TEXAS A&M UNIVERSITY	**CHECKLIST:** Pre-Review		
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The purpose of this checklist is to provide support for IRB staff conducting Pre-review. This checklist or electronic equivalent is to be completed by the IRB staff and retained.[1]

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
☐	NSF	☐	OCR	☐	OTHER	☐	NONE	☐	Tribal Law

Restrictions (Check if applicable)

☐	Principal investigator is Restricted due to lapsed studies that have not been addressed.

Missing Materials

Special Determinations (Check all that apply)

☐	Children	☐	Not significant risk device (FDA)	☐	Waiver/alteration of the consent process
☐	Wards	☐	~~Non-viable neonates~~ [1]	☐	Waiver of HIPAA authorization
☐	Pregnant women	☐	~~Neonates of uncertain viability~~ [1]	☐	Waiver of consent documentation
☐	Prisoners	☐	Individuals with impaired decision-making capacity	☐	~~Waiver of consent for emergency research~~ [1]
☐	Students/Employees				

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	☐	Other		

Final Contingencies

STUDY CLOSURE

☐	Research can be closed.

[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

[2] Strikethrough means this type of research in not conducted at this institution.

mailto: