**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 log** (ICH GCP E6 4.2.4)  *Tip:* *Personnel on the delegation of authority log must complete all required protocol-specific training logs over the life of the study* |
|  | **FDA Form 1572** (21 CFR 312.53(c)) *(if applicable)* |
|  | **Principal Investigator credentials**: |
|  | * CV, signed and dated by PI every two years (ICH GCP E6 4.1.1)   *Tip: Main address should match address in box 1 on 1572.* |
|  | * License, if applicable (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:* FDA form 3455 can be used if there is no sponsor template available |
|  | **Sub-Investigator credentials**: |
|  | * CV, signed and dated by investigator every two years (ICH GCP E6 4.1.1)   *Tip: Main address should match address in box 1 on 1572.* |
|  | * License, if applicable (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:* *FDA form 3455 can be used if there is no sponsor template available* |
|  | **Site staff credentials**:  *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 4.1.1) |
|  | * License, if applicable |
|  | * Current ICH GCP training certificate   *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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|  | **FDA form 1572** (clinical trials involving investigational drugs only) (21 CFR 312)  *Tip: Main address on all documents should match address in Box 1 of 1572 (including PI CV – may provide Site Affiliation Note to File)* |
|  | **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**  *Tip: Information posted on UAB LabSource* <https://www.labsource.hs.uab.edu/>  *CoA lab contact* [Kadambari.Naik@childrensal.org](mailto:Kadambari.Naik@childrensal.org) |
|  | * CAP (ICH GCP E6 8.2.12) |
|  | * CLIA (ICH GCP E6 8.2.12) |
|  | * Reference ranges (ICH GCP E6 8.2.11) |
|  | * Lab Director CV and license (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** (ICH GCP 4.9.7) |
|  | **Site Contact List(s)** |
|  | **Third Party Protocol Vendor List** |
|  | **DEA license for investigators and/or Pharmacy** (ICH GCP E6 4.2.6) |

Notes

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