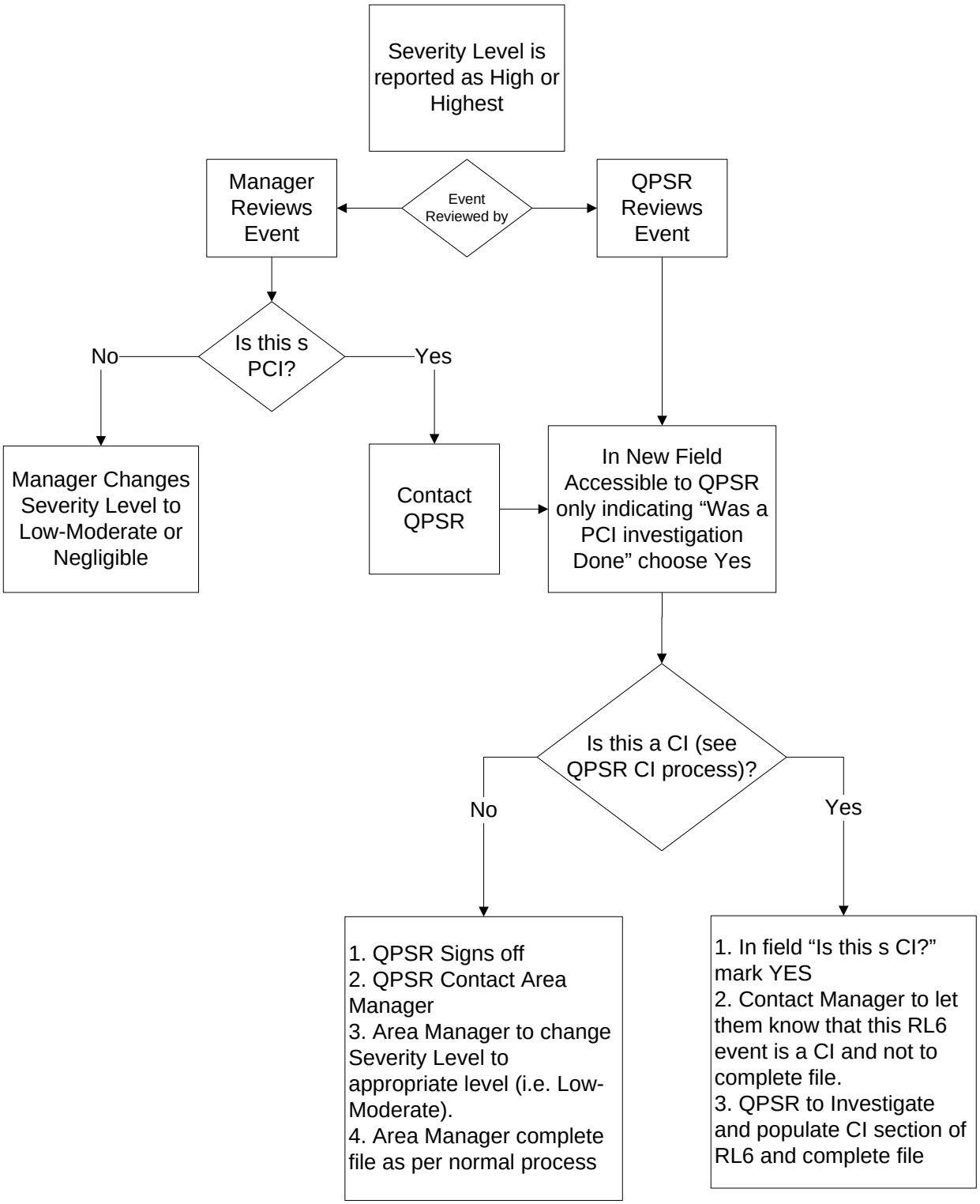
Date	**Name / Title**	**Signature**
May 9, 2019	Dr. S. Navaratnam President and CEO, CCMB	*Original signed by* *Dr. S. Navaratnam*

