Children’s Research Institute

Regulatory File Guidelines

Version 1.0, 31 December 2015
Regulatory File Instructions and General Considerations

The Regulatory File Guideline is a tool for Children’s Research Institute and affiliated sites to achieve regulatory compliance when conducting a study under a Sponsor-Investigator initiated Investigational New Drug (IND) application. Organizing a regulatory file to the standards defined in this guideline will allow study staffs to accurately depict and document the conduct of the study when required by federal regulators, monitors, auditors, and sponsors.

Each section will provide study staffs with guidance for required documentation, the regulation or industry guidance that requires the documentation, and a sample or tool (if applicable).

Instructions:

- Files should be organized prior to the start of the trial and should be continually updated and maintained throughout the conduct of the study.
- The Regulatory File is often referred to as a “regulatory binder,” however, it is not required that the file be kept in a binder. It is acceptable to use other methods of storage, such as a hanging file system. Upon request, the Clinical Research Quality Assurance (CRQA) staff will provide you with an organized binder and guidelines.
- Tailor the file to meet the design of your protocol. Not all protocols will require all elements of the guideline.
- If an alternate or electronic storage system is used for any of the required documents, add a Note to File in place of the documentation in the file. A Note to File should describe the alternative filing system and location as well as justify its use.
  - If a study elects to store any documents electronically, ensure that it is saved on a hospital approved share drive and has been properly backed up.
  - A Note to File template is provided in the Miscellaneous Sample Forms section of the guidance.
- When documentation becomes obsolete due to a newer version, do not discard legacy documents. Instead, archive and maintain the obsolete version in the Regulatory File.
- Define which member(s) of the study staff is responsible for maintaining and updating the regulatory file.
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# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>CITI</td>
<td>Collaborative Institute Training Initiative</td>
</tr>
<tr>
<td>CRFs</td>
<td>Case Report Forms</td>
</tr>
<tr>
<td>CV</td>
<td><em>Curriculum vitae</em></td>
</tr>
<tr>
<td>CRQA</td>
<td>Clinical Research Quality Assurance</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
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<tr>
<td>IDS</td>
<td>Investigation Drug Service</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonisation</td>
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<tr>
<td>IND</td>
<td>Investigational New Drug</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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</tbody>
</table>
Study Identification

**Guidance:**

A study identification section should be included at the beginning of the file and identify basic information about the trial. If any information changes, a new study identification page should be created and should supersede (not replace) previous versions of this section.

**Requirements:**

- Principle Investigator (PI) – Sponsor’s Name
- Study site location and contact information
- Institutional Review Board (IRB) number
- Investigational New Drug (IND) number
- Any other identifying numbers/information
- For multi-center studies, the coordinating center contact information should also be included in this section.
FDA Related Regulatory Documents
Investigational New Drug Submissions

Guidance:

Study staff must provide the entire initial IND submission in the Regulatory File. IND submissions, amendments, annual reports, and communication with the Food and Drug Administration (FDA) are commonly provided stored and documented in a separate binder(s) from the rest of the regulatory documentation. The initial IND submission should be stored at the beginning of the FDA/IND documentation followed by each subsequent amendment, annual report, or communication in chronological order. It is recommended to use the FDA Correspondence Tracking Log to easily document dates of submission and determine future due dates.

If the study is a multi-site study, each site should maintain a copy of its own Form FDA 1572. Each site must provide the main site (coordinating center) with a copy of their Form FDA 1572. The coordinating center must maintain an up-to-date copy of each Form FDA 1572.

Requirements:

- Copy of initial IND application
  - Include the Form FDA 1571 and Form FDA 1572 with the initial submission.
- Copy of amendments to the application
- Copy of all Annual Progress Report submitted to the FDA
- Any communications with the FDA regarding the filing and approval of an IND
  - “Study May Proceed” notification
  - Phone call logs/notes
  - Memos to file documenting conversation topics during phone calls with the FDA

Applicable Regulations:

- 21 CFR 312.2; 312.22, 312.23; 312.41
**Samples/ Tools:**

- FDA Correspondence Tracking Log

- Form FDA 1571 electronic template:
  

- FDA Instructions for completing Form FDA 1571:
  

# FDA CORRESPONDENCE TRACKING LOG

<table>
<thead>
<tr>
<th>1571 #</th>
<th>Item Submitted / Received</th>
<th>Date</th>
<th>Description</th>
<th>Comments</th>
</tr>
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<tr>
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FORM FDA 1572

Guidance:

A Form FDA 1572 must be signed and dated by the PI for each site. Be sure to include all applicable sub-investigators. As the document is updated, store all old versions behind the most current. If an investigator at Children’s Research Institute is the sponsor of a multiple site study, the 1572 Forms for participating sites should be kept in the master file at Children’s National.

If any required information changes, redraft a new form and provide it to the Sponsor-Investigator. A new form must be completed when a change to any of the following categories occurs:

- Principal Investigator
- Sub-Investigator
- Address of Site
- Clinical Laboratory
- IRB

Requirements:

- A copy of the current Form FDA 1572, signed by the PI
  - In file at local site and with sponsor
- All past versions of Form FDA 1572 should be maintained in the file
  - In file at local site and with sponsor

Applicable Regulations:

- 21 CFR 312.53

Samples/ Tools:

- Blank Form:
  
  http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

- Instructions:
  
  http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM223432.pdf

- FDA FAQ:
  
FORM FDA 3674

Requirements:

- The Form FDA 3674 should be contained in the Regulatory File as a part of the initial IND application. If the study is using multiple centers, the additional study sites are not required to provide documentation of the Form FDA 3674.

Applicable Regulations and Policies:

- Food and Drug Administration Amendments Acts (FDAAA) of 2007
- CNMC Policy: RA:HRPP:10:12 Required Registration with ClinicalTrials.gov

Samples/ Tools:

- Blank electronic Form FDA 3674:
- Form FDA 3674 Completion Instructions:
Protocol

**Guidance:**

All versions of the protocol must be stored in the regulatory binder (or alternate storage system documented by a Note to File). It is recommended that the versions are stored in reverse chronological order, with the most current version of the protocol on top. All versions of the protocol should display a version number and version date.

If an Investigator Agreement/signature page is provided in the protocol, it must be signed, dated, and kept in the regulatory file. The principal investigator at each site should sign the Investigator Agreement page in the protocol after IRB approval and prior to the implementation of the protocol. A signed Investigator Agreement/signature page should be maintained for each IRB approved protocol that was utilized at the site.

If a separate binder is kept for Study Product Storage/Accountability in the Investigational Drug Service (IDS) pharmacy, the most current version of the protocol must be provided to the IDS for storage in the pharmacy binder.

**Requirements:**

- All versions of the protocol
- Signed Investigator Agreement (protocol signature page), if applicable

**Applicable Regulations:**

- 21 CFR 312.30
- ICH 8.2.2, 8.3.2

**Samples/Tools:**

- Children’s Research Institute, Sponsor-Investigator Initiated Biomedical Protocol Template

Please contact the CRQA Program to obtain the protocol template.
Investigator Brochure

Guidance:

If the study is a multi-site trial, an Investigator Brochure must be provided by the Sponsor-Investigator to all participating sites.

This section of the regulatory file (or alternate storage system) must include all versions of the Investigator Brochure. It is recommended to file the current version on top and the archived versions in reverse chronological order. An electronic copy of the current version must be provided to the Investigational Drug Service (IDS) Pharmacy to be included with the pharmacy’s documentation.

If the investigational product is already approved or the product is being used off label, a copy of the package insert should be provided in this section of the file.

Requirements:

- All versions of Investigator Brochure
  - Provide a current electronic copy to the IDS for storage in pharmacy files
- Package Insert (if applicable)

Applicable Regulations:

- 21 CFR 312.32, 42, 55, 64
- ICH E6: Section 7
- ICH E6: 8.2.1, 8.3.1

Tools:

- ICH E6: Section 7 provides guidance for the development of an Investigator Brochure.

