This tool was developed to assist Regional Coordinating Centers and their research teams when conducting clinical research study(ies). We encourage self-audits in preparation for monitoring visits, FDA, or NIH audits. This tool could also be used by the research team for investigator-initiated studies without independent monitors to periodically review your records.

This tool is to be used as guidance. Some of the items included on this worksheet may not be applicable to all studies. The Food and Drug Administration (FDA) references are prefaced with 21 CFR, those related to the Common Rule are identified as 45 CFR, and ICH GCP refers to the International Conference on Harmonization, Good Clinical Practice guidelines.

# PROTOCOL INFORMATION

Protocol Title: IRB Number: Principal Investigator:

# REGULATORY REVIEW

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| **Dated, Documented Approvals/Authorizations** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 1. Are all approved versions of the protocol, amendments, admin changes, and/or protocol clarification letters present? |  |  |  |  | *ICH GCP E6 1.44, 4.5.1, 5.11.1(c),5.18.4(l), 8.2.2*  *FDA 21 CFR 56.103, 312.30, 312.53(3), 812.140(a)(1), 812.140(b)(1)* |
| 2. Are all copies of the protocol and protocol amendment signature pages present and signed? |  |  |  |  | *ICH GCP E6 8.2.2* |
| 3. Have investigator-initiated or internally sponsored protocols received necessary regulatory approvals (e.g. IND)? |  |  |  |  | *ICH GCP E6 5.10,5.11.1(c), 5.18.4(l), 8.2.9, 8.3.4, 8.4.7*  *FDA 21 CFR 56.103, 312.20(a), 312.23(11)(e),*  *312.30, 312.33, 312.40, 812.20* |
| 4. Have safety reports been reviewed and reported as appropriate? |  |  |  |  |  |
| 5. Was initial IRB approval granted prior to enrollment of the first subject? |  |  |  |  | *21 CFR 56.103, 56.108, 56.109], [ICH GCP E6*  *4.4.1, Declaration of Helsinki* |
| 6. Are copies of IRB initial and continuing review approvals contained in the file? |  |  |  |  | *ICH GCP E6 1.5, 1.45, 3.1.4, 3.3.6, 4.4.1,*  *5.18.4(l), 8.2.7, 8.3.3, 8.3.4, 8.4.7*  *FDA 21 CFR 56.103, 56.109 (e&f), 56.111,*  *312.66* |
| * Were continuing reviews filed promptly with the IRB without a lapse in approval? |  |  |  |  | *ICH GCP E6 3.1.4, 4.10.1, 5.18.4(l)* |
| * If a lapse in IRB approval did occur, did any prohibited activities occur during lapse? |  |  |  |  | *ICH GCP E6 3.1.4, 4.10.1, 5.18.4(l)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Dated, Documented Approvals/ Authorizations (continued)** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 7. Were changes made to the protocol IRB approved before they were implemented? |  |  |  |  | *ICH GCP E6 3.3.7, 4.5.1, 4.5.4, 5.18.4(l)*  *FDA 21 CFR 312.53(vi)(a), 312.30, 312.66,*  *812.35(a), 812.150 (a)(4)*  *Common Rule 45 CFR 46.103(b)(4)(iii)*  *No change to the protocol may be made without consideration and approval by the committee. [Declaration of Helsinki]* |
| 8. Are IRB approvals present and filed for all IRB submissions? |  |  |  |  | *ICH GCP E6 4.4.1, 4.4.3, 5.11.1(c), 5.11.2,*  *5.11.3, 5.18.4(l), 8.27, 8.3.3*  *FDA 21 CFR 56.103, 56.108, 56.111, 312.66, 812.140(a)(1), 812.140(b)(1)* |
| 9. Have advertisements or other forms of subject recruitment been approved by the IRB and filed appropriately? |  |  |  |  | *ICH GCP E6 3.1.2, 4.4.1, 5.11.1(c), 8.2.3, 8.2.7,*  *8.3.2, 8.3.3*  *FDA 21 CFR 56.109(b)* |
