## SOP 1a: Transmittal Form for Submitting Regulatory Documents

**PROTOCOL NUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**FROM: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(Provide Name of Submitting PO or CLO)

**TO: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(Provide Name of CLO or DCP Regulatory Contractor)

*FOR CLO USE ONLY when submitting PO documents*

**Date of submission to DCP Regulatory Contractor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

| **Documents Included in Transmission** | **Electronic** | **Hardcopy** | **Comments** |
| --- | --- | --- | --- |
| **Form FDA 1572**Original submitted by each site | [ ]  | [ ]  |  |
| **NCI, DCP Financial Disclosure** **Form**Original for each investigator on Form FDA 1572 | [ ]  | [ ]  |  |
| **Delegation of Tasks Form**One individual form completed for each staff member | [ ]  | [ ]  |  |
| **Curriculum Vitae**For each staff member listed on Form FDA 1572 and Delegation of Tasks form (dated within 2 years of submission date) | [ ]  | [ ]  |  |
| **Human Subjects Protection Training**Certificate/other documentation for each staff member on Form FDA 1572 and Delegation of Tasks form(s) | [ ]  | [ ]  |  |
| **Professional Licensure**Current documentation for each staff member on Form FDA 1572 and Delegation of Tasks form, as applicable | [ ]  | [ ]  |  |
| **Laboratory Certification**Current CLIA and CAP certificate for each clinical laboratory on Form FDA 1572 | [ ]  | [ ]  |  |
| **Laboratory Normal Values**For each clinical laboratory listed on Form FDA 1572 | [ ]  | [ ]  |  |
| **Federalwide Assurance (FWA) Number**For each facility listed in Field #3 on Form FDA 1572 | [ ]  | [ ]  |  |
| **IRB/CIRB Approval–Protocol** | **[ ]**  | **[ ]**  |  |
| **IRB/CIRB Approval–Informed Consent** | [ ]  | [ ]  |  |
| **IRB/CIRB Approval–Continuing Review** | [ ]  | [ ]  |  |
| **IRB/CIRB Approval–Recruitment and/or Participant Materials** | [ ]  | [ ]  |  |
| **IRB/CIRB Approval–Investigator’s Brochure and Safety Reports** | [ ]  | [ ]  |  |
| **Investigator’s Brochure** **Acknowledgment Form** | [ ]  | [ ]  |  |
| **Other** (explain in comments) | [ ]  | [ ]  |  |

**Additional comments:**