Institutional Review Board Regulatory Files
Federal Wide Assurance Information

**Guidance:**

Maintain a record of the institute’s Federal Wide Assurance (FWA) Number and expiration of assurance. This information can be obtained on the Office of Human Resource Protection website.

At CNMC, the easiest and most complete way to obtain this information is to contact the IRB. They will provide you with the “Institutional Review Board Letter of Compliance” document clarifying the IRB composition, accreditation, FWA number, and expiration date.

**Requirements:**

- An up-to-date copy of the Institutional Review Board Letter of Compliance
  - All legacy version should be maintained in the regulatory file

**Applicable Regulations:**

- 21 CFR Part 312.66

**Tools:**

- The Office for Human Research Protections FWA Search tool:
  
IRB Approvals

Guidance:

Documentation of all IRB approvals, with no lapse in approval while research is being conducted, is required. It is recommended that approval notifications are stored in chronological order with the initial approval being first.

Requirements:

- All approval notifications from the IRB
- Relevant communication with the IRB
  - Approval notification for Informed Consent Forms
  - Approval notification for any applicable marketing material
- A copy of any annual reports provided to the IRB
- Final report to the IRB

Applicable Regulations:

- 21 CFR 56.109, 110, 111, 115,
- 21 CFR 312.66
- ICH E6 8.2.7, 8.2.8
- FDA Compliance Program Guidance Manual 7348.811 Section E
Informed Consent Forms

**Guidance:**

This section must contain all versions of all consents required by the protocol and approved by the IRB. If a future use consent is required for the study, the consent must be maintained for the lifetime of the sample and 2 years after closure of any additional studies the sample was used in.

**Requirements:**

- Informed Consent Forms
- Assent Forms
- Future Use Consent Forms
- Any IRB approved translations

**Applicable Regulations:**

- 21 CFR Part 50
- ICH E6 3.1.2, 8.3.3

**Samples/Tools:**

- FDA Informed Consent Information Sheet:

  [http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm)
Conflict of Interest Forms

**Guidance:**

Children’s National Medical Center/Children’s Research institute Study-Specific Conflict of Interest Disclosure Form Instructions state

“A Study-Specific Conflict of Interest Disclosure Form must be completed by all Children's National employees who are **Key Personnel**, as identified in the study proposal. **Key Personnel** are members of the study staff who are responsible for the design, conduct, or reporting of the research, regardless of their title or position. This includes the Principal Investigator (PI) and all individuals who conduct the following activities:

- Design or direct the research;
- Serve as co-investigator or study coordinator;
- Enroll research subjects (including obtaining informed consent/parental permission and assent, if applicable);
- Make decisions related to research subjects' eligibility for enrollment in the research;
  - Work as laboratory technicians conducting research;
- Analyze or report research data;
- Submit manuscripts concerning the research for publication as a primary author or co-author.

You must submit an updated disclosure form to both the Grants and Contracts Office and the IRB/OPHS within 30 days of any relevant change in your financial circumstances related to the research. “

**Requirements:**

- A copy of Key Personnel’s signed and dated Conflict of Interest (COI) Form
  - Up to date within 30 days of any relevant change

**Applicable Regulations:**

- COI Study Specific Disclosure Form
  - [http://intranet.childrensnational.org/policies-procedures/Documents/COI Study Specific Disclosure Form.pdf](http://intranet.childrensnational.org/policies-procedures/Documents/COI Study Specific Disclosure Form.pdf)
- 21 CFR Part 54 – Financial Disclosure by Clinical Investigators
- 21 CFR 312.62
- FDA Compliance Program Guidance Manual Program 7348.811, Section H
Protocol Deviations

Guidance:

Subject specific protocol deviations should be stored in the participant files. Non-subject specific protocol deviations should be stored in the protocol deviations section of the regulatory file.

