WORKSHEET: Regulatory Review		
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This worksheet is used when <Regulatory Reviewers> conduct <Regulatory Review>

Check all items that apply		
1. Regulatory		
1.1	☐ Regulated by:	
1.2	☐ DHS-Department of Homeland Security	☐ HHS-Department of Health and Human Services (via FWA)
	☐ DOD-Department of Defense	☐ HHS-Department of Health and Human Services (via funding
	☐ ED-Department of Education	☐ Other Common Rule Agency
	☐ FDA-Food and Drug Administration	☐ <2018 Requirements>
1.3	☐ Requires compliance with ICH-GCP	
1.4	☐ Additional local, state, or international laws apply.	
2. Determinations		
2.1	☐ Waiver of Consent HHS (HRP-300)	
2.2	☐ Waiver of Consent Emergency Research (HRP-301)	
2.3	☐ Waiver of Consent Leftover Specimens (HRP-302)	
2.4	☐ Waiver of Documentation of Consent (HRP-303)	
2.5	☐ Waiver of Assent (HRP-304)	
2.6	☐ Pregnant Women (HRP-305)	
2.7	☐ Neonates of Uncertain Viability (HRP-306)	
2.8	☐ Nonviable Neonates (HRP-307)	
2.9	☐ Prisoners (HRP-308)	
2.10	☐ Unexpected Incarceration (HRP-309)	
2.11	☐ Children (HRP 310)	
2.12	☐ Wards (HRP-311)	
2.13	☐ Scientific and Scholarly Review (HRP-401)	
2.14	☐ Advertisements (HRP-402)	
2.15	☐ Payments (HRP-403)	
2.16	☐ Short Form (HRP-404)	
2.17	☐ Additional Criteria DOD (HRP-405)	
2.18	☐ Additional Criteria ED (HRP-407)	
2.19	☐ Additional Criteria International (HRP-410)	
2.20	☐ Adults Lacking Capacity (HRP-414)	
3. Drugs		
3.1	☐ Evaluate all drugs whose use is specified by the protocol (See "WORKSHEET: Drugs (HRP-326)" for definition of device)	
3.2	☐ For approved drugs ensure that a package insert is available to IRB members	
3.3	☐ Determine IND status and contingencies (See "WORKSHEET: Drugs (HRP-425)")	
3.4	☐ Procedures to control IND drugs are adequate to prevent use in individuals who are not subjects	
3.5	☐ Procedures are in place to comply with sponsor requirements when an investigator holds the IND	

4. Devices	
4.1	☐ Evaluate all devices being evaluated for safety or effectiveness (See "CHECKLIST: Devices (HRP-326)" for definition of device)
4.2	☐ Ensure that a PMA, 510(k), HDE approval or copy of Class I exemption category for approved devices is available to IRB members
4.3	☐ Determine IDE status and contingencies (See CHECKLIST: Devices (HRP-326)")
4.4	☐ Procedures to control IDE devices are adequate to prevent use in individuals who are not subjects
4.5	☐ Procedures are in place to comply with sponsor requirements when an investigator holds the IDE
5. Check	
5.1	☐ The [Organization's] policy allows the research
5.2	☐ The submission is complete
5.3	☐ Investigators and research staff are up to date on training
5.4	☐ Site agreements are in place
5.5	☐ Investigator agreements are in place
5.6	☐ FWA is present for federally funded research
5.7	☐ An agency-specific assurance or assurance addendum is present when required (e.g., DOD)
5.8	☐ Financial declarations have been made
5.9	☐ A management plan is in place for any positive financial declaration
5.10	☐ The [Organization] has no financial interest in the research
5.11	☐ The description of <Legally Authorized Representative> is consistent with laws of the jurisdiction in which the research is conducted
5.12	☐ The description of <Children> is consistent with laws of the jurisdiction in which the research is conducted
5.13	☐ The description of <Guardians> is consistent with laws of the jurisdiction in which the research is conducted
5.14	☐ HIPAA authorization requirements are not needed or are met (See "WORKSHEET: HIPAA Authorization (HRP-427)")
5.15	☐ HIPAA wavier of authorization requirements are not needed or are met (See "WORKSHEET: HIPAA Waiver of Authorization (HRP-428)")
6. Notes	