This document has been created by the LSUHSC-NO IRB and CTO as guidance to help investigators and research staff throughout the process of a Food and Drug Administration (FDA) inspection. This tool could also be used by the research team for investigator-initiated studies to conduct their own quality assurance reviews.

This tool is to be used as guidance. Some of the items included on this worksheet may not be applicable to all studies. Refer to the [Appendix](#Appendix) for details of which regulations, policies or guidance may be referenced for further clarification.

|  |  |
| --- | --- |
| **PROTOCOL INFORMATION** | |
| **PI Name**:Click or tap here to enter text. | **Site Number**: Click or tap here to enter text. |
| **Protocol**: Click or tap here to enter text. | |

|  |
| --- |
| **SUBJECT RECORD REVIEW** |
| **Subject ID Number**: Click or tap here to enter text. |

| **INFORMED CONSENT** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Are the signed, original consent(s)/assent(s) documents present in the study records? |  |  |  |  | Click or tap here to enter text. |
| 1. Are the signed, original HIPAA documents present in the study records? |  |  |  |  | Click or tap here to enter text. |
| 1. Has the subject signed and dated the correct version(s) of the informed consent/assent document(s)? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Determine if the signed consent(s)/assent(s) the appropriate version based on the most recently IRB approved document when informed consent/assent was obtained.* | | | | | |
| 1. Has the legally authorized representative and/or impartial witness signed and dated the correct version(s) of the consent/assent form document(s) as applicable? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all consents complete (full signatures and dates by both parties, all checkboxes include responses, are pages initialed if necessary)? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If the consent form documents are not complete, is there documentation to explain why the dates do not match?* | | | | | |
| 1. Do the signatures and dates for the subject & person obtaining informed consent/HIPAA match? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If the signature dates do not match, is there documentation to explain why the dates do not match?* | | | | | |
| 1. Is the informed consent/assent process, including that the subject was given adequate time to make an informed decision, all of the subject’s questions were answered and the subject was given a copy of the signed informed consent form, documented in the source? |  |  |  |  | Click or tap here to enter text. |
| 1. Did the consent process follow the IRB approved plan, and was the person obtaining consent appropriately delegated this task? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Were there special consent procedures (i.e. for vulnerable populations) IRB approved? If so, were they followed?* | | | | | |
| 1. Has the subject signed the informed consent/assent and HIPAA authorization forms prior to the conduct of study procedures? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If the time informed consent/assent was obtained and/or the time that study procedures were performed were not documented, the informed consent process documentation should include a statement to this effect.* | | | | | |
| 1. Is it documented that the subject was given a copy of the signed HIPAA Authorization Form? |  |  |  |  | Click or tap here to enter text. |
| 1. If re-consent or notification was required, was the process conducted in accordance with the IRB approved plan and documented appropriately? |  |  |  |  | Click or tap here to enter text. |

| **ELIGIBILITY** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Is there appropriate documentation that the subject met the study eligibility criteria (including applicable medical records or source documents to confirm subject’s eligibility)? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Review the subject chart records to confirm that documentation exists in the subject chart to confirm that each of the inclusion criteria was met and each of the exclusion criteria were not met.* | | | | | |
| 1. Was eligibility assessed by an appropriately qualified and delegated individual? |  |  |  |  | Click or tap here to enter text. |
| 1. Were all screening or pre-enrollment activities completed per protocol? |  |  |  |  | Click or tap here to enter text. |

| **STUDY & VISIT PROCEDURES** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Were procedures/assessments completed per protocol? |  |  |  |  | Click or tap here to enter text. |
| 1. If a procedure, or visit, was missed or not completed, was it documented as a deviation with a complete explanation? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Review the subject chart and compare all the procedures performed with those described in the protocol (i.e. text of protocol or protocol calendar/study schematic)* | | | | | |
| 1. Were tests/procedures completed by appropriately qualified and delegated individuals? |  |  |  |  | Click or tap here to enter text. |
| 1. Were all visits completed within the allotted time windows? |  |  |  |  | Click or tap here to enter text. |
| 18a. If not, is this documented as a deviation with a complete explanation? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If the answer to any of the above questions are ‘No’, is there documentation describing the event, how/why it occurred, the immediate measures that were taken (if any) to correct the problem, and how will it be prevented from recurring again in the future?* | | | | | |
| 1. Is the reason for withdrawal or drop-out documented (if applicable)? |  |  |  |  | Click or tap here to enter text. |
| 1. Is there documentation that the subject was provided with study-related compensation (if applicable)? |  |  |  |  | Click or tap here to enter text. |