It is required to use the Protocol Deviation Log to track and document protocol deviations for easy review and identification. Include both subject specific and non-subject specific protocol deviations on the Protocol Deviation Log.

Requirements:

- Non-subject specific protocol deviation forms
- Updated Protocol Deviation Log
  - Log includes both non-subject specific and subject specific protocol deviations

Applicable Regulations:

- CNMC IRB Procedure RA:HRPP:05.079 Protocol Deviations
  - http://intranet.childrensnational.org/policies-procedures/Documents/RA_HRPP_05_07P.pdf

Tools/Samples:

- Protocol Deviations Tracker/Log
# Protocol Deviation Log

<table>
<thead>
<tr>
<th>Date Added To Log</th>
<th>Date of Deviation</th>
<th>Subject Specific (Yes/No)</th>
<th>Subject ID Number (If applicable)</th>
<th>Description</th>
<th>Submitted to IRB (Yes/No)</th>
<th>Date Submitted to IRB</th>
</tr>
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Serious Adverse Events (SAEs)

Guidance:

This section must include all copies of the Serious Adverse Event (SAE) report forms. All SAEs must be recorded and reported according to requirements of the approved protocol. The Serious Adverse Event section must also include initial correspondence, follow-up reports, copies of fax confirmation, e-mail print outs, and other related communications to the FDA, IRB, or sponsor.

Adverse events and unanticipated problems should be reported per the requirements in the Children’s National Medical Center Policy: RA:HRPP:06.02: Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events

Requirements:

- SAE Forms
- Any relevant communication with the FDA, IRB, and sponsor
- Adverse Event Tracking Log
  - If an AE report/log is able to be created through an electronic Case Report Form, it is appropriate to place a print out of a log in the regulatory file in place of a handwritten Adverse Event Tracking Log. Be sure to provide an updated paper print out when new adverse events are recorded.

Applicable Regulations and Policies

- CNMC IRB Policy - RA:HRPP:06.02: Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events
- FDA’s Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Report to IRBs Improving Human Subject Protection
- FDA’s Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE/ Studies

Tools/Samples:

- Adverse Event Tracking Log
Has the participant/subject had any adverse events during the study? □ Yes  □ No

Record diagnoses (if known) or signs/symptoms the participant/subject experienced during the study that qualify as adverse events.

<table>
<thead>
<tr>
<th>Adverse Event (Medical terminology)</th>
<th>Serious Adverse Event</th>
<th>Start Date</th>
<th>End Date - OR - Continuing</th>
<th>Severity</th>
<th>Relatedness</th>
<th>Action Taken with Study Intervention</th>
<th>Action Taken with Investigational Product</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No</td>
<td>□ Yes *</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>□ Continuing</td>
<td>□ Mild □ Moderate □ Severe □ Life-threatening/Disabling □ Death</td>
<td>□ Unrelated □ Unlikely □ Probable □ Possible □ Definite</td>
<td>□ None □ Study Intervention Interrupted □ Study Intervention Discontinued □ Study Intervention Modified</td>
<td>□ None □ IP temporarily interrupted □ IP permanently stopped □ IP modified</td>
</tr>
<tr>
<td>□ No</td>
<td>□ Yes *</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>□ Continuing</td>
<td>□ Mild □ Moderate □ Severe □ Life-threatening/Disabling □ Death</td>
<td>□ Unrelated □ Unlikely □ Probable □ Possible □ Definite</td>
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</tr>
<tr>
<td>□ No</td>
<td>□ Yes *</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>/___/20 (mm/dd/yyyy)</td>
<td>□ Continuing</td>
<td>□ Mild □ Moderate □ Severe □ Life-threatening/Disabling □ Death</td>
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<td>□ None □ IP temporarily interrupted □ IP permanently stopped □ IP modified</td>
</tr>
</tbody>
</table>

CRI- CRQA Program Regulatory File Guidelines, Version 1.0, 13 April 2015,
Good Clinical Practice Regulatory Files
Study Personnel Signature Log/Responsibility List

Guidance:

The study personnel signature log/responsibility list must contain the signatures of all study staff including the PI, sub-PIs, study pharmacists, laboratory personnel, data entry personnel, and anyone making entries or corrections to Case Report Forms (CRFs). The list must be kept current at all times.

