# AUDIT PREPARATION FOR EXTERNAL AUDITS OF CLINICAL TRIALS

## Tip #1: Organization
- Regulatory Binder—include all IRB submissions, IRB approvals and other IRB feedback, correspondence with sponsor and FDA, protocol and ICF versions
- Research Subject Records—tab all source documents, have available and organized to clearly detail each subject’s experience on the study
- SOPs—have your standard operating procedures available for review

## Tip #2: Self-Review
- If time permits, perform a self/site pre-review
- Clearly document any corrections, with “why” and “how” the correction was made
- Review SOPs for amendments, as necessary
- Review Documentation of study staff training and update as necessary
- Review Delegation of Authority Log and update as necessary

## Tip #3: Day of Audit (audit may take several days)
- Secure a quiet room for the audit
- Have all documents for review available and in this room
- Provide a summary of the study to the auditor(s): purpose, date enrollment started, current status, any interruptions, future plans, known areas of concern, action plan
- Assign someone to be available for questions

## Tip #4: Audit Follow Up
- Take notes during the close out visit
- Request summary of audit findings at conclusion of audit—or as soon as available
- If possible, address findings at the time of the close out
- Confirm date response is required and plan for your responses
- At the time of next continuing review, submit your Audit findings and response with your continuing review materials

## Tip #5: Considerations for Every Day
- Amend SOPs as needed to follow corrective action plan
- Manage your study as if an audit is imminent
- When errors are found, address them, correct them, and notify the IRB
- When audit is scheduled, notify IRB (and sponsor, if applicable) and CRSC

## Tip #6: For more information, go to:
[http://www.ucdenver.edu/academics/research/AboutUs/regcomp/education/Pages/Courses.aspx](http://www.ucdenver.edu/academics/research/AboutUs/regcomp/education/Pages/Courses.aspx)
or call the Clinical Research Support Center at 303-724-1111