| **STUDY INTERVENTION** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Was the investigational product administered according to the protocol and under PI supervision (if applicable)? |  |  |  |  | Click or tap here to enter text. |
| 1. Was the correct investigational product regimen followed? (dose, randomization, route of administration, compliance, etc.) |  |  |  |  | Click or tap here to enter text. |
| 1. Is the investigational product being properly documented and accounted for this subject? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Investigational Product refers to both devices and drugs, but each may have different types of accountability records and documentation procedures.* | | | | | |

| **DATA MANAGEMENT** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Did research staff adequately address previous queries/observations? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all CRFs/data collection forms and supporting source documents on file? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all data collection forms (CRFs, source, etc.) complete? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all data collection forms (CRFs, source, etc.) consistent with source data? |  |  |  |  | Click or tap here to enter text. |
| 1. Do all data collection forms and corresponding source documents include documentation of the observer/recorder of the information? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all source documents that were reviewed (including lab reports, ECGs, radiology reports, and all other study related documents) appropriately labeled with subject information (e.g. name, initials, subject ID, MRN [as applicable], etc.)? |  |  |  |  | Click or tap here to enter text. |
| 1. Do CRFs have an appropriate header indicating site information (e.g. PI, site name, site number, etc.) and protocol information (e.g. sponsor, protocol number) as applicable? |  |  |  |  | Click or tap here to enter text. |
| 1. Are all mistakes lined through once (so original entry is legible), dated, and initialed individually? |  |  |  |  | Click or tap here to enter text. |
| 1. Has medical history been appropriately obtained and documented? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If your medical history form allows you to indicate if the condition is currently being treated, confirm the treatment on the concomitant medication log.* | | | | | |
| 1. Is there documentation that the subject’s primary physician was informed of the subject’s participation in the study, if the subject agreed to notify his/her physician? |  |  |  |  | Click or tap here to enter text. |
| 1. Is there appropriate documentation of retained body fluids or tissue samples (if applicable)? |  |  |  |  | Click or tap here to enter text. |
| 1. Are the body fluids or tissue samples being stored and retained according to the IRB approved protocol (if applicable)? |  |  |  |  | Click or tap here to enter text. |
| 1. Is the research chart organized? |  |  |  |  | Click or tap here to enter text. |
| 1. Was data completed in a timely manner (e.g., are CRFs up to date)? |  |  |  |  | Click or tap here to enter text. |
| 1. Is the research data being stored in compliance with the relevant provisions of the IRB approved protocol? |  |  |  |  | Click or tap here to enter text. |
| 1. Are the subject charts/source documents stored in a secure manner consistent with the IRB application? |  |  |  |  | Click or tap here to enter text. |

| **CONCOMITANT MEDICATIONS /TREATMENT** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Are concomitant medications documented appropriately? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Verify that the indication for each concomitant medication is documented in the subject’s medical history.* | | | | | |
| *TIP: Have new medications or treatment been initiated after subject enrollment? If yes, inquire further as these may be an indicator of an adverse event (new medical sign/symptom or worsening of previously reported medical sign/symptom)* | | | | | |
| *TIP: Have new medications or treatment been initiated after subject enrollment? If yes, is the new medication allowed (i.e. not exclusionary or prohibited)?* | | | | | |
| 1. Does the medication information show that the subject has not taken or received any disallowed/ prohibited medications or treatments prior to or during the study? |  |  |  |  | Click or tap here to enter text. |
| 1. Was/Is the blinding maintained according to the IRB approved protocol (if applicable)? |  |  |  |  | Click or tap here to enter text. |

