# SUBJECT CHART SELF-AUDIT TOOL

## PROTOCOL INFORMATION

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## SUBJECT CHART REVIEW

*(Ensure the following have been done for each participant)*

*Date of Initial Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject’s Age at Initial Consent: \_\_\_\_\_\_\_\_\_*

*If minor age at Initial Consent, did subject reach age of majority during participation? \_\_\_\_\_\_\_\_\_\_*

*If so, date: \_\_\_\_\_\_\_\_\_\_\_\_\_*

*Dates of any additional consent/re-consents: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Note: Both the original process and/or documents used to obtain consent/assent, and any additional processes/documents used for the purposes of reconsent during a subject’s participation should be evaluated against the subsequent requirements.*

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| **Informed Consent / Assent** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| When a subject consent signature is required for participation (as established by the IRB application/approval), is the consent(s) (or short forms, if applicable) present in the subject record (all pages), and personally signed and dated by the subject *(or appropriate LAR(s) and other parties such as a witness, if required)*?  *Note any optional procedures or sub-studies subjects declined to assist with subsequent review of whether any procedures were completed without consent:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  | *ICH GCP E6 (R2) 1.26, 1.28, 4.8.8, 4.8.9, 4.8.11, 4.8.12, 8.3.12*  *FDA 21 CFR 50.27, 312.60, 312.62(b), 812.100, 812.140(a)(3)(i)*  *Common Rule 45 CFR 46.117 (a) and (b) (2)*  *IU HRPP Policies: Informed Consent 2.3, 3.3 (signatures), 3.4 (non-English speakers/non-readers), 3.6 (retention of original documents when reconsent is required); Research Data Management 2.0; Research Personnel Responsibilities 2.4. Also, when applicable: Children in Research 2.1, 2.5, 3.3; Adult Individuals Lacking Consent Capacity 2.1, 3.2* |
| **For Non-English Speaking/Reading Subjects:**  If a non-English short form (or, for non-readers, an oral presentation) was used to enroll the subject, was the full study consent document subsequently translated (or, for non-readers, provided in an accessible format) and used to reconsent the subject?  *Note if an exception to this requirement applies:*  *\_\_\_ Research procedures are minimal risk, or*  *\_\_\_ Study participation is short term and will be completed before consent document could be translated, or*  *\_\_\_ IRB granted exception*  Was use of short form reported to the IRB?  If yes, Renewal number/date:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  | *ICH GCP E6 (R2) 1.26, 4.8.6, 4.8.9, 8.3.12*  *FDA 21 CFR 50.27*  *Common Rule 45 CFR 46.117 (b)*  *IU HRPP Policies: Informed Consent 3.4, IRB Review Process 3.6*  *IU HRPP Guidance: Informed Consent* |

