## BEST PRACTICES for the CLINICAL RESEARCH SITE

### Tip #1: Assure the following
- Maintain copies of all IRB approvals required for protocols (all versions), informed consent documents (all versions), reports of Unanticipated Problems, and copies of anything given to the subject
- No research activities may commence prior to IRB approval of study
- Subjects may not participate in any research activities prior to giving informed consent
- The use of white out to make corrections on any research documents is prohibited
- Corrections on study documents, data collections sheets will be made by drawing a line through the error, initialing and dating the error, and entering the correction
- The research team will receive training specific to the protocol

### Tip #2: Training
- Document protocol specific training
- Consider creating and maintaining a Standard Operating Procedure (SOP) specifically for training your research team

### Tip #3: Regulatory Binder
- A regulatory binder is highly recommended.
- Maintain all study related documents: IRB approvals/correspondence; all versions of protocols, consent forms, Investigator’s Brochures; reports of unanticipated problems and other correspondence, in an organized fashion.
- Consider creating and maintaining a Standard Operating Procedure for managing the Regulatory Binder

### Tip #4: Source Documents
- Create a standard operating procedure for the consent process, including documentation of the consent process
- Maintain individual study subject binders for each study.
- Save and secure all documents related to the study in accordance with local and federal regulations and requirements

### Tip #5: Unanticipated Problems (UAPs)
- Adverse events and unanticipated problems must be reported to the IRB in accordance with regulations and policies
- Must report to: IRB (COMIRB in 5 days); Sponsor (per sponsor protocol); and FDA (15 days)

### Tip #6: Amendments to the Protocol
- Do not make any changes without IRB approval, except when a change to the protocol is necessary to protect a subject from immediate hazard.

### Tip #7: Continuing Review
- Assure timely submission of continuing review materials (at least 45 days prior to expiration date). This means your study is not likely to lapse during the review process.
For more information, go to http://www.ucdenver.edu/academics/research/AboutUs/regcomp/education/Pages/Tool%20Kit.aspx or call the Clinical Research Support Center at 720-724-1111. Email: clinicalresearchsupportcenter@ucdenver.edu