IRB Compliance Handouts
# Self-Assessment Checklist

This document can be used to conduct a self-assessment of your clinical research records. It is for your records and will not be collected by OPRS.

<table>
<thead>
<tr>
<th>1 - INFORMATION ABOUT THE STUDY Regulatory Binder</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Approved protocol and amendments</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.2.2</td>
</tr>
<tr>
<td>Copies of IRB approvals and IRB correspondence</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.2.7</td>
</tr>
<tr>
<td>Documentation of IRB approved revisions</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.3.3</td>
</tr>
<tr>
<td>Documentation of IRB approved periodic review</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.3.3</td>
</tr>
<tr>
<td>Subject recruitment procedure</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.2.3</td>
</tr>
<tr>
<td>IRB approved subject recruitment materials</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.3.2 and 8.3.3</td>
</tr>
<tr>
<td>Copies of IRB Approved informed consent</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 8.2.7 – ICH GCP 8.3.3 – ICH GCP 8.3.12</td>
</tr>
<tr>
<td>Compliance forms</td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.northwestern.edu/research/OPRS/irb/hipaa/forms.html">http://www.northwestern.edu/research/OPRS/irb/hipaa/forms.html</a></td>
</tr>
<tr>
<td>Copies of IRB approved HIPAA Compliance forms</td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.northwestern.edu/research/OPRS/irb/hipaa/">http://www.northwestern.edu/research/OPRS/irb/hipaa/</a></td>
</tr>
<tr>
<td>Each version of Investigator Brochure and/or package insert/product information</td>
<td></td>
<td></td>
<td></td>
<td>ICH GCP 7.1</td>
</tr>
<tr>
<td>Signed FDA 1572 (for IND study)</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR 312.53(c)</td>
</tr>
<tr>
<td>For each investigator</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR 312.22(d)</td>
</tr>
<tr>
<td>Copy of the Original and all revisions</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR 312.23(a)</td>
</tr>
<tr>
<td>Signed FDA 1571 (PI is IND sponsor)</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR54</td>
</tr>
<tr>
<td>Copy of the original and all revisions</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR 312.64(d)</td>
</tr>
<tr>
<td>Copy of the Clinical Investigator Financial Disclosure form on file for each investigator? (for IND study)</td>
<td></td>
<td></td>
<td></td>
<td>21 CFR54</td>
</tr>
</tbody>
</table>


| CVs of PIs and team members | ICH GCP 4.1.1  
|                            | ICH GCP 8.3.5 & 8.2.10 |
| Updated Research Personnel List on file | http://www.northwestern.edu/research/OPRS/irb/forms.html  
| Research staff have completed NU mandatory trainings | ICH GCP 2.8  
| The staff signature log, including delegation of responsibility, is completed | ICH GCP 4.1.5  
| Case report form or data collection page templates | ICH GCP 8.3.24  
| Adverse Event report forms and instructions for sponsor and IRB reporting | 21 CFR 312.32 - 21 CFR 312.64(B)  
|                                                   | 21 CFR 312.66 - ICH GCP 1.50  
|                                                   | ICH GCP 4.11.1  
|                                                   | http://www.northwestern.edu/research/OPRS/irb/handbook/index.html  
|                                                   | http://www.northwestern.edu/research/OPRS/irb/forms.html |
| Copy of normal laboratory values | ICH GCP 8.2.11 and 8.3.6  
| Laboratory certification on file (if not using hospital lab) performing work toward the completion of your study | ICH 8.2.12 and 8.3.7  
| IND Safety reports |  
| Subject identification log is completed | ICH GCP 8.3.21  
| Subject enrollment log is completed | ICH GCP 8.3.22  
| Study Drug dispensing log is completed | ICH GCP 8.3.23 |

2 - INFORMATION ABOUT THE SUBJECT

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent Form</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| The appropriate consent form is used and signed prior enrollment of the subject |     |    |     | 21 CFR 50.27(a)  
|                                                                      |     |    |     | ICH GCP 4.8.8 – 8.3-12 |
| Subjects receive a copy of the signed consent form  
| This receipt is documented |     |    |     | 21 CFR 50.27 (a)  
|                                                                      |     |    |     | ICH GCP 4.8.11 |

2
<table>
<thead>
<tr>
<th><strong>HIPAA Compliance</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The Appropriate HIPAA Authorization is signed by the subject</td>
<td></td>
<td><a href="http://www.northwestern.edu/research/OPRS/irb/hipaa/">http://www.northwestern.edu/research/OPRS/irb/hipaa/</a></td>
</tr>
<tr>
<td>The subject receives a copy of the signed HIPAA authorization</td>
<td></td>
<td><a href="http://www.northwestern.edu/research/OPRS/irb/hipaa/">http://www.northwestern.edu/research/OPRS/irb/hipaa/</a></td>
</tr>
<tr>
<td><strong>Eligibility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There is a list of Inclusion/Exclusion criteria completed for the subject</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The list includes signature initials of the person obtaining the information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The subject is eligible according to the protocol</td>
<td></td>
<td>ICH GCP 8.3.14</td>
</tr>
<tr>
<td><strong>Study Treatment/Outcome Response</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study visits were scheduled in accordance with the study protocol</td>
<td></td>
<td>ICH GCP 4.5.1</td>
</tr>
</tbody>
</table>
| Study treatment was prescribed by the authorized investigator according to the protocol |  | ICH GCP 2.7  
ICH GCP 4.6.5 |
| Study treatment monitoring and follow-up procedures were performed according to the protocol |  |  |
| Study treatment was accurately reported on the case report forms when compared to the source document |  | ICH GCP 8.3.14 |
| The subject completed the study and was evaluable for response |  |  |
| Adverse Events were properly reported to the sponsor IRB |  |  |
| **Drug Accountability** |  |  |
| The subject’s treatment doses are accurately reported on the Dispensing Log |  | 21 CFR 312.62 (a)  
ICH GCP 4.6.3  
ICH GCP 4.6.3 |
Regulatory Binder - Sample Table of Contents*

*Depending on the type of study, some of the items listed may not be needed. This serves as a general guide only.