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| **Informed Consent / Assent** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| **For Minor or ILCC Subjects:**  If written assent was required, is the original assent document present in the subject record (all pages) and personally signed by the minor subject or lLCC subject?  *Note: If written assent for the minor / ILCC subject was not required (due to age of minor and/or as a result of IRB approval to not require written assent for a study), this would be N/A.* |  |  |  |  | *ICH GCP E6 (R2) 4.8.12*  *FDA 21 CFR 50.55(g)*  *Common Rule 45 CFR 46.408(a) & (e)*  *IU HRPP Policies: Adult Individuals Lacking Consent Capacity in Research 2.0, 2.2; Children in Research 2.4, 3.2* |
| ***For Adult ILCC Studies:***  *For any individual potentially lacking consent capacity:*   * *was subject appropriately assessed for capacity according to the IRB-approved procedures prior to consent, and, if applicable, on an ongoing basis during participation?* * *were the capacity assessment process and outcomes of that assessment documented?* * *if subject was found to lack consent capacity, was the process for identifying the highest priority LAR(s), their reasonable availability, and communication attempts to those LAR(s) documented?*   ***AND***   * *if subject lost capacity during participation, was LAR consent obtained to continue participation at first required reconsent? or* * *if subject regained capacity during participation, was consent obtained from subject prior to the continuation of study procedures?* |  |  |  |  | *IU HRPP Policies: Adult Individuals Lacking Consent Capacity 2.1, 3.2, 3.3*  *(Documentation of attempts to reach each potential LAR must provide evidence for a minimum of 3 attempts over a minimum of 48 hours, or compliance with an alternative IRB-approved plan, to establish an LAR as not reasonably available.)*  *IU HRPP Guidance: Research with adult individuals lacking consent capacity* |
| **For Children Category 406 Studies:**  *(As classified under 45 CFR 46.406)*  If both parents’ signatures were not obtained for the minor subject’s participation, was the exception from obtaining second parent's consent documented (second parent documented as deceased, unknown, incompetent, or not reasonably available, or documentation that only one parent has legal responsibility for care and custody)? |  |  |  |  | *FDA 21 CFR 50.55(e)(2)*  *Common Rule 45 CFR 46.408 (b)*  *IU HRPP Policies: Children in Research 2.5, 3.3*  *(If exception is that second parent is "not reasonably available", documentation demonstrates at least 3 attempts to contact over at least 48 hours, or compliance with an alternative IRB-approved plan.)* |
| **For Children Studies:**  Upon reaching the legal age of majority (or upon achieving status under Indiana law as a minor who can consent for self), was the subject appropriately consented as an adult participant prior to continuation of study procedures? |  |  |  |  | *IU HRPP Policies: Children in Research 2.1, 3.4*  *IU HRPP Guidance: Conducting research with children* |

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| **Informed Consent / Assent** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Are the consent(s)/assent(s) the appropriate version for the date on which consent/assent was obtained?   * Was consent obtained during a time period in which the study team was aware of new or increased risks that were not reflected in the IRB-approved informed consent document? (i.e., during a period in which an amendment to increase risks or add new risks was being submitted or processed)   *Note: study teams must not enroll new subjects until the revised informed consent document incorporating these risks is reviewed and approved by the IRB.* |  |  |  |  | *ICH GCP E6 (R2) 4.4.1, 4.8.1, 4.8.2*  *IU HRPP Policies: Informed Consent 3.6* |
| **When the IRB approved consent process includes a *conversation*:**  *(Note: Per IU HRPP Policy on Informed Consent 3.2, the IRB must approve a consent process which does not include a conversation)* | | | | | |
| When written consent for participation was required, did the *Person Obtaining Consent (POC) sign and date the consent document?* |  |  |  |  | *ICH GCP E6 (R2) 4.8.8*  *IU HRPP Policies: Informed Consent 3.3* |
| Does the POC signature date match (or pre-date, the subject(s)? (or is the inconsistency otherwise explained in the research records?)  *Note: Earlier date by the POC could occur, for example, if the subject took the consent document home following the consent conversation to further consider.* |  |  |  |  | *ICH GCP E6 (R2) 4.8.8*  *IU HRPP Policies: Informed Consent 3.3*  *IU HRPP Guidance: Informed Consent* |
| **When a subject signature is required:** | | | | | |
| If the consent conversation did not occur in person (face-to-face), was the subject (or LAR) provided with a copy of the consent document prior to the conversation?  If the subject signed the document remotely:   * Was the subject (or LAR’s) signature received and verified by the study team prior to conducting study procedures? * Did the study team document their receipt of the signed document by signing/dating upon receipt? *(Note: as described in IU guidance, best practice includes documentation by the study team to verify when signature was received / confirmed)* |  |  |  |  | *IU HRPP Policies: Informed Consent 3.3*  *IU HRPP Guidance: Informed Consent* |
| Were consent(s)/assent(s) signed by the subject/LAR prior to start of study procedures?  *Documentation of this principle is required by certain regulations\*. If the time of consent/assent signatures and other study procedures are not documented in the subject record to permit verification, the narrative documentation of the informed consent/assent process should include a statement to this effect to fulfill this requirement.* |  |  |  |  | *ICH GCP E6 (R2) 4.8.8*  *FDA 21 CFR 50.20, CFR 312.62(b)\*, 812.140(a)(3)(i)\**  *Common Rule 45 CFR 46.116 (a)(1)*  *IU HRPP Policies: Informed Consent 2.0, 3.3* |