| **ADVERSE EVENTS** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Did the investigator assess all out of range values and/or results (i.e. laboratory values, physical exam findings, ECG results, imaging results, etc.) by documenting whether each is ‘clinically significant’ or ‘not clinically significant’?? |  |  |  |  | Click or tap here to enter text. |
| 1. If a clinically significant or finding of uncertain or unknown clinical significance was observed, is there documentation that the finding was disclosed per the subject’s directive in the informed consent form? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Review the protocol and informed consent form. Will any incidental findings be detected during the study? Did the subject ask to be told of any findings and/or disclose them to a physician/clinic?* | | | | | |
| 1. Have all adverse events (AEs) been appropriately identified? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If a subject reports new symptoms or worsening of previously reported symptoms (e.g. within a study diary, questionnaires, interviews, etc.) have they been recorded as AEs?* | | | | | |
| *TIP: Have clinically significant findings (e.g. laboratory values, findings from physical exams, ECGs, imaging or other procedures, etc.) been documented as AEs?* | | | | | |
| 1. If a clinically significant result was observed or an adverse event occurred, is there documentation that the subject was provided adequate medical care? |  |  |  |  | Click or tap here to enter text. |
| 1. If medications were taken to treat an AE, do the start/end dates of the AE correspond to the medications on the concomitant med log? |  |  |  |  | Click or tap here to enter text. |
| *TIP: Do the start, stop, and/or modification dates for concomitant medications (new meds, change in doses, etc.) correspond to changes in medical status or symptoms (i.e. an AE). if so, do concomitant medication start and end dates correspond to AE start/stop times?* | | | | | |
| 1. Is all adverse event information complete (e.g., type, grade, dates/duration, attribution, reviewed/signed by investigator)? |  |  |  |  | Click or tap here to enter text. |
| 1. Were SAE(s) documented and reported appropriately? |  |  |  |  | Click or tap here to enter text. |

| **PROTOCOL DEVIATIONS** | **Yes** | **No** | **N/A** | **Not Reviewed** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| 1. Were protocol deviations/exceptions documented appropriately (if applicable)? |  |  |  |  | Click or tap here to enter text. |
| 1. Were protocol deviations/exceptions reported to the IRB or other regulatory authorities as necessary? |  |  |  |  | Click or tap here to enter text. |
| *TIP: If the answer to any of the above questions are ‘No’, is there documentation describing the event, how/why it occurred, what measures were taken (if any) to correct the problem, and how will it be prevented again in the future?* | | | | | |
| *TIP: Do any of the deviations/exceptions documented meet the IRB or other regulatory authority reporting criteria?* | | | | | |

|  |
| --- |
| **NOTES:** |
| Click or tap here to enter text. |

**Form Completed By:** Click or tap here to enter text. **Date:** Click or tap to enter a date.

|  |
| --- |
| **APPENDIX** |

The Appendix contains the regulatory references for the questions listed in the Self-Audit Tool.

The Food and Drug Administration (FDA) references are prefaced with *21 CFR*, those related to the Common Rule are identified as *Common Rule*, those related to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule are identified as *HIPAA Privacy Rule* and *ICH GCP E6* refers to the International Conference on Harmonization, Good Clinical Practice guidelines. UW-Madison Human Research Protection Program policies are prefaced with HRPP and the UW-Madison Health Sciences Institutional Review Board policies and guidance are prefaced with HS-IRB. If your study was deferred to another IRB of record, refer to their corresponding policies and guidance. The term “BIMO Manual” refers to the FDA Bioresearch Monitoring (BIMO) audit manual 7348.811, Part III (Inspectional) that can be found at: <http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133569.htm>

A response of “No” to any of the Self-Audit questions may be considered Noncompliance

| **INFORMED CONSENT** | **REFERENCES** |
| --- | --- |
| 1. Are the signed, original consent(s)/assent(s) documents present in the study records? | ***ICH GCP E6:*** *1.28, 4.8.5, 4.8.6, 4.8.8, 4.8.9, 4.8.12, 8.3.12*  ***21 CFR:*** *50.27, 56.111(a)(5), 312.62(b), 812.100, 812.140(a)(3)(i)*  ***HIPAA Privacy Rule:*** *45 CFR 164.508(b)(6)*  ***Common Rule:*** *45 CFR 46.117 (a) and (b)(2)*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID:*](https://kb.wisc.edu/hsirbs/72899) *72899* |
| 1. Are the signed, original HIPAA documents present in the study records? | ***ICH GCP E6:*** *4.8.1, 4.8.2, 4.8.5, 4.8.6, 4.8.9, 8.3.2, 8.3.3*  ***FDA 21 CFR****: 50.27, 56.111(a)(5), 312.62(b), 812.100, 812.140(a)(3)(i)*  ***HIPAA Privacy Rule:*** *45 CFR 164.508(b)(6)*  ***Common Rule:*** *45 CFR 46.117 (a) and (b)(2)*  [*HS-IRB KB Doc ID: 18671*](https://kb.wisc.edu/hsirbs/page.php?id=18671)  [*UW HIPAA Research Guidance*](https://compliance.wisc.edu/hipaa/researchers/) |
| 1. Has the subject signed and dated the correct version(s) of the informed consent/assent document(s)? | ***ICH GCP E6:*** *1.28, 2.9, 3.3.6, 4.4.1, 4.8.1, 4.8.2, 4.8.8, 4.8.13, 4.8.14, 5.18.4(e), 8.3.12*  ***21 CFR:*** *50.20, 50.23, 50.27, 56.111(a)(4) and (5), 312.60, 312.62(b), 812.100, 812.140(a)(3)(i)*  ***Common Rule:*** *45 CFR 46.116, 117 (a)*  ***BIMO Manual****: Part III F.1.a.v*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID:*](https://kb.wisc.edu/hsirbs/72899) *72899* |
| 1. Has the legally authorized representative and/or impartial witness signed and dated the correct version(s) of the consent/assent form document(s) as applicable? | ***ICH GCP E6:*** *4.8*  ***21 CFR:*** *50.20, 50.23, 50.24, 50.27*  ***Common Rule:*** *45 CFR 46.116, 46.117(b)*  ***BIMO Manual:*** *Part III F.1.b.i*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID: 72899*](https://kb.wisc.edu/hsirbs/72899) |
| 1. Are all consents complete (full signatures and dates by both parties, all checkboxes include responses, are pages initialed if necessary)? | ***ICH GCP E6:*** *4.8.8*  ***21 CFR:*** *50.27*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HRPP Research with Adult Participants Lacking Capacity to Consent Polic*y](https://kb.wisc.edu/gsadminkb/page.php?id=29545)  [*HRPP Review of Research Involving Vulnerable Participants*](https://kb.wisc.edu/gsadminkb/page.php?id=29761)  [*HS-IRB KB Doc ID:*](https://kb.wisc.edu/hsirbs/72899) *72899* |
| 1. Do the signatures and dates for the subject & person obtaining informed consent/HIPAA match? | ***ICH GCP E6:*** *4.8.8* |
| 1. Is the informed consent/assent process, including that the subject was given adequate time to make an informed decision, all of the subject’s questions were answered and the subject was given a copy of the signed informed consent form, documented in the source? | ***ICH GCP E6:*** *4.8.3, 4.8.7, 4.8.11*  ***21 CFR:*** *50.27, 56.109, 56.111, 312.62(b), 812.140(a)(3)(i)*  ***Common Rule:*** *45 CFR 46.117(a) & (c)*  [*HS-IRB KB Doc ID:*](https://kb.wisc.edu/hsirbs/72899) *72899* |
| 1. Did the consent process follow the IRB approved plan, and was the person obtaining consent appropriately delegated this task? | ***Common Rule:*** *45 CFR 46.116*  ***ICH GCP E6:*** *2.8, 4.1.5, 4.8.3, 4.8.4, 5.18.4(h)*  ***21 CFR:*** *CFR 312.53(c)(1)(viii) and 812.43*  ***BIMO Manual:*** *Part III F.1.a-b*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID:*](https://kb.wisc.edu/hsirbs/72899) *72899* |
| 1. Has the subject signed the informed consent/assent and HIPAA authorization forms prior to the conduct of study procedures? | ***ICH GCP E6:*** *1.28, 2.9, 3.3.6, 4.4.1, 4.8.2, 4.8.8, 4.8.13, 4.8.14, 5.18.4(e), 8.3.12*  ***21 CFR:*** *50.20, 50.23, 50.25(b)(5), 50.27, 312.60, 312.62(b), 812.100, 812.140(a)(3)(i)*  ***HIPAA Privacy Rule:*** *45 CFR 164.506(b)9(1),*  *164.508 (a)(1), 164.508(b)(3)(1)*  ***Common Rule:*** *45 CFR 46.109(b), 46.116, 46.117*(c)  ***BIMO Manual:*** *Part III F.1.a.iii*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID: 72899*](https://kb.wisc.edu/hsirbs/72899)*,* [*HS-IRB KB Doc ID: 18671*](https://kb.wisc.edu/hsirbs/page.php?id=18671)  [*UW HIPAA Research Guidance*](https://compliance.wisc.edu/hipaa/researchers/) |
| 1. Is it documented that the subject was given a copy of the signed HIPAA Authorization Form? | ***ICH GCP E6:*** *4.8.11*  ***HIPAA Privacy Rule:*** *45 CFR 164.510* |
| 1. If re-consent or notification was required, was the process conducted in accordance with the IRB approved plan and documented appropriately? | ***ICH GCP E6:*** *4.8.2*  [*HRPP Obtaining and Documenting Informed Consent Policy*](https://kb.wisc.edu/gsadminkb/page.php?id=29762)  [*HS-IRB KB Doc ID: 18663*](https://kb.wisc.edu/hsirbs/page.php?id=18663) |