Start and end dates refer to the period that each member was an active member of the study not their dates of employment at the institution.

Use the Key Delegated Study Task Codes section in the bottom right of the template to list common and important study tasks. Provide the appropriate numbers from the Task Codes section in the “Study Tasks” column to define study personnel’s role.

Requirements:

- Current Study Personnel Signature/Responsibility List with the following elements:
  - Name
  - Title
  - Signature
  - Initials
  - Responsibilities
  - Phone Number
  - Email
  - Start and End Date

Applicable Regulations and Policies:

- ICH E6 4.3.1
- FDA’s Guidance for Industry, Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects
- FDA’s Guidance for IRBs, Clinical Investigators, and Sponsors
- IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.
- CNMC Policy RA:HRPP:10.13 Principal Investigator Oversight
### Study Staff Signature Log/ Responsibility List

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
<th>Signature</th>
<th>Study Tasks</th>
<th>Start Date/ End Date</th>
<th>Initials</th>
<th>Phone Number and Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI:</td>
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All personnel involved with the conduct of the study must be listed on this form and provide signatures and initials. Fill in the box to the right with names/ descriptions of tasks to be carried out by study staff. Assign the numbers to the appropriate individuals in the Study Tasks Column of the List. All members of the study listed on the FDA Form 1572 must be listed on this form. Update personnel, roles, and dates as necessary.

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<th>Key Delegated Study Task Codes</th>
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Curriculum vitae and Licensure

**Guidance:**

At a minimum, the *Curriculum vitae* (CV) and licensure section must include the CVs and medical licenses of the PI and each sub-investigator listed on the 1572. However, it is recommended that a CV and appropriate licensure be provided for each member of the study staff. CVs should be signed and dated by the study staff member. Documentation of Medical License must show current expiration date.

Please provide a Note to File if an alternate storage system is utilized.

**Requirements:**

- PI and Sub-Investigators *Curriculum vitae*
- PI and Sub-Investigators Medical License

**Applicable Regulations:**

- ICH E6 4.1.1
- ICH E6 8.2
- 21 CFR 312.53(c)vii
Training

Guidance:

It is required that trainings are documented for study staff. If an alternate filing system is used to document training outside of the Regulatory File please document with a Note to File in the Regulatory File. Document group trainings with the sample Group Training Form or Individual Training Form. Protocol Specific training is required.

Requirements:

- CITI Training
  - Good Clinical Practice
  - Biomedical
- Protocol Specific Training
  - For Protocol Specific training, the investigator must ensure that there is adequate training for all members of the study staff, not just co-investigators. This training must be documented on a signature log for each of the study staff members. For more details, please refer to the link for the FDA Guidance, Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects provided in the regulations section.
- IATA Training (for study staff members shipping biological specimens)

Applicable Regulations:

- 21 CFR 312.53 (g)
- ICH E6 2.8, 4.1, 5.18.3
- FDA Bioresearch Food and Drug Administration, Compliance Program Guidance Manual, Program 7348.811 Section I, Procedures
- The FDA’s Guidance for Industry, Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects

Samples/ Tools:

- Children’s Research Institute – Group Training Form
- Children’s Research Institute – Individual Training Form
Children’s Research Institute
Group Training Form

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Trainer (Printed): ________________________________

Signature: ________________________________

Date: ________________________________

CRI- CRQA Program Regulatory File Guidelines, Version 1.0, 13 April 2015,
# Children’s Research Institute
## Individual Training Form

Name: 

IRB #: Study Title: 

<table>
<thead>
<tr>
<th>Title (Procedures, Protocol, SOP, etc.)</th>
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<th>Initials</th>
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Regulatory Coordinator: ____________________________ Date: ________

CRI- CRQA Program Regulatory File Guidelines, Version 1.0, 13 April 2015,
Case Report Forms (CRFs)

**Guidance:**

This section is used to provide blank case report forms (CRFs) for reference. If blank/example CRFs are maintained electronically, provide a written Note to File in this section detailing location of the CRFs. Be sure to maintain the current version of CRFs.

