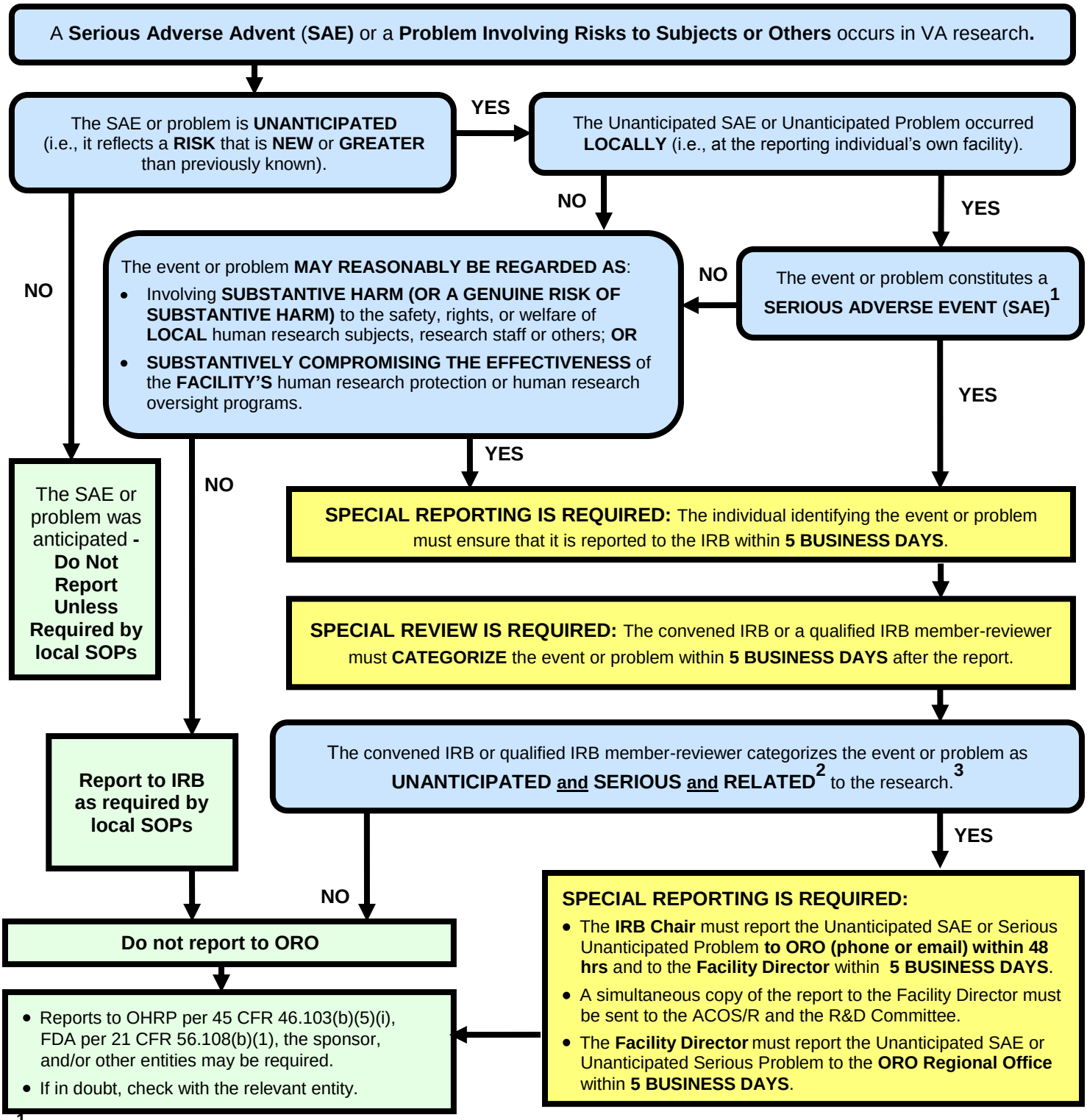
REPORTING SERIOUS ADVERSE EVENTS (SAEs) AND PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS IN VA RESEARCH



1 An SAE is an untoward physical or psychological occurrence in human subject participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome [VHA Handbook 1058.01 §§4b & 4w].

2 "Related" means the event or problem may reasonably be regarded as caused by, or as probably caused by, the research [VHA Handbook 1058.01 §4p].

3 The convened IRB or qualified IRB member-reviewer must also document whether or not action is needed to prevent an immediate hazard to subjects. If consent or protocol modifications are required, the convened IRB must determine whether previously enrolled subjects must be notified, and if so, when and how notification must occur and be documented [VHA Handbook 1058.01 §6d].

[ORO: 12.19.2011]