

IV. Protocol, Review, Approval, and Monitoring

Responsibilities	PI	Unit Admin	Dept. Chair	HSGAO	Dean's Office	VP Research	VP Finance	OSP	OGA	GCA	ORCA	IACUC	IRB	IBC	Research Park	Tech Transfer	Attorney	Auditing	Purchasing	President	Academic Affairs	Health Sciences	Grad School Dean	Gov Relations	Human Resources	RRT	ROC/Grants Admir	Facilities Mgt	Payroll
23. Report unanticipated problems involving risks to subjects or others to the IRB Committee	P																												
24. Evaluate unanticipated problems involving risks to subjects or others relative to severity, relatedness and the extent to which the adverse event was anticipated as defined in the investigator brochure and informed consent documents.	P										O		P				I												
25. Conduct investigations relative to unanticipated problems involving risks to subjects or others to evaluate the extent to which the adverse event should be communicated to stakeholders such as subjects in research sponsors, federal oversight agencies	I										O		P				I												
26. Receive and evaluate reports of serious unanticipated problems involving risks to subjects or others resulting from Committee investigations or PI reports to external oversight agencies											S		P																
27. Communicate unanticipated problems involving risks to subjects or others and results of the investigation to the sponsors and/or federal agencies											O		P																
28. Revise research activity as necessary to respond to serious, unanticipated unanticipated problems involving risks to subjects or others	P		S	S							O		P				I												
29. Suspend or revise research activity as necessary to respond to serious, unanticipated unanticipated problems involving risks to subjects or others			S	S							O		P																