| 10. Is an IRB member roster present and up to date? |  |  |  |  | *UW-Madison researchers refer to the HSIRB Compliance Statement – this will differ at other institutions.* |
| 11. Is an FWA present and up to date? |  |  |  |  | *UW-Madison researchers refer to the HRPP webpages for a copy of the FWA* |
| 12. Has a final protocol closure report been submitted to regulatory authorities and filed appropriately *(if applicable)?* |  |  |  |  | *ICH GCP E6 4.13, 5.18.4(l), 8.4.7 FDA 21 CFR 312.64(c)* |
| 13. Are all versions of the case report forms (CRFs) present? |  |  |  |  | *ICH GCP E6 8.2.2, 8.2.7, 8.3.3* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **FDA Related Documentation** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 51. Have all individuals listed on the 1572 (PI and Sub-I) completed and filed a Financial Disclosure? |  |  |  |  | *FDA 21 CFR 312.53(4), 312.57(b), 312.64(d), 812.110(d)* |
|  |  |  |  |  |  |
| 52. Are all versions of the 1572 present? |  |  |  |  | *FDA 21 CFR 312.53, 312.64(d), 812.140(b)(3)* |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * Is the Investigator Agreement (e.g. FDA 1572 form) complete and amended as needed? |  |  |  |  |  |  |  |  |  |  |  |  | *FDA 21 CFR 312.23* |
| 53. Are all IND/IDE Application and supporting materials (if applicable) available? |  |  |  |  |  |  |  |  |  |  |  |  | *FDA 21 CFR 312.22(d), 312.23(a), 812.20.5* |
| 54. Is a list of studies for which the PI is/was responsible available and up to date? (should include title, start and stop dates) |  |  |  |  |  |  |  |  |  |  |  |  | *FDA Bioresearch Monitoring (BIMO) audit manual 7348.811* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Communication and Correspondence** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 14. Has documentation of IRB correspondence (submission information, etc.) been maintained and filed? |  |  |  |  | *ICH GCP E6 4.9.4, 8.2.1-3, 8.2.7-8, 8.3.2-3,*  *8.2.11, 8.2.17, 8.2.19*  *FDA 21 CFR 812.140(a)(1), 812.140(b)(1)* |
| 15. Has documentation of correspondence (letters, e-mails, meting notes, telephone calls) with the research sponsor and/or contract research organization (CRO) been maintained and filed? |  |  |  |  | *ICH GCP E6 8.2.6, 8.2.19-20, 8.3.10-11, 8.3.17-*  *18, 8.4.5*  *FDA 21 CFR 812.140(a)(1), 812.140(b)(1)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Information Given to Subjects** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 16. Are all versions of the IRB approved informed consent/assent present and filed? |  |  |  |  | *ICH GCP E6 4.8.1, 5.11.1(c), 8.2.2, 8.2.7, 8.3.2,*  *8.3.3*  *FDA 21 CFR 56.109* |
| 17. Are all versions of the IRB approved HIPAA Authorization(s) present and filed? |  |  |  |  | *ICH GCP E6 5.11.1(c), 8.2.2, 8.2.7, 8.3.2, 8.3.3* |
| 18. Have other written materials provided to research subjects (e.g. diaries, questionnaires, visit schedules) been approved by the IRB and filed appropriately? |  |  |  |  | *ICH GCP E6 3.1.2, 5.11.1(c), 8.2.2, 8.2.7, 8.3.2,*  *8.3.3*  *FDA 21 CFR 56.10* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Personnel** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 19. Is a curriculum vitae (CV) present for each member of the study team? |  |  |  |  | *ICH GCP E6 2.7., 2.8, 3.1.2, 4.1.1, 8.2.10, 8.3.5*  *FDA 21 CFR 312.50, 312.53(g)(viii), 812.43(c)(1)* |
