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 Admin	Facilities Mgt	Payroll
Human Subjects - IRB																													
1. Review sponsor rules and regulations as well as applicable contract terms and conditions relative to University policies and procedures to ensure they will be properly included in protocol submission																													
2. Review federal rules and regulations as well as applicable contract terms and conditions relative to University policies and procedures to ensure they will be properly included in the protocol submission																													
3. Provide proposal forms and protocol application materials and help in completing the forms																													
4. Complete protocol application and submit application to appropriate office																													
5. Confirm protocol application is complete and includes all required information																													
6. Request waiver of HIPAA authorization (if appropriate)																													
7. Approve waiver of HIPAA authorization (if applicable)																													
8. Ensure appropriate research personnel have attended required training courses (including HIPAA)																													
9. Determine status of reviews performed by other compliance committees																													
10. Conduct preliminary review and triage of protocol in preparation for Committee review																													

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11. Ensure all inter-institutional agreements related to USA's federal-wide assurance are complete																													
12. Ensure appropriate composition of Committee membership																													
13. Perform required review (expedited or full-board) and communicate decisions to investigators																													
14. Communicate protocol decision to PI																													
15. Communicate protocol decision to sponsor (if applicable)																													
16. Review and incorporate Committee required modifications into protocol materials																													
17. Evaluate and reconcile other compliance committee recommendations into protocol materials																													
18. Ensure appropriate compliance commitees review protocol revisions prior to incorporation into research proposals or initiation of award activities																													
19. Ensure sponsor terms and conditions are consistent with final protocol terms and materials																													
20. Ensure research activities are performed in accordance with reviewed and approved protocol materials																													
21. Ensure research data involving human subjects is not shared unless this is approved																													

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23. Report unanticipated problems involving risks to subjects or others to the IRB Committee																													
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.																													
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																													
26. Receive and evaluate reports of serious unanticipated problems involving risks to subjects or others resulting form Committee investigations or PI reports to external oversight agencies																													
27. Communicate unanticipated problems involving risks to subjects or others and results of the investigation to the sponsors and/or federal agencies																													
28. Revise research activity as necessary to respond to serious, unanticipated unanticipated problems involving risks to subjects or others																													
29. Suspend or revise research activity as necessary to respond to serious, unanticipated unanticipated problems involving risks to subjects or others																													

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13. Evaluate and reconcile other compliance committee recommendations into protocol materials																													
14. Ensure appropriate compliance committees review protocol revisions prior to incorporation into research proposals or initiation of award activities																													
15. Ensure sponsor terms and conditions are consistent with final protocol terms and materials																													
16. Ensure research activities are performed in accordance with reviewed and approved protocol materials																													
17. Maintain records of training and specific required program documents (e.g. occupational health)																													
18. Obtain additional compliance committee approvals as necessary to accommodate potential changes in protocol activities																													
19. Report protocol violation/adverse event to appropriate stakeholders																													
20. Conduct investigations relative to Protocol Violations/Adverse Events to evaluate the extent to which the violation should be communicated to the stakeholders																													
21. Communicate Protocol Violations/Adverse Events to stakeholders, research sponsors, federal oversight agencies, etc. (major problem)																													
22. Communicate Protocol Violations/Adverse Events to stakeholders, research sponsor, federal oversight agencies, etc. (minor problem)																													

IV. Protocol, Review, Approval, and Monitoring

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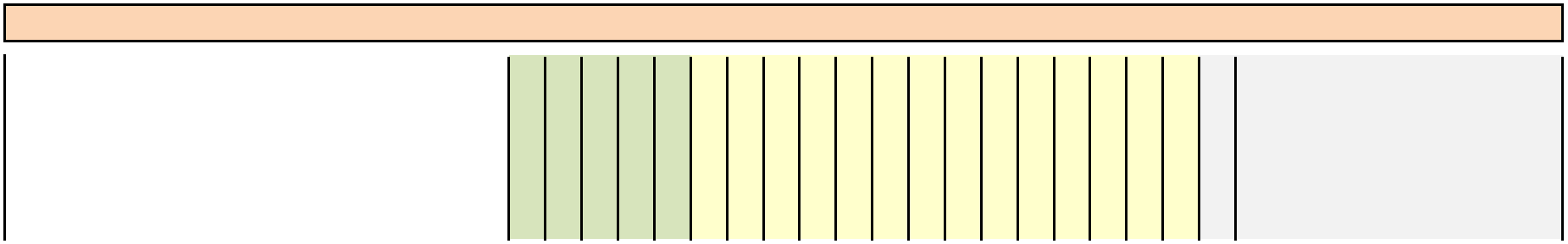
3. Provide required documentation to the appropriate safety committee for review, or perform review in accordance with safety committee policy																													
4. Maintain records of training and specific required program documents																													
5. Complete Incident Reports for committee review and investigation, and possible improvement of existing safety practices and policies																													
6. Collect and review Incident Reports for committee review and investigation, and possible improvement of existing safety practices and policies																													
7. Maintain registration for regulated select agencies and toxins for given labs and develop safety, security, and emergency response plans for the affected group																													
8. Conduct lab surveys to assess compliance and safety and to confirm that conditions reflect the descriptions in ISIS, registrations, and applications																													

Conflicts of Interest - Strategy

1. Define Conflicts of Interest (COI) - Interpret and apply Federal and sponsor regulations to University																													
2. Define COI - apply University interpretations of																													

IV. Protocol, Review, Approval, and Monitoring

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4. Develop COI methodology to help identify, capture, and process COI data, including, for example, COI form development																													
5. Accumulate, report, and communicate to appropriate (non-IT) mgt