

HRP-401 | 2/2/2024

CHECKLIST: Pre-Review

The purpose of this checklist is to provide support for IRB Staff conducting Pre-review. This checklist is to be completed by the IRB staff, signed, dated, and retained.¹

Submission Information

Basic	Submission Details			
Information				
IRB Number:	Click or tap here to enter text.			
Study Title:	Click or tap here to enter text.			
Short Title:	Click or tap here to enter text.			
Investigator:	Click or tap here to enter text.			
Person	Click or tap here to enter text.			
Completing				
Checklist (Name):				
Date Checklist	Click or tap here to enter text.			
Completed:				

Regulatory Oversight (Check all that apply)

	Common	Rule	Requ	irements	prior	to .	January	21	, 20 ⁻	19
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 $\hfill\Box$ Common Rule Requirements as of January 21, 2019

¹ This document satisfies AAHRPP elements I.1.A, I.1.E, I.6.A, I.6.B, I.7.A, I.7.C. I-9, II.3.G, II.4.B, III.2.C



□ DHHS	□ ED / ED*							
□ FDA	☐ Tribal Law							
□ OCR	□ EPA							
□ DOD	□ VA*							
□ DOE	□ EU GDPR							
□ NSF	☐ Other Federal Agency							
□ DOJ	□ ICH-GCP							
	□ None							
*The conduct of this research is disallowed by institutional policy per the HRPP Plan.								
Restrictions (Check if applicable)								
☐ Principal Investigator is Restricted								
Missing Materials								
Click or tap here to enter text.								
Special Determinations (Check all that apply)								
☐ Children	☐ Neonates of uncertain viability							
☐ Wards	☐ Individuals with impaired decision-making capacity							
☐ Pregnant women								
□ <u>Prisoners</u>	☐ Waiver/alteration of the consent process							
☐ Students/Employees	☐ Waiver of HIPAA authorization							
☐ Not significant risk device (FDA)	☐ Waiver of consent documentation							
☐ Non-viable neonates	\square Waiver of consent for emergency research							
	☐ Broad Consent							
Protocol Tracking (Check all that apply)								
☐ Social/Behavioral/Education	☐ Collaborative Study (Lead Site)							
☐ Single-Site Study	☐ Collaborative Study (Participating Site)							
☐ Deception	□ Other							
☐ Certificate of Confidentiality	☐ <u>Clinical Trial</u>							
☐ Biomedical/Clinical	□ Multi-Site Study (Lead Site)							
	☐ Multi-Site Study (Participating Site)							



Date of Signature: Click or tap here to enter text.