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	P										O																		
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	P										O		S																
3. Provide proposal forms and protocol application materials and help in completing the forms											O		P																
4. Complete protocol application and submit application to appropriate office	P																												
5. Confirm protocol application is complete and includes all required information											O		P																
6. Request waiver of HIPAA authorization (if appropriate)	P																												
7. Approve waiver of HIPAA authorization (if applicable)											O		P																
8. Ensure appropriate research personnel have attended required training courses (including HIPAA)	P										O		P																
9. Determine status of reviews performed by other compliance committees											P																		
10. Conduct preliminary review and triage of protocol in preparation for Committee review											O		P																

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

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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 form 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																

IV. Protocol, Review, Approval, and Monitoring

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30. Maintain appropriate, current approvals from all compliance committees during the life of the research activity and appropriate records and documentation	P										O		P																
31. Report to OHRP, FDA and other appropriate oversight organizations significant lapses in compliance procedures that may have exposed research participants to unnecessary risks.											P		I				I												
32. Provide access and information for research participants to withdraw from research protocols	P												O																
33. Prepare and implement responses to external issues raised in investigative reports	I		I		I	I					P		I				I												
34. Notify IRB when protocol activity has ended	P																												
35. Notify PI that a protocol's approval will soon expire and direct investigators to apply for renewal of the approval													P																
36. Prepare reports of protocols nearing approval expirations													P																
37. Prepare reports of expired protocols													P																
38. Communicate protocol's expired status to PI and require PI to stop all protocol activity													P																
39. Communicate expired protocol status to PI													P																
40. Implement action items in the letter from the IRB Board (exp: Suspensions of enrolling new patients for a study)	P																												
41. If applicable, notify Sponsor of expired protocol status	P																												
42. Prepare and submit renewal application for Committee approval	P																												

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Animal Subjects - IACUC																													
1. Review sponsor rules and regulations, applicable award contract terms and conditions, and University policies and procedures to ensure they are properly reflected in protocol materials	P											O																	
2. Provide protocol application materials and help in completing the forms												P																	
3. Complete protocol application materials and submit the application to the IACUC office	P																												
4. Confirm protocol application is complete and includes all required information												P																	
5. Ensure appropriate research personnel have attended required training courses												P																	
6. Conduct preliminary review of protocol in preparation for Committee review												P																	
7. Ensure all inter-institutional agreements related to the University's federal-wide assurance are complete						I					P	I					I												
8. Ensure appropriate composition of the IACUC Committee membership											P	I																	
9. Perform required review (Designated or Full Committee)												P																	
10. Communicate committee decisions to PI (Approved or Request for Clarification/Modification)												P																	
11. Communicate protocol decision to Sponsor (if applicable)	P			I					I																				
12. Review and incorporate Committee required modifications into protocol materials	P																												

IV. Protocol, Review, Approval, and Monitoring

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

IV. Protocol, Review, Approval, and Monitoring

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23. Prepare and implement responses to issues raised in external investigative reports											I	P																	
24. Suspend or revise research activity as necessary to respond to serious protocol violation											I	P																	
25. Report to OLAW, USDA, and AALAC and other appropriate oversight organizations significant lapses in compliance procedures											O	P																	
26. Notify Committee when protocol activity has ended (prior to expiration)	P																												
27. Identify protocols nearing approval expirations												P																	
28. Notify Investigator that a protocol's approval will soon expire and direct Investigator to apply for renewal of the approval or inactivate the protocol												P																	
29. Prepare and submit renewal application for Committee review and approval	P																												
30. Communicate protocol's expired status to PI and require PI to stop all protocol activities.											o	P																	
31. If project suspended, follow action item as detailed in the letter (exp: stop work with animals)	P										O	O																	

Biosafety

1. Provide required documentation for recombinant DNA, exempt select agent, or infectious materials to ORCA.	P																												
2. Administer activities of the University's Institututional Biosafety Committee including development of policies governing use of hazardous materials.											P			P															

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

Conflicts of Interest - Strategy

1. Define Conflicts of Interest (COI) - Interpret and apply Federal and sponsor regulations to University				S		P		S			S					S	I												
2. Define COI - apply University interpretations of Federal/sponsor regulations to individual Schools			P	S	P	O		I			I					I	I												
3. Develop and implement mechanism for reporting, reviewing and responding to COI	S			I		O		S			P					S													

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4. Develop COI methodology to help identify, capture, and process COI data, including, for example, COI form development				I	S	O		S			P					I												
5. Accumulate, report, and communicate to appropriate University leaders overall University COI performance information			S	I	P	O		P			I					I												
6. Develop and recommend COI compliance improvement plan based upon overall University COI performance information				I		O		I			I																	
7. Approve COI compliance improvement plan in step 6						O					I																	
8. Perform and report COI update identifying COIs occurring after initial COI review				S	P				S		S					S												
9. Develop mitigation plan with respect to step 8					P	O		S			S					S												
10. Develop training, education, and communication for Conflicts of Interest	I		I	I	I	O		I	I	I	P					I	I												

Conflicts of Interest - Mechanics

1. Participate in Conflicts of Interest (COI) training and education	P	P	P	P	P	P		P	P	P	O					P											P		
2. Review and understand COI communication materials, such as updates to COI policy and procedures	P		S	S	P	P		S			P																S		
3. Identify potential COI	P	S	S	S	S	S		S			S					S											I		
4. Report potential COI to designated University COI Point Personnel	P	S	S	S	S			S			S					S											I		
5. Review Conflicts of Interest - Significant Financial Relationships		P	P		P	O					S										O	O						
6. Review Conflicts of Interest - Annual Basis		P	P		P						I																		
7. Review Conflicts of Interest - Proposal				P		O		P	P	P	P																		

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8. Review Conflicts of Interest - faculty having a dual appointment		P	P		P						I																		
9. Develop COI management plan resulting from COI review	I	S	S		P	P					P									I	O	O							
10. Oversee mitigation of COI under the COI management plan		S	S		P	O					P						I			I	O	O							
11. Communicate COI to sponsor (if applicable)				I		O			I		P																		