| 20. Have the CVs been signed and dated within the previous 2 years? |  |  |  |  | *industry standard* |
| 21. Are current licenses present for each study team member as applicable? |  |  |  |  | *ICH GCP E6 2.7, 4.2, 8.2.10*  *FDA 21 CFR 312.50, 312.53* |
| 22. Have all members of the study team completed the required human subjects protection training (CITI) and HIPAA training? |  |  |  |  | *ICH GCP E6 4.1.1*  *HIPAA Privacy Rule 45 CFR 164.530(b)(1)*  *FWA terms of assurance* |
| 23. Are all members of the study team considered qualified by education, training, and experience? |  |  |  |  | *ICH GCP E6 2.8, 4.1.1, 4.2.4, 4.3.1*  *FDA 21 CFR 312.50, 312.53, 812.40, 812.43*  *Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent. [Declaration of Helsinki]* |
| 24. Are all staff working on the study listed in the IRB application? |  |  |  |  | *UW-Madison HRPP Policy* [*(http://my.gradsch.wisc.edu/hrpp/10013.pdf*](http://my.gradsch.wisc.edu/hrpp/10013.pdf)*) and*  *UW-Madison Health Sciences IRB Key Personnel Guidance (https://kb.wisc.edu/hsirbs/page.php?id=19529)* |
| 25. Is a staff signature / delegation log present? |  |  |  |  | *ICH GCP E6 2.8, 4.1.5, 4.2.4, 5.18.4(h), 8.3.24*  *FDA 21 CFR 312.53(c)(1)(vi)(g)(viii), 312.5 (viii)*  *Common Rule 45 CFR 46.116* |
| 26. Have changes in staff been documented appropriately? (e.g. has new staff been added to the Delegation of Authority/Signature Log, the IRB application, the 1572, etc.) |  |  |  |  | *ICH GCP E6 8.3.5*  *FDA 21 CFR 312.30(2)(c), 312.66* |
| 27. Is there documentation that all study team members have been trained on the protocol? |  |  |  |  | *ICH GCP E6 4.2.4* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Laboratory Aspects of the Trial** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **References** |
| 28. Are current copies of laboratory accreditation(s) and certification(s) present (e.g. CLIA, CAP)? |  |  |  |  | *ICH GCP E6 8.2.12, 8.3.7*  *UWHC website for lab accreditations:* [*https://uconnect.wisc.edu/servlet/Satellite?cid=1126649*](https://uconnect.wisc.edu/servlet/Satellite?cid=1126649635531&amp;pagename=B_EXTRANET_UWHC_DEPARTMENTS%2FFlexMember%2FShow_Common&amp;c=FlexMember) [*635531&pagename=B\_EXTRANET\_UWHC\_DEPART*](https://uconnect.wisc.edu/servlet/Satellite?cid=1126649635531&amp;pagename=B_EXTRANET_UWHC_DEPARTMENTS%2FFlexMember%2FShow_Common&amp;c=FlexMember) [*MENTS%2FFlexMember%2FShow\_Common&c=Flex*](https://uconnect.wisc.edu/servlet/Satellite?cid=1126649635531&amp;pagename=B_EXTRANET_UWHC_DEPARTMENTS%2FFlexMember%2FShow_Common&amp;c=FlexMember) [*Member*](https://uconnect.wisc.edu/servlet/Satellite?cid=1126649635531&amp;pagename=B_EXTRANET_UWHC_DEPARTMENTS%2FFlexMember%2FShow_Common&amp;c=FlexMember) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Laboratory Aspects of the Trial (Continued)** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 29. Is a CV for the lab director current and on file? |  |  |  |  | *FDA Bioresearch Monitoring (BIMO) audit manual 7348.811* |
| 30. Are normal value(s)/range(s) for medical, laboratory, technical procedures present? |  |  |  |  | *ICH GCP E6 8.2.11, 8.3.6*  *Refer to the UWHC UConnect Clinical Lab Test Directory:*  https://uconnect.wisc.edu/servlet/Satellite?pagen ame=B\_EXTRANET\_UWH\_CLIN\_LAB\_HANDB  OOK/Page/Show\_ClinLab\_Search%26c=Page% 26cid=1139396417691 |
