**All studies, regardless of funding source**

|  |  |
| --- | --- |
|  | Complete the **Delegation of authority log** (ICH GCP E6 4.1.5)  *Tips:*   * Add end dates for all study personnel and have PI initial/date * Have PI sign closeout line (if applicable) * Complete pagination on all pages (Page \_\_ of \_\_) * Delete any unused/blank lines with single strikeout, initials, and date |
|  | Complete **Training logs** (ICH GCP E6 4.2.4)  *Tips:*   * Have PI sign closeout line (if applicable) * Complete pagination on all pages (Page \_\_ of \_\_) * Delete any unused/blank lines with single strikeout, initials, and date |
|  | Ensure all **Principal Investigator credentials** are filed: |
|  | * CV, signed and dated by PI every two years (ICH GCP E6 4.1.1) |
|  | * License, if applicable (every year should be filed) (ICH GCP E6 4.1.1) |
|  | * Current ICH GCP training certificate (ICH GCP 4.1.3)   *Tip:* Request the CITI Completion Report instead of the Completion Certificate so that the courses completed as part of the training are listed |
|  | * Financial Disclosure Form and/or Conflict of Interest Form (21 CFR 54.4)   *Tip:* Sponsored studies may require a new FDF/COI form be signed at the end of the study and/or one year after the site is closed out |
|  | Ensure all **Sub-Investigator credentials** are filed: |
|  | * CV, signed and dated by investigator every two years (ICH GCP E6 4.1.1) |
|  | * License, if applicable (every year should be filed) (ICH GCP E6 4.1.1) |
|  | * Current ICH GCP training certificate (ICH GCP 4.1.3)   *Tip:* Request the CITI Completion Report instead of the Completion Certificate so that the courses completed as part of the training are listed |
|  | * Financial Disclosure Form and/or Conflict of Interest Form (21 CFR 54.4)   *Tip:* Sponsored studies may require a new FDF/COI form be signed at the end of the study and/or one year after the site is closed out |
|  | Ensure **Site staff credentials** are filed:  *Tip:* Everyone listed on the delegation of authority log must provide the following: |
|  | * CV, signed and dated by investigator every two years (ICH GCP E6 4.2.3) |
|  | * License, if applicable (ICH GCP E6 4.2.3) |
|  | * Current ICH GCP training certificate (ICH GCP E6 4.2.3)   *Tip:* Request the CITI Completion Report instead of the Completion Certificate so that the courses completed as part of the training are listed |
|  | Ensure there is documentation of **record retention plans** (SOP or NTF), including address of planned storage (either on site or off site) and site contact information (ICH GCP E6 4.9.5) |

**Multisite studies, regardless of funding source**

|  |  |
| --- | --- |
|  | Ensure that all signed versions of the **FDA form 1572** are filed (21 CFR 312) |
|  | Ensure that all signed **protocol signature pages** are filed (ICH GCP E6 4.5.1) |
|  | Ensure that all **Investigator Brochure (IB)** acknowledgments of receipt are filed, if applicable (ICH GCP E6 4.1.2) |
|  | Ensure there is documentation of **record retention plans** (SOP or NTF), including address of off-site storage and a site contact |

**As applicable:**

|  |  |
| --- | --- |
|  | Ensure all **local laboratory documentation** is filed |
|  | * CAP, renews every 2 years (ICH GCP E6 8.2.12) |
|  | * CLIA, renews every 2 years (ICH GCP E6 8.2.12) |
|  | * Reference ranges (ICH GCP E6 8.2.11) |
|  | * Lab Director CV and license (see staff credentials) |
|  | Ensure all **IATA training for personnel handling lab specimens** is filed |
|  | Ensure **Site Visit** Log for monitor visits is complete and filed (ICH GCP 4.9.7) |
|  | Ensure all **DEA licenses for investigators and/or Pharmacy** are filed (ICH GCP E6 4.2.6) |