**Requirements:**

- Blank case report forms
- Blank data collections sheets

**Applicable Regulations:**

- 21 CRF 312.62
- ICH E6 1.52, 8.3.14, 8.3.15
Laboratory Documentation

**Guidance:**

The Regulatory File should contain high level information in regard to laboratories. This section of the file (or alternate filing system, if documented by a Note to File) must include all certifications and accreditations. Washington, DC is not a Clinical Laboratories Improvement Amendment exempt state, therefore, any clinical laboratories must document accreditation.

Each clinical laboratory should have their own system for storing study documentation and information. The required documentation for the laboratory’s folder differs from the study Regulatory File.

**Regulatory File Requirements:**

- Clinical Laboratory Improvement Amendments (CLIA) Accreditation
- College of American Pathologists Accreditation

**Laboratory Binder Requirements:**

- Shipping and Receiving Documentation
- Storage Temperature Logs
- International Air Transportation Association (IATA) Training Certifications
- Laboratory Procedures

**Applicable Regulations:**

- ICH E6 8.2.11,12
- IATA Guidance:

[https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=iata%20shipping%20requirements%20biological%20samples](https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=iata%20shipping%20requirements%20biological%20samples)
Screening Enrollment Log

Guidance:

The Screening/Enrollment Log should not be located in the Regulatory File, but instead, kept in its own file/binder. All subjects that were screened and consented for participation in the study must be included on the log.

If the subject was consented and screened but not enrolled document the reason for not enrolling.

Requirements:

- Screening and Enrollment Log (stored separately from Regulatory File)

Regulations:

- ICH E6 Section 8.3.20 and 8.3.22
- FDA Compliance Program Guidance Manual Program 7348.811, Section G


Sample/Tools:

- Screening/ Enrollment Log Template
## Screening/Enrollment Log

**IRB Number:**

**Protocol Title:**

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Monitoring Documentation

Guidance:

The FDA requires that sponsors conduct monitoring of all clinical sites conducting research under an IND. It is important to note that a monitor is an individual that is independent from the conduct of the study and reports to the sponsor or sponsor-investigator. At Children’s National, the monitoring process is independent of study team quality control activities.

Requirements:

- Any correspondence with the monitor
- Monitoring reports (if required by Sponsor)

Applicable Regulations:

- 21 CFR 312.56
- FDA Compliance Program Guidance Manual Program 7348.811, Section M
- ICH E6 5.18
- ICH E6 6.2.19-20
Required Documents for the Pharmacy Binder

**Guidance:**

FDA documentation requires investigators and sponsors to be responsible for accountability of investigational agents. Documentation of study product accountability is typically kept in the Investigational Drug Service (IDS) pharmacy. The pharmacy binder should be up to date and available to monitors, auditors, and regulators when required.

Although maintenance and upkeep of the required pharmacy files are delegated to IDS staff, it is the Sponsor/Sponsor-Investigator’s responsibility to ensure that the most up to date versions of each document are provided to the IDS in a timely manner.

**Requirements:**

- Copy of the current protocol
- Study product shipping receipts
- Records documenting the receipt date, quantity, and lot numbers
- Records of preparation/dispensing records
- Study product physical inventories
- Cold chain verification/ temperature logs
- A copy of the Investigator Brochure
- List of authorized prescribers

**Regulations:**

- 21 CRF 312.57,59,61,62,69
- ICH E6 5.14.4
- ICH E8 6.12-18
Miscellaneous Sample Forms
Note To File

Principal Investigator:

IRB#:

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<td>Assessment:</td>
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</table>

Name:  

Signature:  Date:

Role in Study:

CRI- CRQA Program Regulatory File Guidelines, Version 1.0, 13 April 2015,