| 31. Are laboratories used for the study included on the 1572? |  |  |  |  | *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs*  *Frequently Asked Questions – Statement of Investigator (Form FDA 1572), May 2010* |
| 32. Have all lab kits/supplies been utilized before the expiration date? |  |  |  |  | *ICH GCP E6 5.18.4(b)* |
| 33. Are Specimen Logs present and current? |  |  |  |  | *ICH GCP E6 8.3.25* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Clinical Aspects of the Trial** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 34. Are temperature logs for applicable clinic equipment complete and current (refrigerators, freezers, storage cabinets, etc)? |  |  |  |  | *ICH GCP E6 8.2.12, 8.3.7* |
| 35. Are equipment maintenance and calibration records available and current (electronic scales, electronic blood pressure cuff, etc.) (if applicable) |  |  |  |  | *ICH GCP E6 8.2.12, 8.3.7* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Conduct** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **References** |
| 36. Are protocol requirements being followed? |  |  |  |  | *ICH GCP E6 1.44, 2.6, 4.4.1, 4.4.2, 4.5,*  *5.18.4(d), 5.23.1*  *FDA 21 CFR 312.50, 312.53(vi)(a), 312.60,*  *812.100, 812.110*  *Common Rule 45 CFR 46.103(4)(iii)* |
| 37. Are all protocol deviations/violations documented and tracked appropriately? |  |  |  |  | *ICH GCP E6 5.18.4(q)* |
| 38. Is the Subject Screening Log available? |  |  |  |  | *ICH GCP E6 5.18.4(j), 8.3.20* |
| 39. Is the Subject Identification Code List available? |  |  |  |  | *ICH GCP E6 8.3.21, 8.4.3* |
| 40. Is the Subject Enrollment Log available? |  |  |  |  | *ICH GCP E6 8.3.22* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Conduct (Continued)** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 41. Is subject enrollment more than approved by the IRB? |  |  |  |  | *ICH GCP E6 3.3.7, 4.5.1, 4.5.4, 5.18.4(l)*  *FDA 21 CFR 312.53(vi)(a), 312.30, 312.66,*  *812.35(a), 812.150 (a)(4)*  *Common Rule 45 CFR 46.103(b)(4)(iii)*  *No change to the protocol may be made without consideration and approval by the committee. [Declaration of Helsinki]* |
| 42. If subjects have withdrawn, has the reason for withdrawal been documented? |  |  |  |  | *ICH GCP E6 4.3.4* |
| 43. Have additional investigative sites been properly notified of relevant safety information? |  |  |  |  | *ICH GCP E6 8.3.18* |
| 44. Were applicable reportable events submitted to the IRB and applicable authority(ies) promptly with copies present in the regulatory binder (unanticipated problems, deviations, violations, noncompliance, AEs, SAEs, etc.)? |  |  |  |  | *ICH GCP E2 III, E6 3.3.8(c), 4.5.3, 4.10.2,*  *4.11.1, 4.11.2, 5.17.1, 5.17.2, 5.18.4(o),*  *5.18.4(q)*  *FDA 21 CFR 56.108, 312.32, 312.64(b),312.66,*  *812.46(b), 812.140, 812.150*  *Common Rule 45 CFR 46.103(b)(5)(i)*  *The researcher must provide monitoring information to the committee [Declaration of Helsinki]* |
| 45. If there has been new information identified that may affect adversely the safety of the subject or the conduct of the trial, has it been appropriately reported to the IRB? |  |  |  |  | *ICH GCP E6 3.3.8(d), 4.8.11 FDA 21 CFR 812.46(b)(1-2)* |
| 46. Have changes in facilities or equipment been documented appropriately? |  |  |  |  | *ICH GCP E6 5.18.4(b)* |
| 47. Is there reason to believe that the Investigator has, and is continuing to provide appropriate oversight of the study and/or study team? |  |  |  |  | *ICH GCP E6 4.2.4*  *FDA 21 CFR 312.53 (c)(vi)(c), 312.60* |
