



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

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



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