| **ELIGIBILITY** | **REFERENCES** |
| --- | --- |
| 1. Is there appropriate documentation that the subject met the study eligibility criteria (including applicable medical records or source documents to confirm subject’s eligibility)? | ***ICH GCP E6:*** *5.18.4(c)(ii), 5.18.4(i)*  ***21 CFR:*** *312.60*  ***BIMO Manual:*** *Part III F.3.b.i* |
| 1. Was eligibility assessed by an appropriately qualified and delegated individual? | ***ICH GCP E6:*** *2.8, 4.1.5, 4.3.1*  [*FDA Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety and Welfare of Study Subjects*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects)  ***BIMO Manual:*** *Part III F.2.c.iv* |
| 1. Were all screening or pre-enrollment activities completed per protocol? | ***ICH GCP E6:*** *4.5* |

| **STUDY & VISIT PROCEDURES** | **REFERENCES** |
| --- | --- |
| 1. Were procedures/assessments completed per protocol? | ***ICH GCP E6:*** *1.44, 2.6, 2.8, 4.1.5, 4.2.4, 4.5.1, 4.5.2, 4.5.3, 4.5.4, 5.18.4(d), 5.18.4 (h)(m)(iv and v)*  ***21 CFR:*** *312.60, 812.100, 812.110(b), 812.140(a)(4)*  [*FDA Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety and Welfare of Study Subjects*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects)  [*FDA Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors - FDA Inspections of Clinical Investigators*](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf) *Section IV* |
| 1. If a procedure, or visit, was missed or not completed, was it documented as a deviation with a complete explanation? | ***ICH GCP E6:*** *4.5.3, 5.18.4(m)(iv)* |
| 1. Were tests/procedures completed by appropriately qualified and delegated individuals? | ***ICH GCP E6:*** *1.44, 2.6, 2.8, 4.1.5, 4.2.4, 4.5.1, 4.5.2, 4.5.3, 4.5.4, 5.18.4(d), 5.18.4 (h)(m)(iv and v), 5.18.4 (n), 8.3.10, 8.3.24*  ***21 CFR:*** *312.60, 812.100, 812.140(a)(4)*  [*FDA Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety and Welfare of Study Subjects*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects)  [*FDA Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors - FDA Inspections of Clinical Investigators*](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf) *Section IV* |
| 1. Were all visits completed within the allotted time windows? | ***ICH GCP E6:*** *4.5.2* |
| 18a. If not, is this documented as a deviation with a complete explanation? | ***ICH GCP E6:*** *4.5.3*  [*HS-IRB KB Doc ID: 18312*](https://kb.wisc.edu/hsirbs/page.php?id=18312) |
| 1. Is the reason for withdrawal or drop-out documented (if applicable)? | ***ICH GCP E6:*** *5.18.4 (m)(v)*  ***21 CFR:*** *312.33(b)(4)* |
| 1. Is there documentation the subject was provided with study-related compensation (if applicable)? | ***ICH GCP E6:*** *4.5.1, 4.5.2, 4.8.10 (k)* |