| 48. Is Monitoring Visit correspondence on file? |  |  |  |  | *ICH GCP E6 5.18.6, 8.2.20, 8.3.10, 8.3.11, 8.4.5*  *FDA 21 CFR 812.140(a)(1), 812.140(b)(1)* |
| 49. Has the monitoring log been signed and dated? |  |  |  |  | *ICH GCP E6 8.3.10*  *Guidance for Industry: Guidelines for the Monitoring of Clinical Investigations, Jan. 1998* |
| 50. Is there a DSMC/DSMB for this study? |  |  |  |  | *ICH GCP E6 8.3.11, 8.3.18* |
| * If Yes, are all DSMB reports and recommendations on file |  |  |  |  |  |
| * Have all DSMB reports been submitted to the IRB? |  |  |  |  |  |

# INVESTIGATIONAL/STUDY PRODUCT

This section should be used for products under investigation as part of the clinical research study in question (e.g. investigational drugs, devices, biologics, FDA approved drugs or devices being evaluated for a new indication, etc.)

*NOTE: If your study is utilizing the Pharmaceutical Research Center for drug management, several of the questions below may relate to PRC responsibilities, not those of the research team.*

|  |  |  |
| --- | --- | --- |
| **Product Name** | **Product Description**  (include dose if applicable) | **Product Location** |
|  | | |
| *This section of the Worksheet should be completed separately for each Investigational/Study Product* | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Handling** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 55. Is an Investigator’s Brochure (all versions), or instructions for handling investigational/study product(s) and trial-related materials for each Investigational/Study Product present and up-to-date? |  |  |  |  | *ICH GCP E6 2.4, 5.12.2, 5.14.3, 5.18.4(f),*  *8.2.1, 8.2.14, 8.3.1*  *FDA 21 CFR 312.23(5), 312.55, 812.140(b)(4)(i)* |
| 56. Is a list of all authorized prescribers (with accompanying signatures) present? |  |  |  |  | *FDA Bioresearch Monitoring (BIMO) audit manual 7348.811* |
| 57. Are CVs of pharmacists current and on file? |  |  |  |  | *FDA Bioresearch Monitoring (BIMO) audit manual 7348.811* |
| 58. Are licenses of pharmacists current and on file? |  |  |  |  | *FDA Bioresearch Monitoring (BIMO) audit manual 7348.811* |
| 59. Are decoding procedures for blinded trials available? |  |  |  |  | *ICH GCP E6 1.10, 4.7, 5.13.4, 8.2.17, 8.4.6* |
| 60. Is the Master Randomization list available? |  |  |  |  | *ICH GCP E6 1.48, 4.7, 8.2.18* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Storage** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
|  |  |  |  |  |  |
| 61. Area secured? |  |  |  |  | *ICH GCP E6 5.14.3, 5.18.4(c)(i)* |
|  |  |  |  |  |  |
| 62. Temperature log kept? |  |  |  |  | *ICH GCP E6 5.13.2, 5.18.4(c)(i)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Inventory** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 63. Inventory done monthly/tracked? |  |  |  |  | *ICH GCP E6 4.6.3, 5.18.4(c)(i), 8.3.23*  *FDA 21 CFR 312.57, 312.60* |
| 64. Physical inventory count matched accountability record?  *(If No, List Discrepancies below)* |  |  |  |  | *ICH GCP E6 4.6.3, 8.3.23, 8.4.1*  *FDA 21 CFR 312.57, 312.60, 812.140(a)(2)* |
| 65. Are the investigational/study products appropriately packaged and clearly coded and/or labeled? |  |  |  |  | *ICH GCP E6 5.13.1, 8.2.13*  *FDA 21 CFR 312.6, 312.23(7)(d), 812.5* |