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| **Informed Consent / Assent** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Is the informed consent process documented in the subject record including:   * when a subject signature is required, the subject (or LAR) was given ample time to read/review the document; * all of the subject’s (or LAR’s) questions were answered; * when a subject signature is required, a copy of the informed consent was offered/provided to the subject to keep?   *Note: The process of reconsent (or notification of new information through other methods) should also be documented in the subject record.* |  |  |  |  | *ICH GCP E6 (R2) 4.8.7, 4.8.11*  *FDA 21 CFR 50.27(a)*  *Common Rule 45 CFR 46.116 (a)(4)*  *IU HRPP Policies: Informed Consent 2.3 (subject/LAR provided with adequate time to read the document, or form is read to subject/LAR; and copy given); 3.2 (exchange of information typically through a conversation; opportunity for questions to be answered), 3.6 (documentation of reconsent process)*  *IU HRPP Guidance: Informed Consent*  *(FDA regulations & IU Policy allow subjects to receive either a signed or unsigned copy of consent; GCP requires the copy to be a signed copy)* |
| Did the consent process follow the IRB-approved plan, and was the Person Obtaining Consent IRB-approved for this function *(i.e. as key personnel for studies that are greater than minimal risk)*? |  |  |  |  | *ICH GCP E6 (R2) 4.8.3, 4.8.5*  *IU HRPP Policies: Informed Consent 2.3, 3.2; Research Personnel Responsibilities 2.3*  *IU HRPP Quick Guide: Research Personnel* |
| If consent was revised and reconsent (or notification) was required, was the subject/LAR reconsented (or notified) in an appropriate\* timeframe?  *\*If reconsent (or notification of subjects) was required, the process should follow the IRB-approved plan outlined at the time of consent form revision/approval; if a timeline for reconsent/notification was not specified in the amendment submission, the timeliness of reconsent/notification then depends on the seriousness of the new information, but should be accomplished prior to exposing the subject to the new risk or new procedure.* |  |  |  |  | *ICH GCP E6 (R2) 4.8.2, 4.8.11*  *IU HRPP Policies: Informed Consent 3.6; Research Personnel Responsibilities 2.4* |
| If study/consent includes optional procedures, were only those procedures for which the subject gave permission completed?  *Note: A subject/LAR may also change their decision upon reconsent and optional procedures must then discontinue and/or be terminated (i.e., storage of samples for future research)* |  |  |  |  | *IU HRPP Policies: Informed Consent 2.3, 3.6* |
| If consent was withdrawn, was data collection discontinued? *(or was the subject’s permission to continue to follow his/her health and collect clinical data from his/her medical records after withdrawal from the research interventions obtained?)* |  |  |  |  | *IU HRPP Policies: Informed Consent 3.7* |

