**HRPO ID:**

**Title:**

**Principal Investigator/Project Director:**

**Previous PI (if applicable):**

**Campus/Department/Division:**

**Current Status (***check one***):**

[ ]  Project is currently **open** to participant enrollment

[ ]  Project is closed to participant enrollment but participants are still actively participating in the study

[ ]  Project is closed to participant enrollment and participation is complete

[ ]  Other, please explain:

**Section 1: Self-Audit Directives**

[Brief paragraph highlighting the reason for requesting the PI to conduct a self-audit. Insert any specific directives that the PI is to focus on (compliance with CAPA, informed consent self-audit only etc.]

[To be completed by office directing the self-audit]

**Section 2: Study/Enrollment Status**

**Current Reported Enrollment Status**

|  |  |
| --- | --- |
| Adult Participant Enrollment Status |  |
| * Number of participants currently approved to enroll:
 |  |
| * Number of participants consented to date:
 |  |
| * Number of participants consented but screen-failed:
 |  |
| * Number of participants withdrawn:
 |  |
| * Number of currently active participants:
 |  |
| * Number of participants in follow-up/long term follow-up:
 |  |
| * Number of participants who have completed participation:
 |  |

|  |  |
| --- | --- |
| Minor Participant Enrollment Status |  |
| * Number of participants currently approved to enroll:
 |  |
| * Number of participants consented to date:
 |  |
| * Number of participants consented but screen-failed:
 |  |
| * Number of participants withdrawn:
 |  |
| * Number of currently active participants:
 |  |
| * Number of participants in follow-up/long term follow-up:
 |  |
| * Number of participants who have completed participation:
 |  |

|  |  |
| --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** |
| Are you maintaining electronic or hardcopy documentation to track participant enrollment (e.g. a log that lists all participants who signed consent-including screen-failures- and documents whether they were enrolled the study)? | [ ]  Yes, if yes please provide a copy of the log. [ ]  No, if no then complete the attached site screening and enrollment source |
| Did the number of participant(s) who signed informed consent/assent (*including those who screen-failed*) ever exceed the total number approved by the IRB according to myIRB application section 2.1a and/or 2.2b? | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| Was any participant(s) enrolled in the study more than one time? | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |

**Section 3: Informed Consent**

|  |  |
| --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** |
| **Were there any Expired/Outdated Consent documents?*** Refer to myIRB to confirm what consent(s) should have been executed during a particular timeframe.
* When a change is made to a consent document, no matter how small, that newer version should be used once it is approved.
* ***Please note***, when a project is open to enrollment, at continuing review a newly stamped consent document is always approved.
	+ This occurs even if there were no changes made to the consent document during the continuing review.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Invalid Consent documents?** * A consent is considered invalid if there is not a HRPO stamp on every page, if the consent document itself is missing pages, if any part of the consent document text is cut off/missing or unreadable.
* Example of an invalid stamp:

