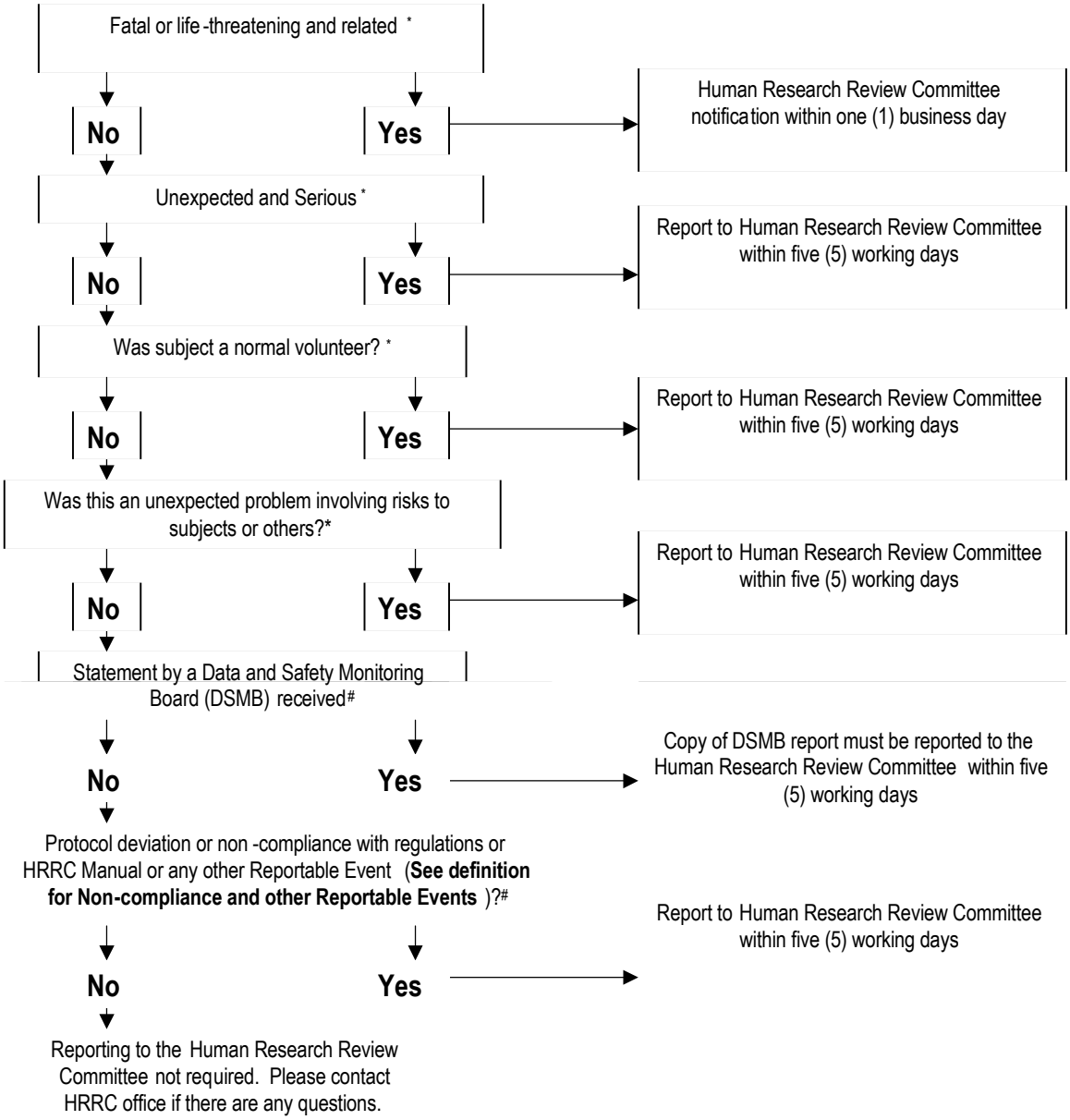
Flowchart for Investigator Reporting Adverse Events or Unexpected Problems



***** Internal adverse events (events that occur onsite or at a site where a UNM/VA Investigator is the coordinator for a multicenter study) must be reported on the Human Research Review Committee (HRRC) Internal Adverse Event Reporting Form. This form must be entirely completed and signed by a study investigator or it will not be reviewed by the HRRC. External adverse events should be submitted attached to an External IND Safety Report Log or a cover memo.

Rather than completing an adverse event form, Data Safety Monitoring Board reports, Noncompliance, and other Reportable Events may be submitted with a cover memo including HRRC #, principal investigator's name, study title, dates, and brief description of issues surrounding event being reported.

Source: University of New Mexico, Health Sciences Center, Human Research Review Committee, Albuquerque.