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| **Authorization** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| When a subject signature is required for participation, is the authorization present in the subject record (all pages), personally signed by the subject/LAR and dated with the date of signature? |  |  |  |  | *HIPAA Privacy Rule 45 CFR 164.508(c)(1)(vi)*  *IU HRPP Policies: Use of PHI in Research 2.1, 3.2* |
| **For Adult ILCC Studies:**  If a subject regained capacity during participation, was appropriate authorization provided by the subject prior to the collection of additional health information? |  |  |  |  | *IU HRPP Policies: Adult Individuals Lacking Consent Capacity 3.3*  *IU HRPP Guidance: Research with adult individuals lacking consent capacity* |
| **For Children Studies:**  Upon reaching the legal age of majority, did the subject for whom authorization was initially provided by a parent/guardian (as a minor) provide appropriate self-authorization as an adult prior to the collection of additional health information? |  |  |  |  | *IU HRPP Policies: Children in Research 3.4* |
| Are all authorizations complete with subject name and address *(address is a required field per Indiana State Law)*, and if applicable, legal authority section? |  |  |  |  | *HIPAA Privacy Rule 45 CFR 164.508(c)(1)(vi)*  *Indiana Code §16-39-1-4*  *IU HRPP Policies: Use of PHI in Research 2.1* |
| Is it documented that subject was given a copy of the signed and completed HIPAA Authorization Form? |  |  |  |  | *HIPAA Privacy Rule 45 CFR 164.508(c)(4)*  *IU HRPP Policies: Use of PHI in Research 2.1* |
| Are the subject’s records absent of evidence to suggest non-authorized access, use, or disclosures?  *Note: including access or use of PHI by a non-IRB-approved study team member, and/or disclosure to a non-approved/non-specified entity (i.e., not identified on Authorization form)?* |  |  |  |  | *HIPAA Privacy Rule 45 CFR 164.508(a)*  *IU HRPP Policies: Research Personnel Responsibilities 2.1, 2.5; Use of PHI in Research 2.1, 3.6*  *IU HRPP Quick Guide: Research Personnel* |

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| **Recruitment** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Was this subject recruited according to the IRB approved recruitment procedures and with IRB approved recruitment materials? |  |  |  |  | *FDA Guidance for IRBs and Clinical Investigators: Recruiting Study Subjects*  [*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects)  *For FDA-regulated research, the IRB must review and approve the FINAL versions of any printed, audio, or video advertisements.*  *IU HRPP Policies: Recruitment of Human Subjects 2.1; Use of PHI in Research 3.3* |

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| **Eligibility** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Is there appropriate documentation that the subject met/didn’t meet eligibility criteria *(including applicable medical records to confirm subject’s eligibility)?*   * Were all screening or pre- enrollment / randomization activities completed per protocol? * Were all eligibility criteria available and reviewed prior to continuing with post-screening procedures (including prior to exposure to the study intervention)? |  |  |  |  | *ICH GCP E6 (R2) 4.5.1, 4.5.2*  *FDA 21 CFR 312.60, 812.100*  *IU HRPP Policies: Research Personnel Responsibilities 2.3, 2.4* |
| * If not, are approval waivers present *(from both the sponsor, if applicable, and the IRB)* for the inclusion/exclusion criteria not fulfilled by (or not reviewed for) the subject? |  |  |  |  |
| Was eligibility assessed by an appropriately qualified and delegated individual (including personnel designation in the IRB application)?  *Is the final eligibility determination attributable to the individual performing this task (i.e., by a signature and date at the time of review)?* |  |  |  |  | *ICH GCP E6 (R2) 2.8, 4.1.5, 4.3.1*  *FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects* [*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)  *IU HRPP Policies: Research Personnel Responsibilities 2.1; Research Data Management 2.0*  *IU HRPP Quick Guide: Research Personnel* |
| During the subject’s participation, did the subject experience any change in vulnerable status, such as:   * Appointment of a medical guardian (guardian of person) * Loss of decisional capacity * Pregnancy * Becoming a prisoner   If yes, was the subject’s continued participation, reviewed and approved by the IRB (if the research was not already approved to include the relevant vulnerable population)? |  |  |  |  | *IU HRPP Policies: Adult Individuals Lacking Consent Capacity in Research 3.1; IRB Review Process 2.3; Prisoners in Research 3.2, 3.3; Research Personnel Responsibilities 2.4* |

