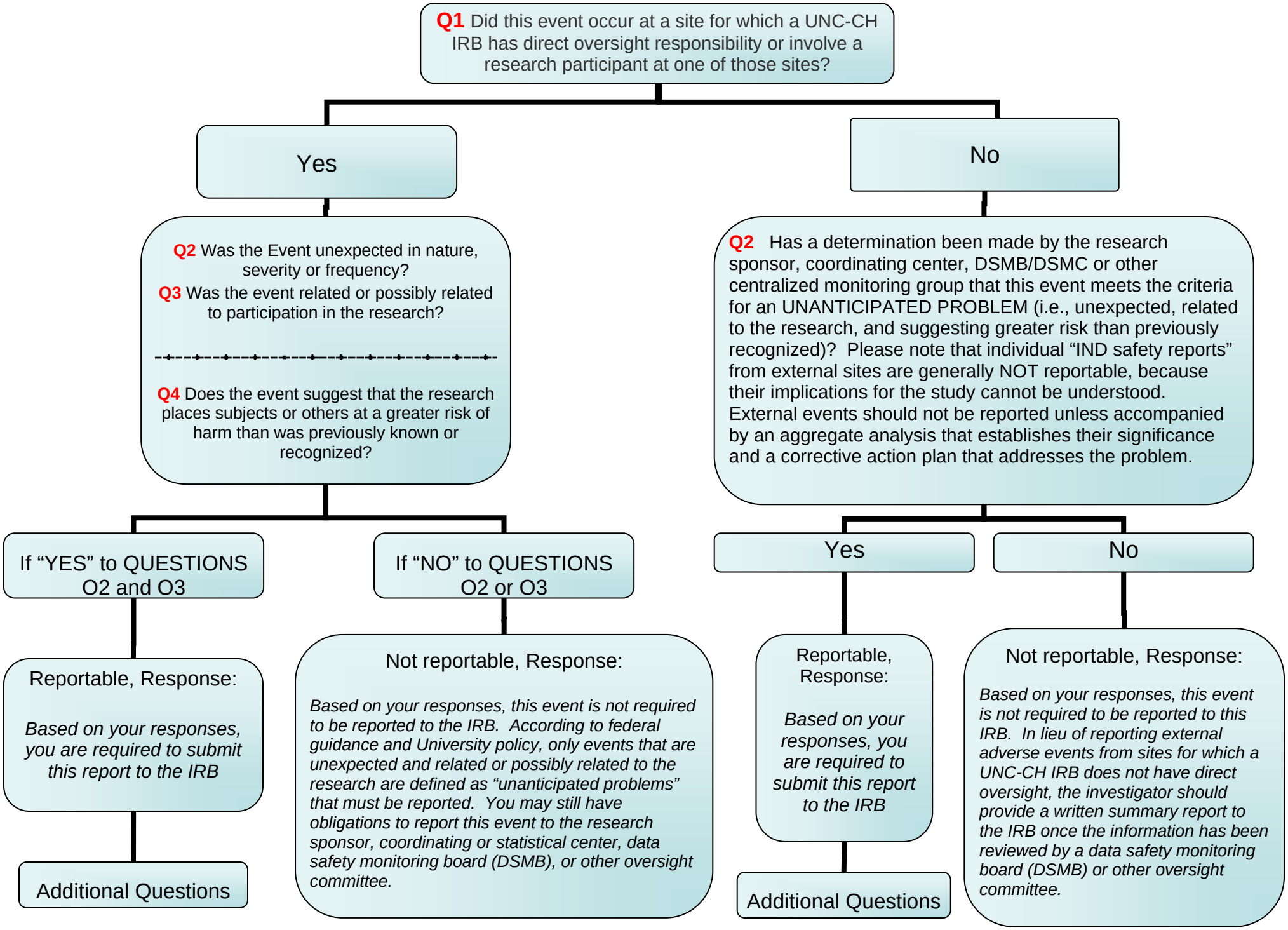
Q1 Did this event occur at a site for which a UNC-CH IRB has direct oversight responsibility or involve a research participant at one of those sites?
Yes
No
Q2 Was the Event unexpected in nature, severity or frequency?
Q3 Was the event related or possibly related to participation in the research?
Q4 Does the event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?
Q2 Has a determination been made by the research sponsor, coordinating center, DSMB/DSMC or other centralized monitoring group that this event meets the criteria for an UNANTICIPATED PROBLEM (i.e., unexpected, related to the research, and suggesting greater risk than previously recognized)? Please note that individual "IND safety reports" from external sites are generally NOT reportable, because their implications for the study cannot be understood. External events should not be reported unless accompanied by an aggregate analysis that establishes their significance and a corrective action plan that addresses the problem.
If "YES" to QUESTIONS O2 and O3
If "NO" to QUESTIONS O2 or O3
Yes
No
Reportable, Response:
Based on your responses, you are required to submit this report to the IRB
Additional Questions
Not reportable, Response:
Based on your responses, this event is not required to be reported to the IRB. According to federal guidance and University policy, only events that are unexpected and related or possibly related to the research are defined as "unanticipated problems" that must be reported. You may still have obligations to report this event to the research sponsor, coordinating or statistical center, data safety monitoring board (DSMB), or other oversight committee.
Reportable, Response:
Based on your responses, you are required to submit this report to the IRB
Additional Questions
Not reportable, Response:
Based on your responses, this event is not required to be reported to this IRB. In lieu of reporting external adverse events from sites for which a UNC-CH IRB does not have direct oversight, the investigator should provide a written summary report to the IRB once the information has been reviewed by a data safety monitoring board (DSMB) or other oversight committee.