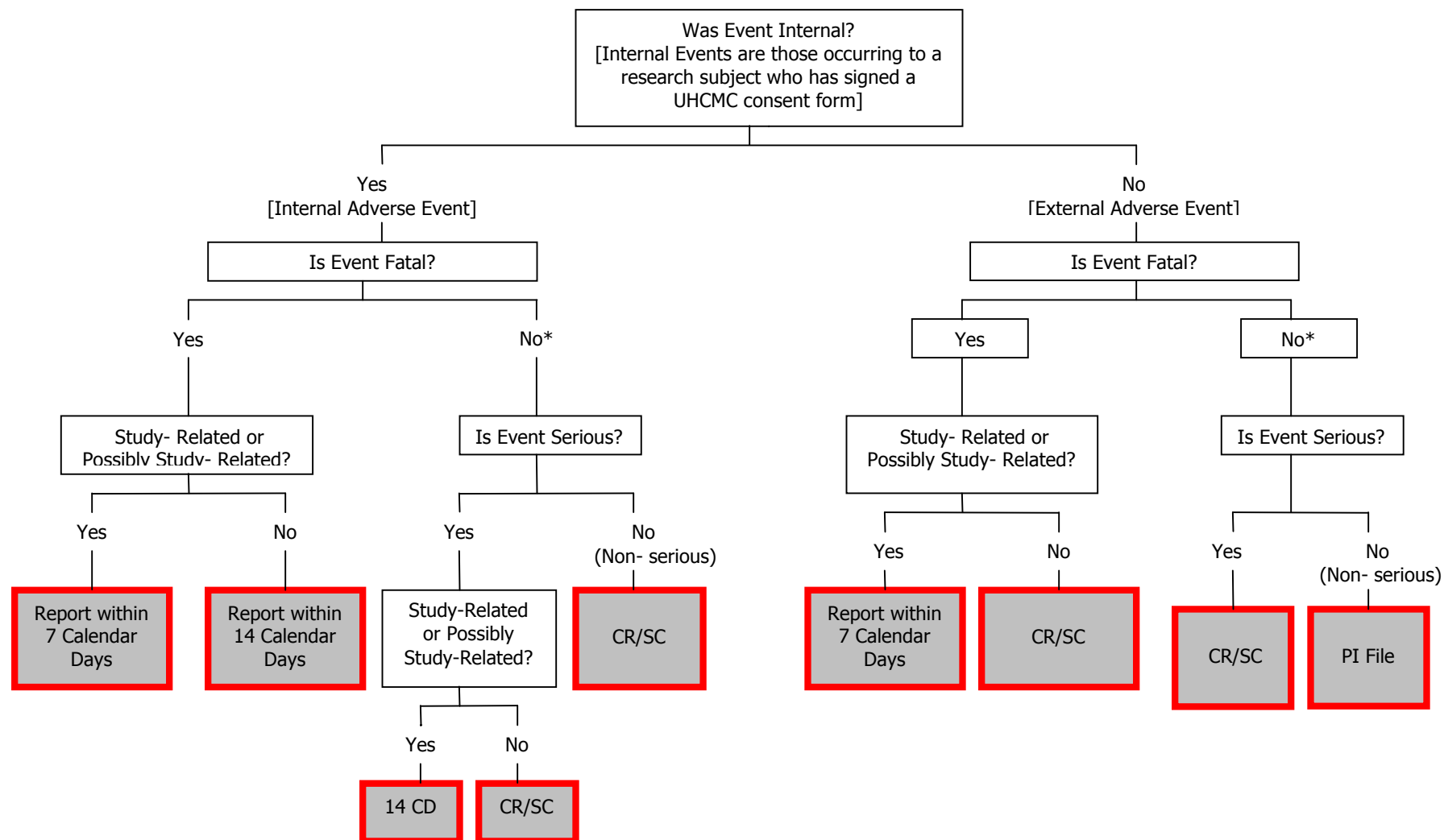


# University Hospitals Case Medical Center IRB Adverse Event Reporting Flowchart for Protocols with Greater than Minimal Risk



**\* Any event that changes the risk/benefit ratio or causes a change in the protocol or consent form must be reported to the UHCMC IRB within 14 calendar days of learning of the event or being notified of a required change.**

**14 CD** = Report within 14 calendar days

**CR/SC** = Report at Continuing Review and Study Closure (which ever is first)

**PI File** = Retain in Investigator File