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| **Study Intervention**  **& Outcomes** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Was the study intervention\* - whether biomedical or social/behavioral in nature – administered according to the protocol (or IRB approved plan) and under PI supervision (if applicable)?  *(including randomization, protocol required order of procedures, and for interventions involving an investigational biologic/drug/device product\*, was the product given, applied, or implanted according to the protocol, with appropriate dose and infusion rates for drugs/biologics, and/or with co-administered drugs or procedures, etc.)*  *\*(includes both investigational interventions and/or SOC interventions required by protocol)* |  |  |  |  | *ICH GCP E6 (R2) 4.2.5, 4.3.1, 4.6, 4.7, 8.3.23*  *FDA 21 CRF 312.61, 312.62 (a) and (b); 812.110 (b) and (c), 812.140(a)(2) and (a)(3)(iii)*  *IU HRPP Policies: Research Personnel Responsibilities 2.3, 2.7* |
| * Were adjustments in the study intervention done according to protocol or for appropriate medical care of subjects (if applicable)?   *(including required intervention or dose modifications, or device removal, due to adverse events or subject compliance; may include sponsor consultation/notification if required, etc.)* |  |  |  |  |
| * For interventions involving an investigational biologic, drug, or device product, is the investigational/study product(s) being properly documented and accounted for this subject? |  |  |  |  |
| Were tests/procedures completed per protocol and by appropriately qualified and delegated individuals? |  |  |  |  | *ICH GCP E6 (R2) 2.6, 2.8, 4.1.5, 4.2.4, 4.5*  *FDA 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* [*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)  *FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors – FDA Inspections of Clinical Investigators* [*http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf*](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf)*, Sec. IV*  *IU HRPP Policies: Research Personnel Responsibilities 2.1, 2.3* |
| * If a procedure, or visit, was missed or not completed, was it documented as a deviation and further explained? |  |  |  |  |
| Were all interactions/visits completed within the allotted time windows? |  |  |  |  |
| * If not, is this documented as a deviation and further explained? |  |  |  |  |
| Is the reason for subject withdrawal or dropout documented, if applicable? Was appropriate safety follow-up completed, if applicable?   * Was the withdrawal reported to the IRB (at renewal or study closure)? |  |  |  |  | *ICH GCP E6 (R2) 4.3.4*  *FDA 21 CFR 312.33 (b)(4), 312.62 (b), 812.140 (a)(3)(ii) and (iii)*  *IU HRPP Policies IRB Review Process 3.6, 3.8; Research Personnel Responsibilities 2.4* |

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| **Data Management** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Are all supporting source documents and CRFs on file?  Are CRFs complete and consistent with source data? |  |  |  |  | *ICH GCP E6 (R2) 1.9, 1.11, 1.22, 1.23, 1.51, 1.52, 1.63, 2.10, 4.9.0 – 4.9.5, 8.3.13. 8.3.14*  *(GCP E6 4.90 requires records to be attributable, legible, contemporaneous, original, accurate, and complete with changes traceable, not obscuring the original entry, and explained if necessary, via an audit trail)*  *FDA 21 CFR 312.62(b), 812.140 (a)*  *IU HRPP Policies: Research Data Management 2.0, 3.1; Research Personnel Responsibilities 2.5*  *(IU policy requires recordkeeping to enable the reconstruction of the entire study process, including retention of source documents, and to enable verification of the accuracy of all data with sufficient clarity, completeness, and organization that an external reviewer could readily determine that the IRB approved protocol was followed, institutional policies were followed, data are true and accurate, and regulatory requirements have been met)* |
| Do all source documents include documentation of the observer/ recorder of the information? |  |  |  |  |
| For paper documents, have all observations/data been recorded legibly, and in ink? |  |  |  |  |
| Are all revisions lined through once (so original entry is legible), dated, and initialed by the editor? |  |  |  |  |
| Was data completed in a timely manner (e.g., are CRFs up to date)? |  |  |  |  |
| Are the subject’s charts/source documents stored, and transmitted (if applicable) in a secure manner and in accordance with the IRB approved plan? |  |  |  |  | *ICH GCP E6 (R2) 2.11*  *IU HRPP Policies: Research Personnel Responsibilities 2.5; Use of PHI in Research 3.1*  *IU UITS Knowledge Base:*   * *"About confidential information in email"* [*https://kb.iu.edu/d/aktv*](https://kb.iu.edu/d/aktv) * *"Ensure that mail sent from your Exchange account to an outside address is encrypted by CRES"* [*https://kb.iu.edu/d/bbum*](https://kb.iu.edu/d/bbum) |
| Is there appropriate documentation of retained body fluids or tissue samples (if applicable)? |  |  |  |  | *ICH GCP E6 (R2) 8.3.25*  *IU HRPP Policies: Research Data Management 2.0* |
| Do the records include documentation of subject compensation (if applicable)? Did the compensation align with the IRB-approved plan? |  |  |  |  | *IU HRPP Policies: Recruitment of Human Subjects 3.1; Research Data Management 2.0* |

