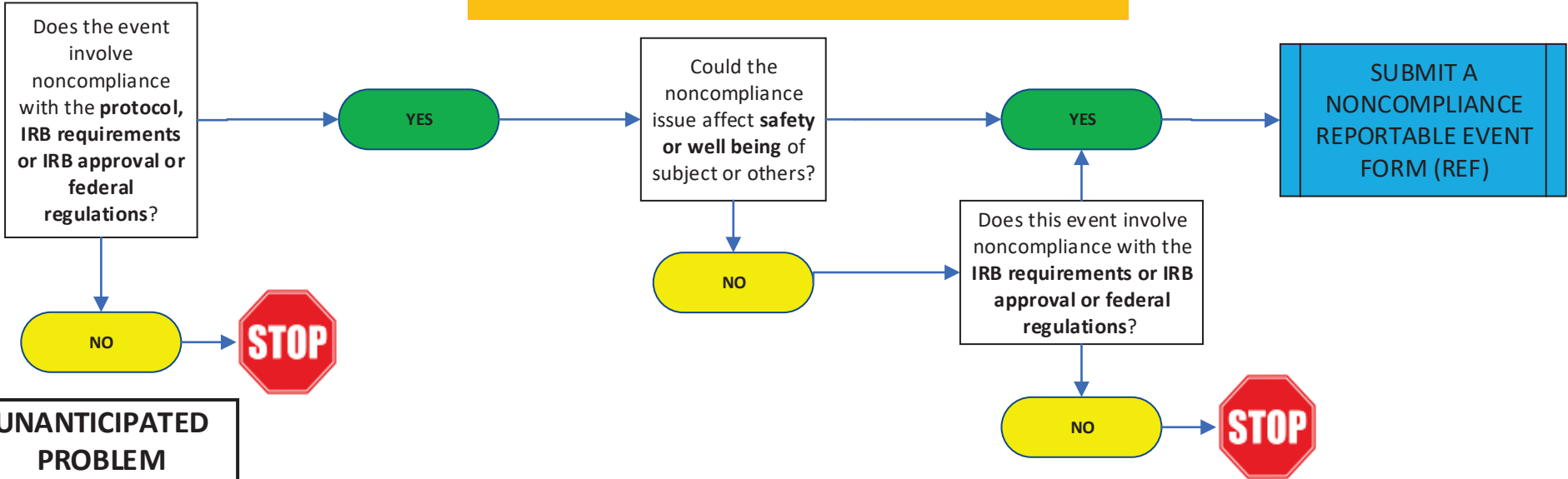
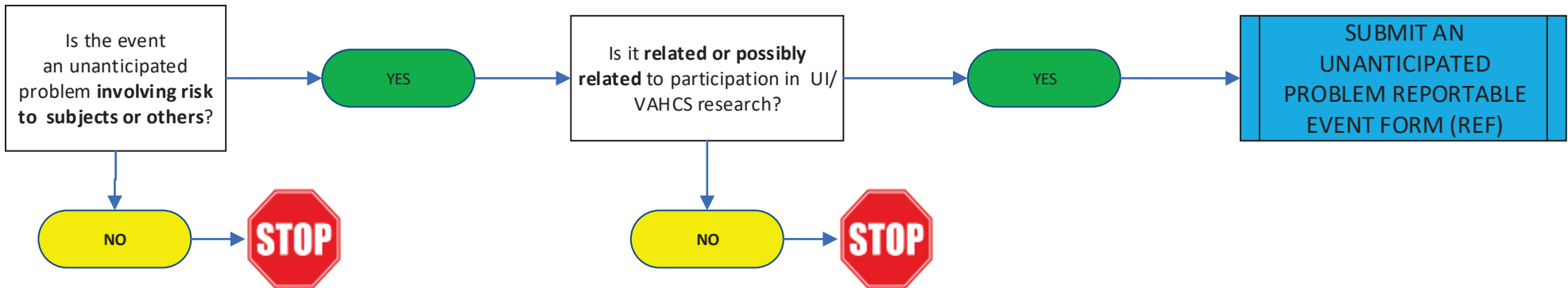


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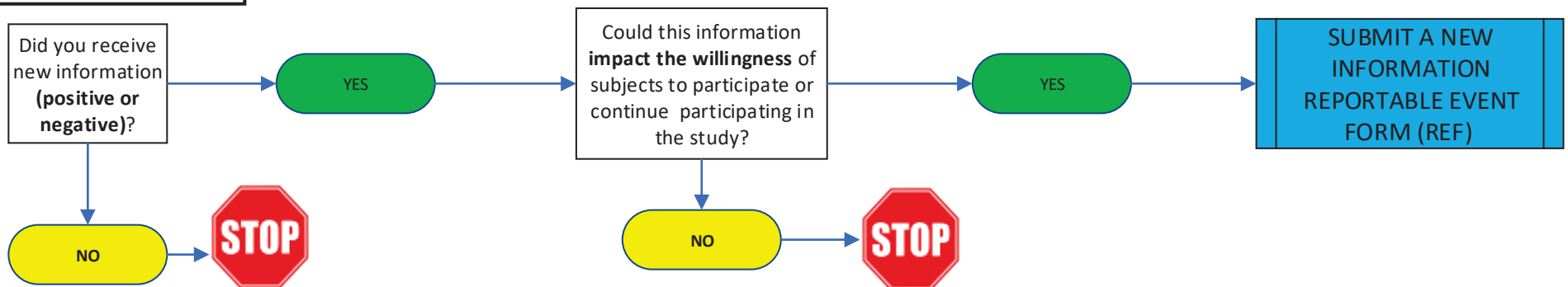
NONCOMPLIANCE



