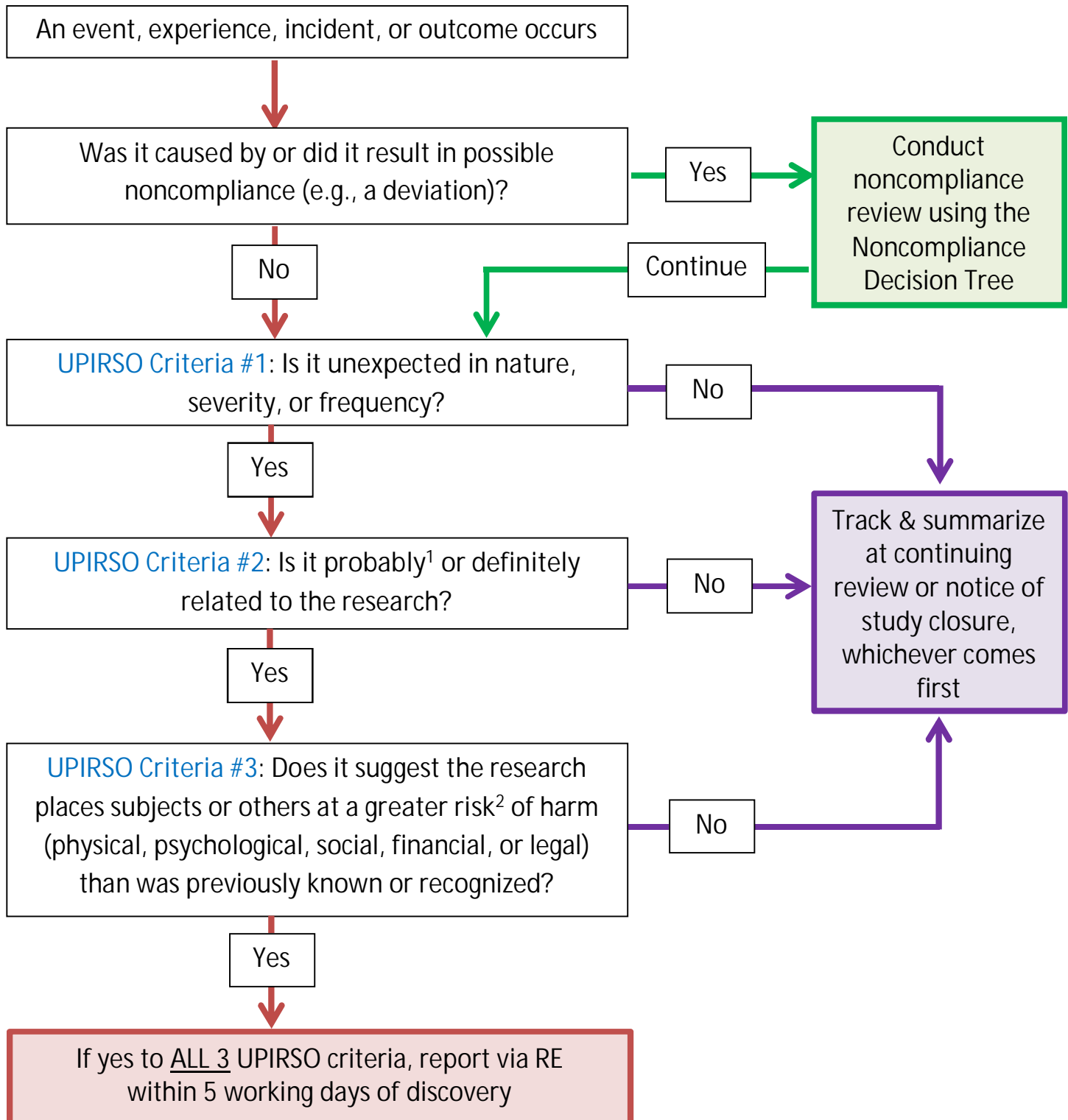


Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) Decision Tree:
What and When to Report to the UTSW HRPP/IRB*



* See [section 9.0 in the HRPP policy and procedure manual](#) and the RE FAQs for more information on UPIRSOs.

¹ Probably means having more evidence for than against; more likely than not; over 50% chance. Possibly means not sure; don't know; less likely; could/might/maybe.

² Is it NEW information that indicates participating in the RESEARCH poses new or increased risks to subjects or others?

NOTE: UPIRSOs require changes to research documents/investigational plans (e.g., protocol, IB, ICF, consent process) or other corrective actions to protect the integrity of the research or the rights, safety, or welfare of subjects or others. Therefore, if no changes are being made as a result of the event, it is probably not a UPIRSO.