Guidance for researchers

Vanessa's Law, SAEs, RLS, and how they apply to researchers at Covenant Health

What is Vanessa's Law?

Vanessa's Law or the *Protecting Canadians from Unsafe Drugs Act* was introduced as legislation in honor of Vanessa Young who died in 2000 of a cardiac event, found to be as result of a prescription drug that was eventually pulled from the market. The corresponding legislation was introduced to protect Canadians from unsafe drugs, and received final Royal Assent in November 2014. As a result of Vanessa's Law, health-care institutions are required to report on adverse drug reactions to Health Canada effective December 16th, 2019. [Overview of Vanessa's Law] Vanessa's Law enforces mandatory reporting from all hospitals for serious adverse drug reactions related to therapeutic products including: pharmaceuticals, biologic drugs, radiopharmaceutical drugs, disinfectants, medical devices, and drugs for urgent public health need. Health Canada's guidance relative to Vanessa's Law for adverse events exempts reporting relative to clinical trials that involve drugs and medical devices because there are reporting provisions already in place elsewhere. [Summary of therapeutic products not subject to the adverse event guidance].

What are research-related Serious Adverse Events (SAEs) and how are they reported?

Definitions sourced from the Alberta Clinical Research Consortium (ACRC) Glossary:

Serious Adverse Event (SAE) - "*An untoward experience that is fatal, life-threatening, disabling or which results in in-patient hospitalization or prolongation of hospitalization. In addition, congenital anomaly and occurrence of malignancy are always considered a Serious Adverse Event.*"

SAEs also include **Serious Adverse Drug Reactions (SADRs)** – "*An adverse drug reaction that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.*"

Additional definitions for reference: [ICH GCP Glossary]

A research study Principal Investigator (PI) is **required to report all SAEs for any clinical trials to the relative product Sponsor** and as outlined within the study protocol. The Sponsor in turn is responsible to report those SAEs to Health Canada in accordance with the *Food and Drug Regulations* [Sections: C.05.014 and C.08.010] and *Medical Device Regulations* [Sections: 79(3) and 69(2)]. Such reporting requirements are in compliance with International Council for Harmonization – Good Clinical Practice (ICH-GCP) guidelines [https://ichgcp.net/].

Note: For Investigator-initiated clinical trials, the Investigator is considered the Sponsor and accordingly is responsible to report to Health Canada as per the regulations indicated above.
In addition to reporting to a study Sponsor, the PI is required to report all SAEs for any such clinical trials to the research ethics board(s) (REB) that approved the trial, and in accordance with the ICH-GCP.

REB reportable events include adverse events that are:

- Serious, unexpected, and related or possibly related to the study (reportable within 15 calendar days of event); and
- Fatal or life threatening events (reportable within 7 calendar days of event).

Local Alberta Health Information Act (HIA)-designated REBs:

- Health Research Ethics Board (HREB) – Reporting Requirements and Local Serious Adverse Event Report
- Conjoint Health Research Ethics Board (CHREB) – Reportable Events Guidance and links
- Health Research Ethics Board of Alberta (HREBA) – Reportable Local Adverse Events and links

What is required reporting within Covenant Health?

Covenant Health utilizes the RLS to track, address and mitigate adverse events, close calls and/or hazards within healthcare facilities. The RLS also enables reporting - voluntary and mandatory, to both internal departments and external organizations. Reporting adverse events, close calls and hazards through RLS is recommended at Covenant Health [Policy III-45], and reporting of clinically serious adverse events to the most responsible health practitioner and manager/manager on-call is mandatory. [Listing of Mandatory and Recommended Adverse Events]; [Information and links to RLS].

Key Messages for Principal Investigators:

- ✓ Adverse events, close calls and hazards **should be reported** (voluntary) through the RLS system;
- ✓ All clinically serious adverse events **must be reported** to the most responsible Covenant Health practitioner and manager;
- ✓ All adverse events – SAEs and including SADRs, **must be reported** to the study sponsor as established within the study protocol; and
- ✓ All adverse events – SAEs and including SADRs, **must be reported** to the local REB(s) that approved the study.