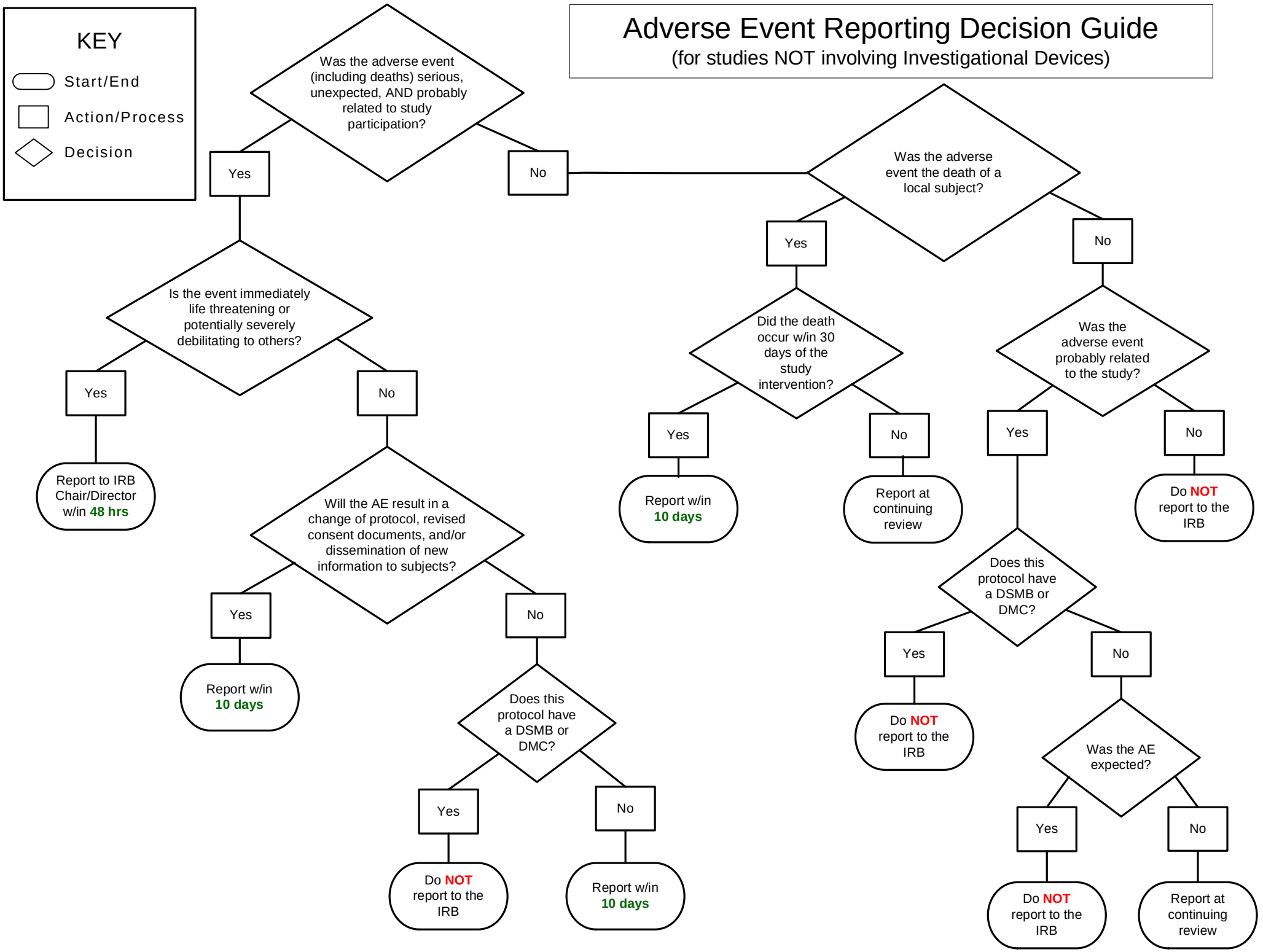
Adverse Event Reporting Decision Guide

(for studies NOT involving Investigational Devices)