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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 |  | |  |
| * Product Safety Surveillance Branch (Safety Office) |  | |  |
| * Data Management |  | |  |
| * Medical Writer |  | |  |
|  | | | |
| **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: |