This worksheet is used when Regulatory Reviewers conduct Regulatory Review.

1. Regulatory
   - Regulated by:
     - [ ] DHS - Department of Homeland Security
     - [ ] DOD - Department of Defense
     - [ ] DOE - Department of Energy
     - [ ] DOJ - Department of Justice
     - [ ] ED - Department of Education
     - [ ] EPA - Environmental Protection Agency
     - [ ] FDA - Food and Drug Administration
     - [ ] HHS - Department of Health and Human Services (via support)
     - [ ] HHS - Department of Health and Human Services (via FWA)
     - [ ] VA - Veterans Affairs
     - [ ] Other Common Rule Agency
   - [ ] Requires compliance with ICH-GCP
   - [ ] Additional local, state, or international laws apply.

2. Determinations
   - [ ] Waiver of Consent HHS (HRP-300)
   - [ ] Waiver of Consent Emergency Research (HRP-301)
   - [ ] Waiver of Consent Leftover Specimens (HRP-302)
   - [ ] Waiver of Documentation of Consent (HRP-303)
   - [ ] Waiver of Assent (HRP-304)
   - [ ] Pregnant Woman (HRP-305)
   - [ ] Neonates of Uncertain Viability (HRP-306)
   - [ ] Nonviable Neonates (HRP-307)
   - [ ] Prisoners (HRP-308)
   - [ ] Unexpected Incarceration (HRP-309)
   - [ ] Children (HRP-310)
   - [ ] Ward (HRP-311)
   - [ ] Non-Significant Risk Device (HRP-313)
   - [ ] Scientific and Scholarly Review (HRP-401)
   - [ ] Advertisements (HRP-402)
   - [ ] Payments (HRP-403)
   - [ ] Short Form (HRP-404)
   - [ ] Additional Criteria DOD (HRP-405)
   - [ ] Additional Criteria DOJ (HRP-406)
   - [ ] Additional Criteria ED (HRP-407)
   - [ ] Additional Criteria EPA (HRP-408)
   - [ ] Additional Criteria IDA (HRP-409)
   - [ ] Additional Criteria International (HRP-410)
   - [ ] Adults Lacking Capacity (HRP-414)

3. Drugs
   - [ ] Evaluate all drugs whose use is specified by the protocol (See "WORKSHEET: Drugs (HRP-425)" for definition of drug)
   - [ ] For approved drugs ensure that a package insert is available to IRB members
   - [ ] Determine IND status and contingencies (See "WORKSHEET: Drugs (HRP-425")
   - [ ] Procedures to control IND drugs are adequate to prevent use in individuals who are not subjects
   - [ ] Procedures are in place to comply with sponsor requirements when an investigator holds the IND

4. Devices
   - [ ] Evaluate all devices being evaluated for safety or effectiveness (See "WORKSHEET: Devices (HRP-426)" for definition of device)
   - [ ] Ensure that a FMA, 510(k), HDE approval or copy of Class I exemption category for approved devices is available to IRB members
   - [ ] Determine IDE status and contingencies (See "WORKSHEET: Device (HRP-426")
   - [ ] Procedures to control IDE devices are adequate to prevent use in individuals who are not subjects
   - [ ] Procedures are in place to comply with sponsor requirements when an investigator holds the IDE
## 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 supported research

5.7 An agency-specific assurance or assurance addendum is present when required (e.g., DOD, Department of Navy, Air Force)

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 waiver of authorization requirements are not needed or are met (See "WORKSHEET: HIPAA Waiver of Authorization (HRP-428)"

## Notes