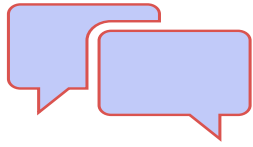# GOOD DOCUMENTATION PRACTICE

Tips to help you ensure integrity of the data!

KEY ATTRIBUTES FOR GOOD DOCUMENTATION PRACTICE

- ☐ **Attributable:** Should be clear who has documented the data
- ☐ **Legible:** information is readable, permanent and not obscured
- ☐ **Contemporaneous:** Information is documented in a timely manner
- ☐ **Original:** The source information is accessible and preserved in the original form
- ☐ **Accurate:** Accurate, consistent and real representation of facts

EXAMPLES OF SOURCE DOCUMENTS

- ☐ Informed Consent Forms
- ☐ HIPAA Authorization Forms
- ☐ Visit/Contact notes
- ☐ E-Mail
- ☐ IRB correspondence
- ☐ Sponsor Correspondence
- ☐ Laboratory results
- ☐ Test results (X-ray, MRI, etc
- ☐ Medical Records supplied by subject
- ☐ Medical Records created throughout study
- ☐ Questionnaires
- ☐ Surveys
- ☐ Case Report Forms – only if data is entered directly.

ABOUT DOCUMENTATION CORRECTIONS

- ☐ Do not obliterate previous data
- ☐ Date the change
- ☐ Identify the person making the change
- ☐ State reason for change
- ☐ Do not use white out
- ☐ Correct mistake with a single line through error
- ☐ Make correction next to error or use footer notes if not enough space
- ☐ Write an explanation for the error
- ☐ Sign and date correction

SIGNING AND DATING

- ☐ Sign / Initial / Date entries at time they are made
- ☐ Never sign anyone else's name
- ☐ Do not pre / post date

REASONS FOR CORRECTIONS

- ☐ Recording error
- ☐ Late entry
- ☐ Spelling error
- ☐ Technical error
- ☐ Wrong date
- ☐ Dosing error
- ☐ Not legible
- ☐ Transcription error
- ☐ Clarity
- ☐ Miscalculation
- ☐ Original entry ok