# ADVERSE DRUG REACTIONS (ADR) AND MEDICAL DEVICE INCIDENTS (MDI)
# General Standard Operating Procedure for staff for RL submissions

**Please reference WRHA policy:**
**Adverse Drug Reaction (ADR) Documentation and Reporting – #110.000.480**
**Medical Device Incident (MDI) Mandatory Reporting to Health Canada - #110.000.490**

| Step | Actions | Person Responsible | When |
|---|---|---|---|
| 1 | Ensure safety of Patient/Client or other person.<br>Complete assessment and provide care, as indicated. | Immediate Care Team | Immediately |
| 2 | In any staff-to-staff report, transfer or handoff, communicate information about the ADR or MDI to the next care provider. | Health Care Providers | At report, transfer or handoff |
| 3 | Follow steps 2 – 7 in Patient/Client Safety Event Standard Operating Procedure for Initial Event Management, as applicable. See https://home.wrha.mb.ca/quality/files/InitialManagement.pdf | Most appropriate team members available and Manager/Designate | As soon as possible |
| 4 | Report the ADR (as soon as the reaction is recognized) or MDI in RL<br>• There is a specific tile in RL for ADRs<br>• For MDIs, choose the tile that corresponds to the event type and respond in the affirmative to the (mandatory) box associated with *Equipment Involved/Malfunctioned?*<br>• Complete at a minimum, the mandatory fields within RL. If additional information is available, complete remainder of recommended optional fields.<br>• Include information in the "Person Affected Details" of the form<br>• Provide your name and contact information in case further information is needed | Health Care Providers<br><br>Physician or delegate | As soon as possible |
| 5 | Document in the Patient Health Record's integrated progress notes (IPN) (or equivalent):<br>• the Patient/Client reaction,<br>• the treatment provided (in relation to the ADR or MDI), and,<br>• that the ADR/MDI was reported in RL | Health Care Providers | As soon as possible |
| 6 | Where applicable for ADR<br>1. Document the ADR on the Face Sheet (i.e. Inpatient Summary Sheet) to facilitate coding by WRHA Health Information Services (according to national standards)<br>2. Update the Single Source of Truth for Allergies and Intolerances for the patient in the Health Record. | Physician or delegate<br><br>Health Care Providers | As soon as possible |
| 7 | Ensure the Patient/Client is informed to avoid or mitigate harm (ADRs - from re-exposure to the drug). | Health Care Providers | As soon as possible |

| Step | Actions | Person Responsible | When |
|---|---|---|---|
| 8 | Upon RL notification of a new submission:<br>• For MDIs in hospitals, consult with Clinical Engineering, as applicable<br>• Review and include additional information, as needed, in the mandatory fields<br>• De-identify information entered in the narrative fields to comply with the Personal Health Information Act | Site Representative | Upon RL notification and within 7 business days |
| 9 | For ADRs and MDIs, check with the site representative before adding or changing information in the RL file to ensure the correct information is submitted to Health Canada (the data may already have been submitted to Health Canada). | Site Managers with scope to access RL file | Ongoing |