FAU	**WORKSHEET 320:** Quality Assurance Program and Audits		
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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, complete, 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
☐ **Yes** ☐ **No**	Study administered by IRB authorized personnel only and at approved sites (Look for signatures or notes by personnel not on the list) Comments
☐ **Yes** ☐ **No**	IRB stamped ICD correct current version used and in study file. Comments
☐ **Yes** ☐ **No** ☐ **NA**	ICD signed, dated and witnessed (as applicable). Comments
☐ **Yes** ☐ **No** ☐ **NA**	Parental permission/authorization document signed, dated. Comments
☐ **Yes** ☐ **No** ☐ **NA**	Assent document signed dated. Comments
☐ **Yes** ☐ **No**	Consent obtained prior to study procedures/and or screening as applicable. Comments
☐ **Yes** ☐ **No**	Participant or legally authorized representative provided with a copy of the consent document. Comments
☐ **Yes** ☐ **No**	Participant records/source documents organized, readable and secured. Comments
☐ **Yes** ☐ **No**	Study events and progress notes on the conditions of the participant throughout study. Comments
☐ **Yes** ☐ **No**	Data collected recorded and stored as appropriate. Comments
☐ **Yes** ☐ **No** ☐ **NA**	All copies correspondence with participant is in the study record. Comments
☐ **Yes** ☐ **No** ☐ **NA**	Withdrawal form research participation including reason documented.

	Comments
☐ Yes ☐ No ☐ NA	Compensation is documented and concurs with the IRB approval for compensation in the informed consent document. Comments
☐ Yes ☐ No ☐ NA	All Adverse Events (AE) reported to the IRB, sponsor, 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 IRBs and Principal Investigator. Comments
☐ Yes ☐ No ☐ NA	All adverse events recorded in participant record. Comments
☐ Yes ☐ No ☐ NA	All protocol deviations reported to the IRB, sponsor and appropriate regulatory agency within required timeline. Comments
☐ Yes ☐ No ☐ NA	IRB notified of unanticipated problems involving risk to participants at site. Comments