APPENDIX I


Critical Incident Reporting and Review Process
Note: Upon Submission of Initial and Final Reports to MBHealth, Senior Leadership Provides Summaries to the Board of Directors
All Staff
Physician
CCMB Patient Representative
CancerCare Manitoba
CIRC
Regional Health Authority
Report an Event
RL6 Risk Event Severity Selection = High or Highest
Recommendations Tasked Appropriately to Implement. Staff Must Report Progress to QPSR Within180 Days of the CI being declared
QPSR Patient Safety Physician or Other, Reviews & Provides Clinical Assessment to CIRC Lead
Review Determines Event to be a Critical Incident
N
Y
QPSR Notified, Event in RL6 Identified NOT a Critical Incident
Physician Attends Initial Disclosure Meeting & Provides Apology
CCMB Physician May Attend Final Disclosure
Patient Rep Office to Arrange Initial Disclosure Meeting with Patient, Physician & CIRC Lead
Patient Rep Documents Disclosure in Patient Chart
Continued Communication with Patient & QSPR as Required
Patient Rep Arranges/ Attends Final Disclosure and Documents In Pt Chart. CI Disclosure Survey is Offered to Patient
QPSR Responds to RL6 PCI Alert, Identifies Review Lead
Lead - Gathers Facts, Creates Chronology & Assesses Harm
Clinical Assistance Required
N
Y
Gathering Information
Event in RL6 Identified as a Critical Incident & Notifies Area Manager
Occurred at RHA Outside CCMB
N
Y
A CI is Declared, CCMB Executive & Physician are Notified and a Formal Declaration is sent to the MB Government
President & CEO Briefed on CI
Lead – Advises Patient Rep Office to Discuss Initial Disclosure with the CCMB Physician & then the Patient
Is RHA Involved ?
Y
N
QPSR Notifies MB Government of Recommendations Status
RHA Involved is Requested to be on CIRC
Charts are Reviewed, CIRC Carries Out Safety Reviews
CIRC Writes a Final Report Complete With Recommendations
Executive Review and Advise of Acceptable Recommendations
CIRC Lead calls Recommendations Implementation Meeting to Task Recommendations
CIRC Lead Arranges Final Disclosure
Final Report and PSLA are Submitted to MB Government (90 days)
Final Disclosure Takes Place
CIRC Lead Sends Patient a Final Disclosure Letter and PSLA
RHA Quality Dept. Reviews PCI
Event Declared by RHA, and a Formal Declaration is sent to the MB Government
CCMB may be Requested on CIRC
Lead Arranges Initial Disclosure Meeting with Patient, Physician & CIRC
LEGEND
CCMB ONLY
RHA ONLY
CIRC PROCESS
DEFINITIONS
QPSR - Quality Patient Safety and Risk, CCMB
CI – Critical Incident
PCI – Potential Critical Incident
CIRC – Critical Incident Review Committee
RHA – Regional Health Authority
RL6 - Event Reporting System used at CCMB
PSLA – Patient Safety Learning Advisory
Updated: March 2, 2017

APPENDIX II

Potential Critical Incident Process in RL6: Risk



APPENDIX III

CRITICAL INCIDENT REVIEW COMMITTEES (CIRCs)

As soon as possible after an event is confirmed as a Critical Incident (CI), a CIRC will be appointed by CancerCare Manitoba or the site where the CI occurred.

Certain individuals must be excluded as a member of the CIRC, specifically anyone who:

- has a conflict of interest in the CIRC (e.g. Manager of the involved Unit);
- was or is directly involved in providing care to the patient;
- has a potential future role in disciplinary matters arising from the CI or the program or site involved (e.g. Program Director /Medical Director, as outlined in 3.5);
- is the ongoing patient/family support person.

The appropriate size and type of CIRC will depend on the CI. There are a number of possibilities:

- Site based single person CIRC - the most common and efficient type of CIRC;
- Site based CIRC made up of two or more persons - appropriate if the case is complex or involves more than one program within a site;
- Regional CIRC made up of one or more person(s) - appropriate if the case involves more than one facility, more than one program within the region or if the issues are highly “visible”; and
- External CIRC - appropriate if a consultant outside CancerCare Manitoba is required.

In all cases a CIRC will:

i) Reconstruct the sequence of events:
   - Debrief (hear the story of) involved staff;
   - Debrief (hear the story of) involved patient and family;
   - Gather records.

ii) Meet with persons who are sources of applicable information.
iii) Consult with appropriate persons regarding recommendations.
iv) Prepare the final report.
v) Ensure that all CIRC documents are marked “Privileged under Section 9 of the Manitoba Evidence Act” and stored in a confidential file in a locked office.

As needed a CIRC will:

i) Seek expert opinions.
ii) Obtain standards and protocols from external sources.
iii) Seek information from non-CancerCare Manitoba sources (e.g. family physician, paramedics, pharmacy, literature, etc.).
iv) Convene meeting of clinical experts to assist the CIRC to formulate recommendations.

Special situations for a CIRC:

i) If there are serious concerns about the competence or performance of a provider, a CIRC may and should contact the President and CEO.
ii) If a CIRC member has a mandatory reporting duty to a licensing body, the CIRC should make the disclosure preferentially through the President and CEO and/or Director of Nursing.
iii) If there are serious concerns about possible criminal activity, a CIRC may involve police, preferentially by notifying the President and CEO.

APPENDIX IV

MANUAL EVENT REPORTING – Reporter Name and Date: _____

General information about the event

Event Type *	
Specific Event Detail *	
Type of Person Affected *	
Injury Incurred? *	
Equipment Involved/Malfunctioned? *	
Brief Factual Description *	
Contributing Factors *	
Immediate Actions *	
Suggestion(s) for avoiding similar Event in future *	
Severity Level * (Negligible, Low/Moderate, High, Highest)	

When and where the event occurred

Event Date *

Time (00:00)

Site *

Area *

Details of the person affected by the event

Last Name *

First Name *

CR# *

PHIN

Disease Site Group *

Is this Patient on a Clinical Trial? *

Oncology Type *

Gender *