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| **Team Ready Protocol Package Requirements:** **Package must contain all of the following; otherwise, it will not be processed further:** |
| Protocol Short Title: | S# (XX-XX) | IND#  | Date: |
|  |
| **Requirement:** | **Integrated Product Team (IPT)/Working Group (WG) Chair/Lead Confirmation:***(Check all that apply)* | **Regulatory Project Coordinator (RPC)/designee Verification:***(Check all that apply)* |
| - Protocol | Version Number: Version Date:  |  |
| - Informed Consent Form | Version Number: Version Date:  |  |
| - Current Investigational Brochure | Version Number: Version Date:  |  |
| - Correct templates with version number and date |  |  |
| - Food and Drug Administration documentation (e.g., pre-IND/other meeting minutes, if applicable) |  |  |
| - IPT/WG comments/concurrence matrix inclusive of reviews from: |  |  |
| * IPT/WG Chair/Lead
 |  |  |
| * IPT/WG Technical/Clinical Subject Matter Experts (e.g., Principal Investigator, Study Coordinator, Sponsor’s Medical Expert (SME), and/or other SMEs)
 |  |  |
| USAMMDA: |  |  |
| * Regulatory Affairs Scientist
 |  |  |
| * Product Technical Operations (PTO) Scientist
 |  |  |
| * Clinical Monitor/Clinical Trial Manager
 |  |  |
| * Biostatistician
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| * Product Safety Surveillance Branch (Safety Office)
 |  |  |
| * Data Management
 |  |  |
| * Medical Writer
 |  |  |
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| **To Be Completed by the Regulatory Project Coordinator (RPC)/designee –** (*select one*)**:** |
| Date package received by the RPC/designee | Date: |
| [ ] Package sent to the Protocol Review Board | Date:  |
| [ ] Package rejected; IPT/WG Chair/Lead notified by e-mail | Date: |
| RPC/designee signature: | Date:  |