	WORKSHEET: 320 Quality Assurance Program and Audits		
	NUMBER	DATE	PAGE
	HRP-320	30 June 2023	1 of 2

The purpose of this worksheet is to provide support for the HRPP team in the conduct of Quality Assurance Audits. This worksheet should be completed and maintained with the audit file.

1 Details

PI Name	
IRB#	
Initial Approval Date	
Funded/ Funding Source	
Enrollment Cap	
Vulnerable Populations	
Audit Date	

2 Regulatory Documentation	
☐ Yes ☐ No	Regulatory documents organized, completed and available. Comments
☐ Yes ☐ No	Staff training records available Comments
☐ Yes ☐ No	Study training manual for new team members available Comments
☐ Yes ☐ No	All staff approved by IRB prior to initiating work Comments
☐ Yes ☐ No	All amendments tracked and approved prior to implementation Comments
☐ Yes ☐ No	Correspondence with IRB, sponsor, and collaborators on file Comments
3 Study Conduct	
☐ Yes ☐ No	Inclusion/Exclusion criteria met per IRB approved protocol Comments
☐ Yes ☐ No	Screening, study treatment/procedures, performed per IRB approved protocol Comments

☐

	Comments
☐ Yes ☐ No ☐ NA	Compensation is documented and concurs with IRB approval for compensation in the informed consent Comments
☐ Yes ☐ No ☐ NA	All Adverse Events (AE) reported to the sponsor, the IRB, and appropriate regulatory agency within required timeline requirements Comments
☐ Yes ☐ No ☐ NA	Serious Adverse Events (SAE) followed to resolution, return to baseline, completion, or judged acceptable by the and Principal Investigator Comments
☐ Yes ☐ No ☐ NA	All adverse events recorded in participant record Comments
☐ Yes ☐ No ☐ NA	All protocol deviations reported to the sponsor and IRB, and appropriate regulatory agency within required timeline Comments

☐ Yes ☐ No ☐ NA