**All studies, regardless of funding source**

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|  | **Delegation of authority log** (ICH GCP E6 4.1.5)  *Tips:*   * Key personnel should also be listed in Box 6 of the FDA form 1572 * Key personnel should also be listed on the IRB personnel form * Key personnel should also be listed on the Responsible Personnel List (RPL) that is submitted to OSP |
|  | **Training logs** (ICH GCP E6 4.2.4)  Include training log(s) for all new IRB approved iterations of the protocol (amendments) and protocol related documents for which the sponsor requires training (i.e., Investigator’s Brochure, manuals, “Dear Investigator” letters, etc.)  *Tip:* Personnel on the delegation of authority log must complete all required protocol-specific training logs over the life of the study |
|  | Maintain **Principal Investigator credentials** over the life of the study |
|  | * 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 |
|  | Maintain **Sub-Investigator credentials** over the life of the study: |
|  | * 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 |
|  | Maintain **Site Staff credentials** over the life of the study:  *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. |

**Multisite studies, regardless of funding source**

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|  | Update & file all signed versions of the **FDA form 1572** (clinical trials involving investigational drugs only) (21 CFR 312)  *Tips:*   * Licensed sub-investigators who are added to /removed from the delegation log should be added to/removed from Box 6 of the 1572 * If site locations change, these changes should be made to Box 3 of the 1572 * Be mindful of the form’s expiration date * Sponsors may send out revised 1572s when central locations (i.e., labs) change |
|  | **Protocol signature page** (ICH GCP E6 4.5.1) |
|  | **Investigator Brochure (IB) acknowledgment of receipt**, if applicable (ICH GCP E6 4.1.2) |
|  | **Lead Site/Sponsor Contact List** |
|  | **Local Site Contact List** |

**As applicable**

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|  | **Local laboratory documentation** |
|  | * 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) (ICH GCP E6 8.2.10 and ICH GCP E6 8.2.12) |
|  | **IATA training for personnel handling lab specimens** |
|  | **Site Visit Log for monitor visits** |
|  | **DEA license for investigators and/or Pharmacy** (ICH GCP E6 4.2.6) |

Notes

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