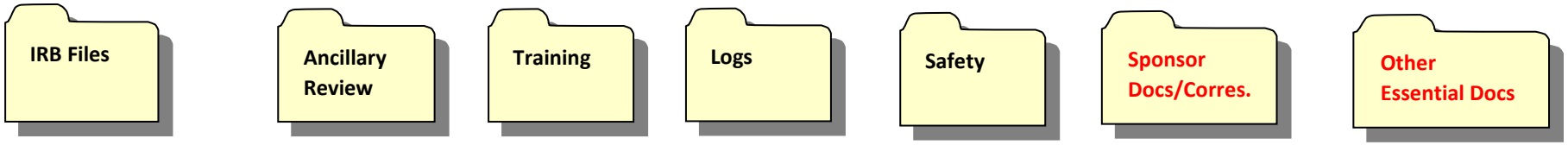
Example of Electronic Regulatory Files



- Current Approved Protocol
- Current Approved ICF
- IRB Submissions and Approvals
  - Initial
  - Mods
    - MOD001
    - MOD002
  - CR
    - CR001
    - CR002
  - Recruiting/Subject Materials
- Gen Corres.
- IRB FWA & Roster

- Scientific Review
- Fiscal Review

- Human Subject Training
- Protocol Specific Training
- Other

- DAL
- Screen-Enrollment
- Reportable and Nonreportable Events

- DSM Reports
- UAPs and Deviations
- Planned Deviations
- SAEs
- Corres.

- Initiation Package
- Signed Amends
- Safety reports
- Signed Investigator Brochures
- Sample Label
- Random and Blinding
- CRFs
- Monitoring

- Financial Disclosures
- CVs
- MLs
- Lab Certs Ranges
- Drug Account.
- Agreements
- Form FDA 1572

- All Human Subject Studies
- Additional documentation if FDA/GCP