**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  |
|  | * 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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