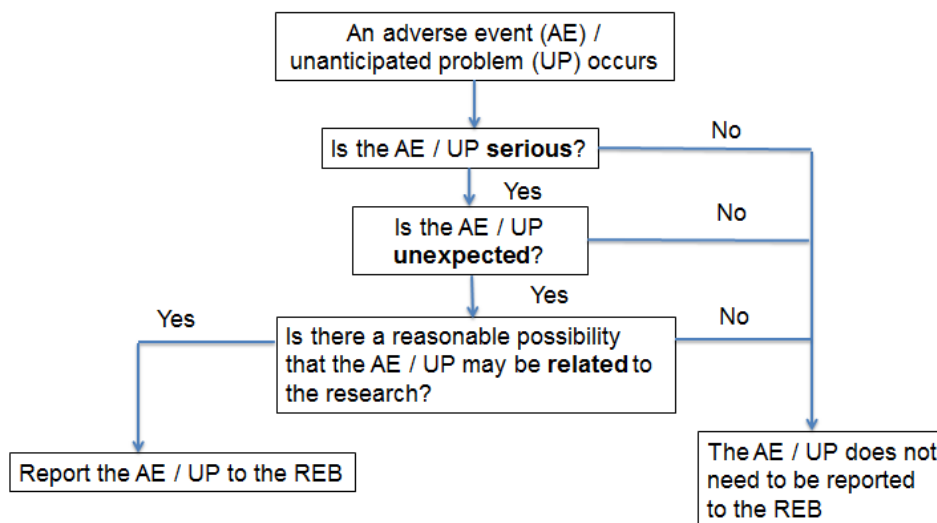


QUICK REFERENCE TOOL FOR REPORTING SERIOUS ADVERSE EVENTS (SAEs) / UNANTICIPATED PROBLEMS (UPs) TO THE Network REB

Network (**LOCAL**) SAEs/ Unanticipated Problems (UPs):

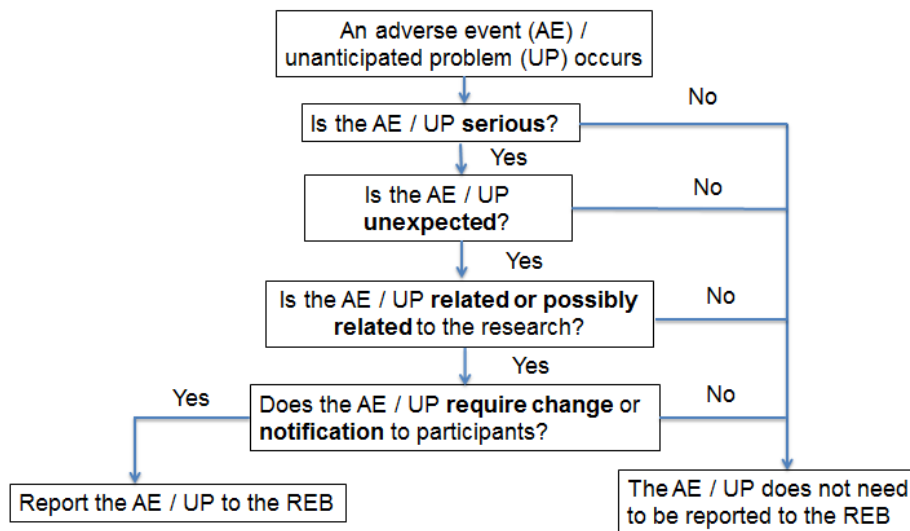
Report if **serious AND unexpected AND related** or **possibly related** to the research.

Note: Follow the study protocol, Sponsor's study specific SOPs, 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** using the 'Network REB Updated Safety Information Reporting Form'

For more information: <http://stmichaelshospitalresearch.ca/wp-content/uploads/2015/10/REB-guidelines-for-reporting-saes.pdf>