## 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:**