| 66. Expiration date tracked, if applicable? |  |  |  |  | *ICH GCP E6 4.6.3, 8.3.23*  *FDA 21 CFR 312.57, 312.60]* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Accountability Records** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 67. Math additions/subtractions within Product Accountability Records (PAR) are correct?  *(If No, List Discrepancies below)* |  |  |  |  | *ICH GCP E6 4.6.3, 5.18.4(c)(iv), 8.3.2, 8.3.23,*  *8.4.1*  *FDA 21 CFR 312.57, 312.60, 312.62(a), 812.140(a)(2-3)* |
| 68. Investigational/Study Product log numbers are correctly reflected? |  |  |  |  | *ICH GCP E6 4.6.3, 8.4.1*  *FDA 21 CFR 312.57, 312.60* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Shipment Records** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 69. Shipment invoice/packing slip located for each PAR shipment receipt entry? |  |  |  |  | *ICH GCP E6 4.6.3, 5.18.4(c)(iv), 8.3.8, 8.3.23,*  *8.4.1*  *FDA 21 CFR 312.57(a), 312.60, 812.140(a)(2), 812.140(b)(2)* |
| 70. For each shipment invoice, there is a corresponding PAR shipment receipt entry? |  |  |  |  | *ICH GCP E6 4.6.3, 5.18.4(c)(iv), 8.3.8, 8.3.23,*  *8.4.1*  *FDA 21 CFR 312.57(a), 312.60, 812.140(a)(2)* |
| 71. Shipment amounts, dates and lot number(s) match? |  |  |  |  | *ICH GCP E6 4.6.3, 8.3.8, 8.3.23, 8.4.1*  *FDA 21 CFR 312.57(a), 312.60, 812.140(a)(2)(i)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Dispensing Records** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **References** |
| 72. Investigational/Study product dispensing dates/doses match source documents? |  |  |  |  | *ICH GCP E6 4.6.3, 5.18.4(m)(ii), 8.3.23, 8.4.1*  *FDA 21 CFR 312.60, 312.61, 312.62(a), 812.140(a)(2-3)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product Destruction/Disposition** | **Yes** | **No** | **N/A** | **Not Reviewed** | **References** |
| 73. The destruction/disposition of the investigational/study product complies with the approved protocol and applicable regulatory requirements? *(e.g. drug lost, device malfunction/failure)* |  |  |  |  | *ICH GCP E6 5.18.4(c)(v), 8.3.8*  *FDA 21 CFR 312.59, 312.60, 312.62(a), 812.110(e), 812.140(a)(2), 812.140(b)(2),*  *812.140(b)(6)* |

# SUBJECT CHART REVIEW

***ENSURE THE FOLLOWING HAVE BEEN DONE FOR EACH PARTICIPANT***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Informed Consent** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 74. Has subject signed and dated the correct informed consent/assent document(s) prior to start of study procedures? |  |  |  |  |  | *ICH GCP E6 1.28, 2.9, 3.3.6, 4.4.1, 4.8.2, 4.8.8,*  *5.18.4(e), 8.3.12*  *FDA 21 CFR 50.20, 50.23, 50.27, 312.60,*  *312.62(b), 812.100, 812.140(a)(3)(i)*  *Common Rule 45 CFR 46.116, 117 (c)* |
| 75. Has the legally authorized representative and/or impartial witness signed and dated the consent/assent form document(s)? |  |  |  |  |  | *ICH GCP E6 4.8*  *FDA 21 CFR 50.20, 50.23, 50.24, 50.27*  *Common Rule 45 CFR 46.116, 46.117(b)1 & 2* |
| 76. Is the informed consent/assent process, including that the subject was given a copy of the informed consent, documented in the source? |  |  |  |  |  | *ICH GCP E6 4.8.11*  *FDA 21 CFR 50.27, 312.62(b), 812.140(i)*  *Common Rule 45 CFR 46.117(a) &(c)* |
| 77. Has the subject signed all applicable versions of the Informed Consent/Assent and HIPAA forms? |  |  |  |  |  | *ICH GCP E6 4.8.2*  *FDA 21 CFR 50.20, 50.25(b)(5)*  *Common Rule 45 CFR 46.109(b)* |