Subject Logs and Lists
- Screening Log
- Enrollment Log
- Drug Dispensing Log (sometimes kept in the pharmacy)

Patient Data
- Subject Informed Consent Forms (All Versions)
- Documentation of Consent Process (See template)
- Source Documents (as applicable), for example: Pain scales, Participant diaries/calendars, Inpatient and outpatient medical records, Pathology reports Radiology reports, Medicine/radiation administration records, Surgical reports, Laboratory reports, Admission forms, Flow sheets

Contact Logs and Monitoring
- Contact Information of Sponsor, and/or CRO Personnel as applicable
- Pre-Site Visit/Site Initiation
- Monitoring Visit Log
- Monitoring Reports
- Telephone Contact Log
- Monitoring Plans
- Study Closeout Information/Findings

Protocol and Amendments
- Protocol
- Amendments
- Signature Pages (as applicable)
- IRB Approval Letter and/or Correspondence

Case Report Forms
- Blank Samples of All CRFs
- CRF Completion Guidelines

Investigator Information
- FDA Forms 1571, 1572 or Declaration of the Investigator
- Curriculum Vitae (current CV)
- Medical Licenses/Certifications
- Financial Disclosure Statements (or FDA Forms 3454, 3455)
- Signature on Delegation of Authority Logs
- Training Certifications
- Other Training Records

Sub-Investigator, Study Team Information
- Curriculum Vitae (current CV)
- Medical Licenses/Certifications
- Financial Disclosure Statements (FDA Form 3455)
- Signature on Delegation of Authority Logs
- CITI Training Certifications; Other Training Records
IRB Documents
• Applications
• Approvals
• Member Roster/Assurances
• Communications
• All Approved Informed Consent/Assent Form Versions Including Translations
• Advertisements for Subject Recruitment
• Other Subject Information

Adverse Events including AE report forms and instructions for sponsor and IRB reporting

Notes to File
• All documents generated to clarify deviations or occurrences. (These can address general study-related items or subject-specific issues. Subject-specific notes can be maintained in the individual research file, but copies should be present.)

Laboratory Information
• Certifications (CAP, CLIA or CLIA waiver, if applicable)
• CV licenses, certifications of Lab Director
• Lists of Relevant Reference Ranges/Lab Normals (Normal Lab Values)
• Shipment and Storage Records for Biological Samples

Investigational Product (Drug/Device) Accountability Records (If applicable)
• All versions of IB on file
• Package insert/product information on file for each investigational product

Study Reports
• Interim and/or Final Study Reports
• Any Audit (FDA, Sponsor, 3rd Party)

Contracts and Grants (Most financial information should not be in the reg binder but some items cross-over)
• Clinical Trial (CTA) or Study Agreements
• Confidentiality Agreements (CDA)
**Personal Roles & Responsibilities Form**

**Site Specific Study**

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### Notes for Completing This Form

- A: P.I. Initials
- B: P.I. from ID M.D.
- C: Study Coordinator
- D: PI Investigator
- E: Co-Investigator
- F: Other
- G: Study Name (in red)

### Designation of Responsibilities (Circle Those That Apply)

- P. Essential documents
- E. Phlebotomy
- D. Physical examination
- C. Dispensing medication
- B. CPR certified
- A. Ongoing consent

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**Date**

**Investigator's Name**

---

**Investigator's Signature**

---

**I certify that I have reviewed and agreed to the study responsibilities as defined and accepted by the site personnel.**
### Ineligibility Code Key

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>No</td>
</tr>
<tr>
<td>Y</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Note:** Volunteers should not be considered screened unless they have completed the informed consent process.

<table>
<thead>
<tr>
<th>Initials</th>
<th>Date of Enrollment</th>
<th>Eligible?</th>
<th>Signed Consent?</th>
<th>Participant ID</th>
<th>Location and Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**DOCUMENTATION OF CONSENT PROCESS**

Subject Name/ID #: ______________________________________________________

Person obtaining consent initial each completed step in the process:

___ Informed consent was discussed with subject for the above referenced study. Copy of the consent form was provided for subject and/or authorized subject representative review.

___ Subject and/or authorized subject representative was given adequate time to read the consent form and discuss the study with study investigators and/or family members.

___ All questions were answered. Subject and/or authorized subject representative was given time to discuss.

___ Subject and/or authorized subject representative signed and dated the informed consent.

___ A copy of the consent form was provided to the subject and/or authorized subject representative upon conclusion of the consent process.

___ During informed consent process, the following questions were asked by the subject and/or authorized representative and were answered by study personnel:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

___ Consent has been signed prior to any study procedures being performed.

Consent process documented by: ______________________________________________

Print Name

Signature  Date

Version 9/1/2011
Consent Process Checklist

1. Is informed consent obtained from each subject prior to the start of any study procedures? (including screening procedures to determine eligibility)

2. Is the IRB approved consent form (approval stamp on the last page or approval date in footer (eIRB)) used to consent each subject?

3. Is the original dated and signed consent form on file for each subject?

4. Did all consented subjects receive a copy of their signed and dated consent form?

5. Do you document your files to indicate each subject received a copy of their signed and dated consent form?

6. Was a copy of each subject’s signed consent form placed in subject’s medical record? (if appropriate)

7. Where do you keep signed consent forms for this study?

8. How do you assure you are using the IRB currently approved consent form?

9. Who presents the consent form to the individuals?

10. How do you know you are using the IRB currently approved form?