| **STUDY INTERVENTION** | **REFERENCES** |
| --- | --- |
| 1. Was the investigational product administered according to the protocol and under PI supervision (if applicable)? | ***ICH GCP E6:*** *4.3.2, 4.6.3, 4.6.5, 4.6.6, 4.7, 5.18.4(c)(ii) and (iv), 5.18.4(m)(ii), 8.3.23*  ***21 CFR:*** *312.61, 312.62(a) and (b), 812.110(b) and (c), 812.140(a)(2) and (a)(3)(iii)* |
| 1. Was the correct investigational product regimen followed? (dose, randomization, route of administration, compliance, etc.) | ***ICH GCP E6:*** *4.6.3, 5.18.4 (c)(ii), 5.18.4(m)(ii), 8.3.23*  ***21 CFR:*** *312.60, 312.62* |
| 1. Is the investigational product being properly documented and accounted for this subject? | ***ICH GCP E6:*** *1.33, 4.6.3, 8.3.23*  ***21 CFR:*** *312.62(a), 812.140(3)(iii)* |

| **DATA MANAGEMENT** | **REFERENCES** |
| --- | --- |
| 1. Did research staff adequately address previous queries/observations? |  |
| 1. Are all CRFs/data collection forms and supporting source documents on file? | ***ICH GCP E6:*** *1.11, 1.23, 1.51, 1.52, 2.10, 4.9.4, 4.9.5, 5.18.4 (k), 8.3.13, 8.3.14*  ***21 CFR:*** *312.62, 812.140(a)* |
| 1. Are all data collection forms (CRFs, source, etc.) complete? | ***ICH GCP E6:*** *2.10, 4.9.1, 5.18.4(k), 5.18.4(m)(i), 8.3.14*  ***21 CFR:*** *312.62(b), 812.140*  ***BIMO Manual:*** *Part III F.3.a.ii* |
| 1. Are all data collection forms (CRFs, source, etc.) consistent with source data? | ***ICH GCP E6:*** *4.9.2, 5.18.4(k), 5.18.4(m)(i), 8.3.14*  ***BIMO Manual:*** *Part III F.3.a.ii* |
| 1. Do all data collection forms and corresponding source documents include documentation of the observer/recorder of the information? | ***ICH GCP E6:*** *5.18.4(k), (m)(i),* 8.3.14  ***BIMO Manual:*** *Part III F.3.a.i* |
| 1. Are all source documents that were reviewed (including lab reports, ECGs, radiology reports, and all other study related documents) appropriately labeled with subject information (e.g. name, initials, subject ID, MRN [as applicable], etc.)? | ***ICH GCP E6:*** *1.52, 1.58, 8.3.13*  ***21 CFR:*** *312.62(b)* |
| 1. Do CRFs have an appropriate header indicating site information (e.g. PI, site name, site number, etc.) and protocol information (e.g. sponsor, protocol number) as applicable? | ***ICH GCP E6:*** *1.52, 8.3.13* |
| 1. Are all mistakes lined through once (so original entry is legible), dated, and initialed individually? | ***ICH GCP E6:*** *2.10, 4.9.1, 4.9.3, 5.18.4(k), 5.18.4(n), 8.3.15* |
| 1. Has medical history been appropriately obtained and documented? | ***ICH GCP E6:*** *5.18.4(m)(iii), 8.3.13*  ***21 CFR:*** *312.62(b), 812.140(3)* |
| 1. Is there documentation that the subject’s primary physician was informed of the subject’s participation in the study, if the subject agreed to notify his/her physician? | ***ICH GCP E6:*** *4.3.3* |
| 1. Is there appropriate documentation of retained body fluids or tissue samples (if applicable)? | ***ICH GCP E6:*** *8.3.25* |
| 1. Are the body fluids or tissue samples being stored and retained according to the IRB approved protocol (if applicable)? |  |
| 1. Is the research chart organized? |  |
| 1. Was data completed in a timely manner (e.g., are CRFs up to date)? | ***ICH GCP E6:*** *4.9.1, 5.18.4(k)* |
| 1. Is the research data being stored in compliance with the relevant provisions of the IRB approved protocol? | ***ICH GCP E6:*** *2.10,* 2.11, 4.9.4  ***21 CFR:*** *56.111(a)(7)*  [*HRPP Protecting Research Participants Privacy Interests and Confidentiality of Data*](https://kb.wisc.edu/gsadminkb/page.php?id=29561) |
| 1. Are the subject charts/source documents stored in a secure manner consistent with the IRB application? | ***ICH GCP E6:***2.11, 4.9.4  ***21 CFR:*** *56.111(a)(7)*  [*HRPP Protecting Research Participants Privacy Interests and Confidentiality of Data*](https://kb.wisc.edu/gsadminkb/page.php?id=29561) |