| 78. Did the subject sign new versions at the first visit following approval of a new Informed Consent/HIPAA version? *(if reconsent required)* |  |  |  |  |  | *ICH GCP E6 4.8.2* |
| 79. Did the subject sign a HIPAA Authorization Form prior to the initiation of study procedures? |  |  |  |  |  | *ICH GCP E6 4.8.2*  *HIPAA Privacy Rule 45 CFR 164.108 (a)(1), 164.508(b)(3)1), 164.506(b)91)* |
| 80. Is it documented that subject was given a copy of the HIPAA Authorization Form? |  |  |  |  |  | *ICH GCP E6 4.8.11*  *HIPAA Privacy Rule 45 CFR 164.510(4)* |
| 81. Are all pages of the original signed Informed Consent/HIPAA present? |  |  |  |  |  |  |
| 82. 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 FDA 21 CFR 50.27* |
| 83. Do the subject & person obtaining informed consent/HIPAA dates match? |  |  |  |  |  | *ICH GCP E6 4.8.8* |
| 84. Are all copies of the signed and dated consent/assent and HIPAA documents present in the subject’s research file/chart? |  |  |  |  |  | *FDA 21 CFR 312.62(b),*  *HIPAA Privacy Rule45 CFR 164.508(b)(6)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Eligibility** | **Yes** | **No** | | **N/A** | **Not**  **Reviewed** | **References** |
| 85. Is there appropriate documentation that the subject met/didn’t meet eligibility criteria (including applicable medical records to confirm subject’s eligibility)? |  |  |  |  |  | *ICH GCP E6 5.18.4(c)(ii), 5.18.4(i) FDA 21 CFR 312.60* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Eligibility (continued)** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 86. Are there approval waivers for inclusion/exclusion criteria not fulfilled by subject? |  |  |  |  |  | *ICH GCP E6 5.18.4(i)* |
| 87. Were all screening or pre- enrollment/randomization activities completed per protocol? |  |  |  |  |  | *ICH GCP E6 4.5.1, 4.5.2, 5.18.4(i)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study & Visit Procedures** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 88. Were tests/procedures completed per protocol? |  |  |  |  |  | *ICH GCP E6 1.44, 4.5.1, 4.5.2, 5.18.4(d), 5.18.4*  *(h)*  *FDA 21 CFR 312.60* |
| * If a procedure, or visit, was missed or not completed, was the reason properly documented? |  |  |  |  |  | *ICH GCP E6 4.5.3, 5.18.4(m)(iv)* |
| 89. Were all visits completed within the allotted time windows? |  |  |  |  |  | *ICH GCP E6 4.5.1, 4.5.2* |
| * If not, is this documented as a deviation and further explained? |  |  |  |  |  | *ICH GCP E6 4.5.3* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Data Management** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 90. Are all CRFs and supporting source documents on file? |  |  |  |  |  | *FDA 21 CFR 312.62* |
| 91. 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 FDA 21 CFR 312.62(b)* |
| 92. Are CRFs consistent with source data? |  |  |  |  |  | *ICH GCP E6 4.9.2, 5.18.4(k), 5.18.4(m)(i), 8.3.14* |
| 93. 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* |
| 94. 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* |
| 95. Has medical history been appropriately obtained and documented? |  |  |  |  |  | *ICH GCP E6 5.18.4(m)(iii), 8.3.13 FDA 21 CFR 312.62(b), 812.140(3)* |
| 96. Did the investigator document ‘clinically significant’ or ‘not clinically significant’ for all out of range values? |  |  |  |  |  | *ICH GCP E6 4.3.1 FDA 21 CFR 312.62(b)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Data Management (continued)** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 97. Appropriate documentation of retained body fluids or tissue samples *(if applicable)*? |  |  |  |  |  | *ICH GCP E6 8.3.25* |
