

 <p style="text-align: center;"> University of Missouri- Columbia School of Medicine </p>	<p>Subject: Clinical Trial Documentation</p> <p>Function: Clinical Trials</p> <p>Office of Compliance & Quality</p>	<p>Procedure No: <u>C&Q 01</u></p> <p><u>05/01/2008</u> Effective Date</p>
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Clinical Trial core documents must be provided to the Office of Compliance & Quality at the time of IRB approval.

PURPOSE:

The Office of Compliance & Quality is responsible for monitoring clinical trials in order to prevent, detect and correct potential non-compliance. The purpose of this policy is to allow C&Q to identify current clinical trials, conduct an initial coverage analysis, conduct claim reviews, randomly select clinical trials for periodic audit, monitor informed consents through the Research Participant Advocacy program and monitor registration as required by regulation (e.g. www.clinicaltrials.gov)

PROCEDURE:

For each IRB-approved Clinical Trial, the Research Coordinator must:

- Complete the Request for Dictionary Entry (see Attachment A) and forward to the Administrative Associate for Research Billing
- Review the checklist (see Attachment B) and provide the required documents to the Coordinator for Healthcare Compliance by email, by faxing to 884-7327 or by hard-copy to DC021.00.