RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Pre-Review

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3.102 (HRP-401)	11/30/24	1 of 1

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. This worksheet is in the eIRB+ system.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

Regulatory Oversight *(Check all that apply)*

☐	**Common Rule Requirements prior to January 21, 2019**					☐	**Common Rule Requirements as of January 21, 2019**		
☐	DHHS	☐	DOD	☐	DOJ	☐	EPA	☐	Other Federal Agency
☐	FDA	☐	DOE	☐	ED	☐	VA	☐	ICH-GCP
☐	OCR	☐	NSF	☐	Tribal Law	☐	EU GDPR	☐	None

Restrictions (Check if applicable)

☐	Principal investigator is Restricted

Missing Materials

Special Determinations (Check all that apply)

☐	Children	☐	Not significant risk device (FDA)	☐	Waiver/alteration of the consent process
☐	Wards	☐	Non-viable neonates	☐	Waiver of HIPAA authorization
☐	Pregnant women	☐	Neonates of uncertain viability	☐	Waiver of consent documentation
☐	Prisoners	☐	Individuals with impaired decision-making capacity	☐	Waiver of consent for emergency research
☐	Students/Employees			☐	Broad Consent – not being utilized

Protocol Tracking (Check all that apply)

☐	Social/ Behavioral/ Education	☐	Biomedical/Clinical	☐	Clinical Trial
☐	Single-Site Study	☐	Collaborative Study (Lead Site)	☐	Multi-Site Study (Lead Site)
☐	Deception	☐	Collaborative Study (Participating Site)	☐	Multi-Site Study (Participating Site)
☐	Certificate of Confidentiality	☐	FWA required for other sites for federally supported research when RU is the prime awardee	☐	Other

Notes

STUDY CLOSURE

☐	Research can be closed.

Sign		**Date**	