| **CONCOMITANT MEDICATIONS /TREATMENT** | **REFERENCES** |
| --- | --- |
| 1. Are concomitant medications documented appropriately? | ***ICH GCP E6:*** *5.18.4(m)(iii)*  ***21 CFR:*** *312.62(b), 812.140(3)(iii)*  ***BIMO Manual:*** *Part III F.3.b.v* |
| 1. Does the medication information show that the subject has not taken or received any disallowed/ prohibited medications or treatments prior to or during the study? | ***ICH GCP E6:*** *5.18.4 (c)(ii), 5.18.4(m)(ii-iii)*  ***21 CFR:*** *812.140(3)(iii)* |
| 1. Was/Is blinding maintained according to the IRB approved protocol (if applicable)? | ***ICH GCP E6:*** *4.7, 5.13.4, 8.2.17, 8.4.6* |

| **ADVERSE EVENTS** | **REFERENCES** |
| --- | --- |
| 1. Did the investigator appropriately assess all out of range values and/or results (i.e. laboratory values, physical exam findings, ECG results, imaging results, etc.) by documenting whether each is ‘clinically significant’ or ‘not clinically significant’?? | ***ICH GCP E6:*** *1.2, 2.7, 4.3.1, 4.3.2, 4.11.2*  ***21 CFR:*** *312.62(b)*  ***BIMO Manual:*** *Part III F.3.b.iv* |
| 1. If a clinically significant or finding of uncertain or unknown clinical significance was observed, is there documentation that the finding was disclosed per the subject’s directive in the informed consent form? |  |
| 1. Have all adverse events (AEs) been appropriately identified? | ***ICH GCP E6:*** *5.18.4(m)(iii)*  ***21 CFR:*** *312.62(b), 812.140(a)(3)(ii)*  ***BIMO Manual:*** *Part III F.3.b.iii* |
| 1. If a clinically significant result was observed or an adverse event occurred, is there documentation that the subject was provided adequate medical care? | ***ICH GCP E6:*** *4.3.2*  ***21 CFR:*** *312.62(b), 312.60, 812.100, 812.140(a)(3)(ii)*  ***Common Rule:*** *46.116(f)* |
| 1. If medications were taken to treat an AE, do the start/end dates of the AE correspond to the medications on the concomitant med log? | ***ICH GCP E6:*** *5.18.4(m)(iii)* |
| 1. Is all adverse event information complete (e.g., type, grade, dates/duration, attribution, reviewed/signed by investigator)? | ***ICH E2A:*** *III*  ***ICH GCP E6:*** *1.2, 5.18.4(m)(iii)* |
| 1. Were SAE(s) documented and reported appropriately? | ***ICH E2A:*** *III*  ***ICH GCP E6:*** *4.11, 5.17.1, 5.17.3, 5.18.4(m)(iii), 5.18.4(l), 5.18.4(o), 8.3.16, 8.3.17*  ***21 CFR:*** *312.32, 312.62(b)*  [*HS-IRB KB Doc ID: 18324*](https://kb.wisc.edu/hsirbs/page.php?id=18324) |

|  |  |
| --- | --- |
| **PROTOCOL DEVIATIONS** | **REFERENCES** |
| 1. Were protocol deviations/exceptions documented appropriately (if applicable)? | ***ICH GCP E6:*** *4.5.1, 4.5.2, 4.5.3, 4.5.4, 5.3.7, 5.18.4(l), 5.18.4(q)*  ***21 CFR:*** *56.108, 312.66, 812.140(4)*  [*HS-IRB KB Doc ID: 18324*](https://kb.wisc.edu/hsirbs/18324) |
| 1. Were protocol deviations/exceptions reported to the IRB or other regulatory authorities as necessary? | ***ICH GCP E6:*** *3.3.8(a), 4.5.1, 4.5.2, 4.5.4, 5.3.7, 5.18.4(l), 5.18.4(q)*  ***21 CFR:*** *56.108, 312.66, 812.150(a)(4)*  [*HS-IRB KB Doc ID: 18324*](https://kb.wisc.edu/hsirbs/18324) |