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| **Medical/Safety Oversight**  **and Adverse Events** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Did the investigator document ‘clinically significant’ or ‘not clinically significant’ for all out-of-range values and/or results (laboratory values, physical exam findings, ECG results, imaging results, etc.)? |  |  |  |  | *ICH GCP E6 (R2) 1.2, 2.7, 4.3.1, 4.3.2* |
| Have all adverse events (AEs) been appropriately identified and documented (including severity, relatedness, expectedness, dates/duration, and reviewed/signed off by a medically qualified and delegated individual)?  Tips for ensuring all AEs have been identified/captured:   * If subject reports new health problems or transient symptoms (e.g. within the study diaries, questionnaires, interviews, etc.), have these been recorded as AEs? * Have clinically significant findings (e.g. laboratory values, or findings from physical exams, ECGs, imaging or other procedures, etc.) been documented appropriately as AEs? * Have concomitant medications been started or stopped? New meds, change in doses, etc., usually correspond to a change in medical status or symptoms (i.e. an AE); also, do con med start/stop dates taken for an AE correspond to AE start/stop times? |  |  |  |  | *ICH GCP E6 (R2) 1.1, 1.2, 1.50, 1.60, 2.7, 4.1.2, 4.3.1, 4.3.2, 4.11.2*  *FDA 21 CFR 312.62 (b), 312.64(b), 812.140(a)(3)(ii)*  *FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects* [*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)  *IU HRPP Policies: Research Personnel Responsibilities 2.1; Research Data Management 2.0, 3.1* |
| Were AEs reported appropriately (to IRB promptly, if applicable, and to sponsor, etc.)? |  |  |  |  | *ICH GCP E6 (R2) 1.1, 1.50, 1.60, 4.11, 8.3.16, 8.3.17*  *FDA 21 CFR 312.62(b), 312.64 (b), 812.140 (a)(1) and 812.140(a)(3)(ii)*  *IU HRPP Policies: Research Personnel Responsibilities 2.3; Reportable Events 2.1, 2.3* |

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| **Protocol Deviations**  **(Assessment and Reporting)** | **Yes** | **No** | **N/A** | **Not**  **Reviewed** | **REFERENCES** |
| Is documentation of assessment for prompt reporting present? |  |  |  |  | *IU HRPP Policies: Reportable Events 2.1, 2.2, 2.3; Research Personnel Responsibilities 2.1*  [*IU*](file:///\\ads.iu.edu\hnetfs\IU-VPR\Group\ORC\HRPP\QIO\Auditing%20(HSR)\Administrative\Website\Future\IU) *HRPP Guidance: Reportable Events* |
| Were protocol deviations/exceptions reported to the IRB, as necessary? (prior to implementation; promptly, or annually) |  |  |  |  | *ICH GCP E6 (R2) 4.5.1 – 4.5.4*  *FDA 21 CFR 56.108, 312.66, 812.140(4) and 812.150(4)*  *IU HRPP Policies: Reportable Events 2.1, 2.2, 2.3; Research Personnel Responsibilities 2.1*  [*IU*](file:///\\ads.iu.edu\hnetfs\IU-VPR\Group\ORC\HRPP\QIO\Auditing%20(HSR)\Administrative\Website\Future\IU) *HRPP Guidance: Reportable Events* |

Form Completed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_