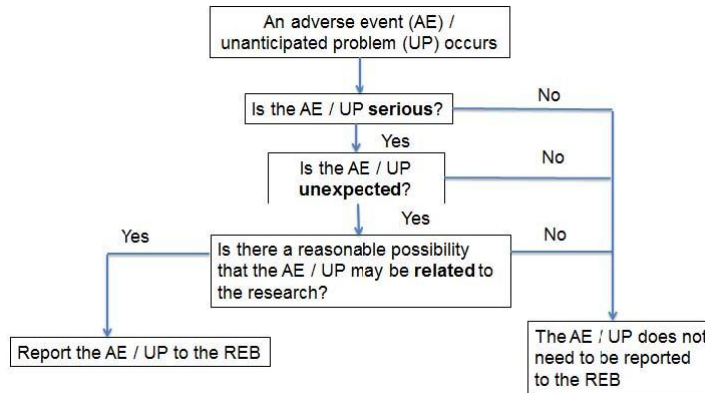
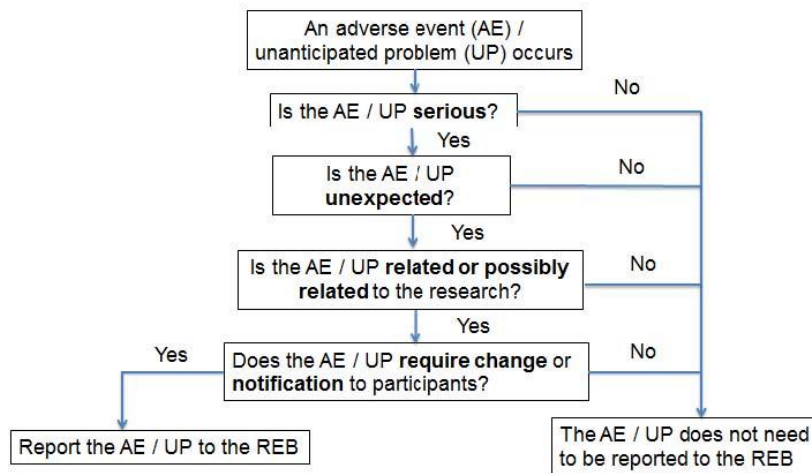


QUICK REFERENCE TOOL FOR REPORTING SERIOUS ADVERSE EVENTS (SAEs) / UNANTICIPATED PROBLEMS (UPs) TO THE SJHC REB

LOCAL SAEs/ Unanticipated Problems (UPs): Report if **serious AND unexpected AND related** or **possibly related** to the research. *Note: Follow the study protocol, the Sponsor's study specific SOPs, SJHC REB study specific requirements and regulatory authority requirements (as applicable).*



EXTERNAL SAEs/ Unanticipated Problems (UPs): Report if **serious AND unexpected AND related** or **possibly related** to the research **AND requires a change** to the research or notification to research participants



PERIODIC SAFETY UPDATE REPORT (PSUR*): Submit a summary of all suspected unexpected SAEs that have occurred in the reporting period in **table format**.

***PSUR:** a summary report prepared by the Market Authorization Holder (MAH) that provides a periodic but comprehensive assessment of the worldwide safety data of a medicinal product. The PSUR can be an important source for the identification of new safety signals, a means of determining changes in the benefit-risk profile, an effective means of risk communication to regulatory authorities and an indicator for the need for risk management initiatives, as well as a tracking mechanism for monitoring the effectiveness of such initiatives.

Thank you to St. Michael's Hospital REB for allowing us to adopt this form and modify as needed.

Version: November, 2016