| 98. Is the data quality complete and acceptable? |  |  |  |  |  | *ICH GCP E6 2.10, 4.89.1, 5.18.4(k), 8.3.14 FDA 21 CFR 312.62(b)* |
|  |  |  |  |  |  |  |
| 99. Is the research chart organized? |  |  |  |  |  |  |
| 100. Was data completed in a timely manner (e.g., are CRFs up to date)? |  |  |  |  |  | *ICH GCP E6 5.18.4(k)* |
| 101. Are the subject charts/source documents stored in a secure manner? |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Concomitant Medications**  **/Treatment** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 102. Are concomitant medications documented appropriately? |  |  |  |  |  | *ICH GCP E6 5.18.4(m)(iii)*  *FDA 21 CFR 312.62(b), 812.140(3)(iii)* |
| 103. 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) FDA 21 CFR 812.140(3)(iii)* |
| 104. Was the correct investigational treatment regimen followed? (dose, randomization, compliance) |  |  |  |  |  | *ICH GCP E6 5.18.4 (c)(ii), 5.18.4(m(ii) FDA 21 CFR 312.60, 312.62* |
| 105. Are copies of the orders or prescriptions for the investigational/study product on file in the subject chart? |  |  |  |  |  | *ICH GCP E6 1.33, 4.6, 8.3.23*  *FDA 21 CFR 312.62(a), 812.140(3)(iii)* |
| 106. Is the investigational/study product being properly accounted for this subject? |  |  |  |  |  | *ICH GCP E6 1.33, 4.6.3, 8.3.23*  *FDA 21 CFR 312.62(a), 812.140(3)(iii)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Adverse Events** | **Yes** | **No** | | **N/A** | **Not**  **Reviewed** | **References** |
| 107. Is all adverse event information complete (e.g., type, grade, dates/duration, attribution, reviewed/signed by investigator)? |  |  |  |  |  | *ICH GCP E2A III, E6 1.2, 5.18.4(m)(iii)* |
| 108. Was the occurrence of new adverse event indicated on the corresponding visit source document? |  |  |  |  |  | *ICH GCP E6 5.18.4(m)(iii) FDA 21 CFR 312.62(b)* |
| 109. If subject reports new health problems (e.g. study diary, questionnaire, etc.), do these correspond to the adverse event source document? |  |  |  |  |  | *ICH GCP E6 5.18.4(m)(iii) FDA 21 CFR 312.62(b)* |
| 110. Do concomitant medications taken for an adverse event correspond to AE start/stop times? |  |  |  |  |  | *ICH GCP E6 5.18.4(m)(iii)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Adverse Events (continued)** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 111. Clinically significant findings (e.g. laboratory or other diagnostic values) were documented appropriately? |  |  |  |  |  | *ICH GCP E6 2.7, 4.3.1, 4.3.2, 4.11.2, 5.18.4(m)(iii) FDA 21 CFR 312.62(b)* |
| 112. Were clinically significant findings documented as adverse events? |  |  |  |  |  | *ICH GCP E6 2.7, 4.3.1, 4.11.2, 5.18.4(m)(iii) FDA 21 CFR 312.62(b)* |
| 113. Were SAE(s) reported appropriately? |  |  |  |  |  | *ICH GCP E2A III, E6 4.11.1, 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*  *FDA 21 CFR 312.32, 312.62(b)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Protocol Deviations** | **Yes** | **No** | | **N/A** | **Not Reviewed** | **References** |
| 114. Were protocol deviations/exceptions reported to the IRB, as necessary? |  |  |  |  |  | *ICH GCP E6 3.3.8(a), 4.5.1, 4.5.2, 4.5.3, 4.5.4,*  *5.3.7, 5.18.4(l), 5.18.4(q)*  *FDA 21 CFR 56.108, 812.140(4)* |

**Notes:**

Form Completed By: Date: