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

For more information contact the Quality Assurance Dept at 520-621-5196 bpernic@email.arizona.edu