UNANTICIPATED PROBLEM

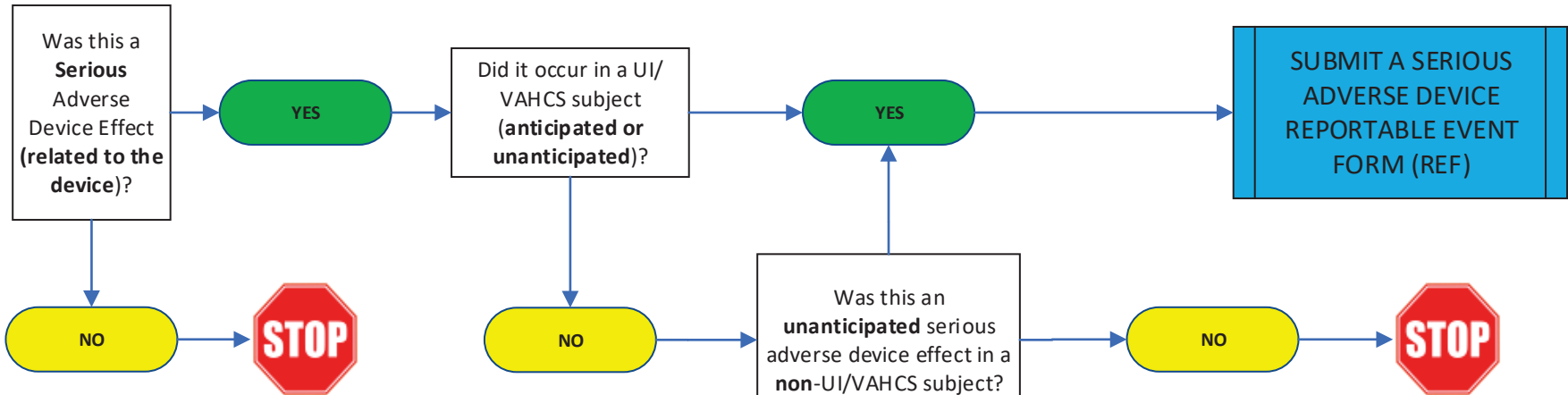


NEW INFORMATION

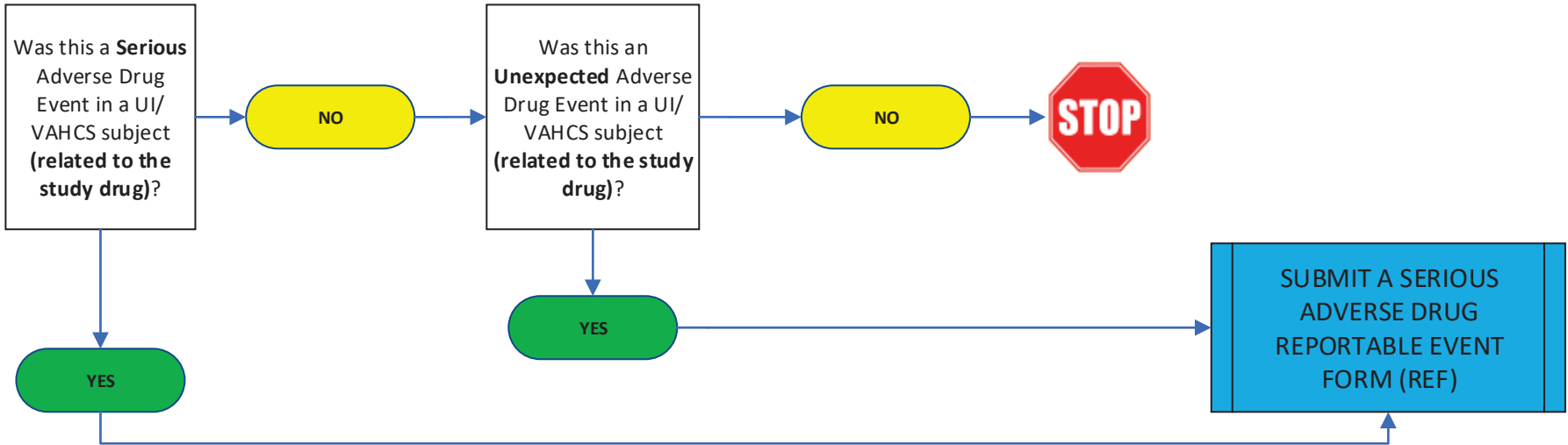


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**SERIOUS ADVERSE
DEVICE EFFECT**



**SERIOUS ADVERSE
DRUG EVENT**



** It is considered unexpected if it was not a known risk listed in the IB, protocol/consent or if it occurred more frequently or was more severe than expected.