Preparation for Scientific Review - Checklist Only

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SOP #: RPS-2	**Next Review Date: 04/2014**
Version #: 1.0	**Review Interval Period: Biennial**
Approved Version #: 1.0 Date: 04/2012	**Policy Reference:**

To provide a checklist to use in the Quality Control process for protocols, protocol appendices, and consents.

Step 1: The Protocol document and any appendices will be reviewed and corrected

- Typographical errors
- Editorial corrections
- Correct formatting (CTEP format, NCI IRB format)
- General readability
- Content (as applicable)
    - Table of Content
    - Face sheet
    - Précis
    - Registration information
    - Phase of study (i.e. Phase 1 dose escalation information with definitions of DLT and MTD)
    - Multi-Institutional guidelines
    - Correct versions of adverse event criteria and response criteria
    - Section for Sample Storage, Tracking and Disposition
    - Statistical Section matches objectives and number of patients
    - Section on Human Subjects Protections
    - NCI IRB AE reporting requirements, expedited and annual, IND Safety Reports
    - IND sponsor, FDA and/or OBA and IBC safety reporting
    - Data and Safety Monitoring Plan
- Consistency
    - Between sections
    - With the references
    - Referencing sections
    - Referencing tables, figures and appendices
    - Page numbers are match document in table of content

Step 2: The protocol consent will be reviewed and corrected

- Typographical errors
- Editorial corrections
- Correct formatting (CTEP format, NCI IRB format)
- Eighth grade readability
- FDA required items (See 21CFR 50.25 Elements of Informed Consent)