C:\Users\morrisam\Documents\My Received Files\5448FC4A.PNG | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Missing Consent documents?*** Confirm that you have a signed consent document on file for each participant enrolled, including screen-failures and any participant who has been withdrawn.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was the correct type of consent document used on the correct participant population?** * For example, did the healthy control participant sign the healthy control consent document or did they sign a consent intended for the disease control population?
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Study Procedures Executed Prior to or without Consent?*** Check the informed consent signature date of the participant and compare it to the date the first study procedure was completed/occurred.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Answerable Items Left Blank or Incorrectly Executed in the consent documents?*** Answerable items should be initialed by the participant or the participant’s parent/legal guardian/and/or legally authorized representative.
* Check marks or X should not be used
* If an answerable item is left blank, it must be treated as “no” and would be considered incorrectly executed.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was there any Participant Signature Boxes that were Incorrectly Executed or Left Blank?*** Participant signature boxes should be completed to the fullest extent by the participant.
	+ No one other than the participant should complete any component of the participant’s signature box.
* Anything left blank would be considered incorrectly executed.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was there any Legally Authorized Representative (LAR) Signature Boxes that were Incorrectly Executed or Left Blank?*** LAR signature boxes should be completed to the fullest extent by the LAR.
	+ No one other than the LAR should complete any component of the LAR’s signature box.
* Anything left blank would be considered incorrectly executed
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was there any Consent documents that were Obtained from Non-Verified or Incorrect LAR?*** If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.
* If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.
	1. Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
	2. Adult child;
	3. Parent;
	4. Brother or sister;
	5. Relative by blood or marriage.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Parent/Legal Guardian Signature Box Sections Incorrectly Executed or Left Blank?*** Parent/legal guardian signature boxes should be completed to the fullest extent by the parent/legal guardian.
	+ No one other than the parent/guardian should complete any component of the parent/guardian signature box.
* Anything left blank would be considered incorrectly executed.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Consent documents Obtained from Non-Verified or Incorrect Parent/Guardian?*** If the participant has a legal guardian or attorney-in-fact this individual must sign as the parent/legal guardian.
* Please note, caregivers, step-parents, grandparents etc. are not considered legal guardians unless official paperwork has been filed and approved by the court.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were the PI/Designee Signature Box Sections completed by the person who obtained consent from the participant?*** PI/Desginee signature boxes should be completed to the fullest extent by the person who obtained consent from the participant.
	+ No one other than the person who obtained consent from the participant should complete any component of this signature box.
* Anything left blank would be considered incorrectly executed.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was Consent Obtained by a Non-HRPO Approved Person?*** Review myIRB myProject section 3 to see who is designated as “yes” to consent process involvement in the research team section.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Signature Date Discrepancies?*** Review the signature dates on the informed consent document(s):
	+ Were they signed on different days? If yes, can you tell why?
	+ The PI/Designee should never sign prior to the participant.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Expired Assent/Outdated Assent documents used?*** Refer to myIRB to confirm what assent(s) should have been executed during a particular timeframe.
* When a change is made to an assent document, no matter how small, that newer version should be used once it is approved.
* ***Please note***, when a project is open to enrollment, at continuing review a newly stamped assent document is always approved.
	+ This occurs even if there were no changes made to the assent document during the continuing review.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Assent documents that were Incorrectly Executed or Left Blank?*** If the myIRB section 2.4 details that minor individuals are providing written assent, please review to ensure assent was obtained in accordance with what was approved.
* Minor assent documents should be completed to the fullest extent by the minor participant.
	+ No one other than the minor participant should complete any component of the minor participant’s signature box.
* Anything left blank would be considered incorrectly executed.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were there any Study Procedures Executed Prior to or without assent?*** Check the assent signature date of the minor participant and compare it to the date the first study procedure was completed/occurred.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was there any documentation of verbal consent/assent?*** When documenting verbal consent, at a minimum, the research records should contain documentation of the:
	+ date of the conversation,
	+ version of the consent/assent document used,
	+ person who obtained verbal consent/assent from the participant, and the
	+ response the participant gave to participating in the study.
 | [ ]  Yes [ ]  No, If no please explain belowExplanation: |

**Section 4: Confidentiality / Privacy**

|  |  |
| --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** |
| **Was any Data Collected Outside of the consent or HIPAA authorization?*** Review myIRB protocol section 1.8.a or myIRB 1.24 to confirm what can be accessed prior to obtaining HIPAA authorization/consent from the participant.
 | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Was any Data or Specimens shared outside of the research team?** | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |
| **Were Research Records Maintained According to Section 5 of the myIRB Application?** | [ ]  Yes [ ]  No, if no please explain belowExplanation: |

**Section 5: Eligibility of Participants**

|  |  |
| --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** |
| **Is there inclusion/exclusion documentation on file for each participant?*** Documentation should include that inclusion/exclusion criteria were met prior to study entry and should also document the source it was verified from (*per participant, per the medical records, etc*.) as well as who completed the verification (research team member).
* If interviewing participants was used as a method of verifying eligibility, there should be documentation that captures the participant’s response and a place for the interviewer to sign and date.
 | [ ]  Yes [ ]  No, If no please explain belowExplanation: |
| **Were any participants enrolled that did not meet all inclusion/exclusion criteria?** | [ ]  Yes, If yes please explain below [ ]  NoExplanation: |

**Section 6: Interventions / Observations/ Study Documentation**

|  |  |  |
| --- | --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** | **Participant ID #s** |
| **Prohibited/ Concomitant** | Recordings of Prohibited/Concomitant Medications is consistent and complete between Source Documentation and Case Report Forms (CRF/eCRF)? | [ ]  Yes [ ]  No, If no please explain belowExplanation: |  |
| **Medications** | Protocol prohibited medications are found in Source Documentation/(e)CRF?.  | [ ]  Yes [ ]  No, If no please explain belowExplanation: |  |
| **Study Product administration Process** | Study product has been administered per protocol/MOP and documented accordingly?Please note: This includes a review of the documentation supporting correct mixing procedures, labeling, cold and custody chain, licensed personnel, and blinded/unblinded handling and administration. | [ ]  Yes [ ]  No, If no please explain belowExplanation: |  |
| **Missed Visits and Follow-up** | Has any participant missed one or more study visits?Please note, if yes:* Missed visits should be documented and reported according to protocol and institutional requirements.
* Documentation of attempts to contact the participant should be present in the research record (i.e., phone call, certified mail, etc.)
* If missed visits resulted in a protocol deviation(s), they should be recorded and reported (as appropriate) as protocol deviations.
 | [ ]  Yes, if yes please explain below[ ]  No Explanation: |  |
| **Missed Lab Tests/ Procedures** | Have all protocol-required lab tests and procedures been performed according to protocol?Please note: if yes, missed tests/procedures should be recorded and reported (as appropriate) as protocol deviations. | [ ]  Yes, if yes please explain below[ ]  No Explanation: |  |
| **Study Product / Study Discontinuation** | Have any participants discontinued study product or study visits?Please note, if yes, all protocol-required steps should be followed and documented in the | [ ]  Yes, if yes please explain below[ ]  No Explanation: |  |
| **Source Documentation** | If CRFs are used as source documentation, have they been signed/dated and credentialed as required? * Please note, documentation of CRFs serving as source documents should be noted in the Protocol, MOP, or SD agreement/statement at the beginning of the study

Have all source entries been signed and dated by the person completing them?Have signatures of personnel signing source documentation present in the Staff Signature List or Delegation of Authority Log in the Regulatory File?Have error corrections been properly corrected with a single line and initials and date of the person making the correction?* Please note, it is also best practice to document the reason the correction has been made.
 | [ ]  Yes, if yes please explain below[ ]  No Explanation: |  |
|  |  |  |  |

**Section 7: Safety Monitoring / Adverse Events**

|  |  |  |
| --- | --- | --- |
| **Self-Audit Review Questions** | **Self-Audit Results** | **Participant ID #s** |
| **UP, AE, SAE Identification and Reporting** | UPs, AEs, and SAEs have been identified, recorded, and reported properly and within the protocol specified timelines? | [ ]  Yes [ ]  No, If no please explain belowExplanation: |  |
| **Documentation**  | Protocol prohibited medications are found in Source Documentation/(e)CRF?.  | [ ]  Yes [ ]  No, If no please explain belowExplanation: |  |

**Section 8: Essential Regulatory Documentation at Local Site**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Self-Audit Review Questions** | **Yes** | **No** | **N/A** | **Comments** |
| **Protocol**  | A current and IRB approved copy of the Protocol is on file. All previous versions of the Protocol are on file.Signed versions of the protocol signature page are available for each version of the Protocol.Any lapses have been documented properly. |[ ] [ ] [ ]   |
| **Consent Document(s)** | A current and IRB approved copy of the Consent Document is on file.All previous versions of the Consent Document are on file. Any lapses have been documented properly. |[ ] [ ] [ ]   |
| **Local Regulatory Approvals** | All local, state, and/or special authorizations related to the protocol are maintained and up-to-date. |[ ] [ ] [ ]   |
| **Federal Wide Assurances (FWA)** | Current Federal Wide Assurance and IRB Registration documents for governing regulatory bodies (e.g., IRB), issued from OHRP, are present and include expiration dates. |[ ] [ ] [ ]   |
| **IRB Membership** | The IRB Roster or Membership composition is on file and has been updated annually. If the IRB does not provide a roster, Official IRB documentation is present stating that names are not released. |[ ] [ ] [ ]   |
| **IRB Approvals** | The initial IRB Approval for the Protocol and the Consent Document(s) is present.Continuing Review Approval(s) are present. (Annually)IRB Approvals for information given to study subjects are on file. (Advertisements, Recruitment Scripts, Subject Information Materials)Periodic Reports are present (if applicable).Approvals for any protocol/consent/assent amendments are present. |[ ] [ ] [ ]   |
| **Curricula Vitae (CVs) or Biosketches** | Current CVs or biosketches are present for Principal Investigator and all sub-investigators listed on the 1572. For non-IND studies, CVs should be dated any time on or after the start of the study. For IND studies, CVs should be updated every 2 years. |[ ] [ ] [ ]   |
| **Licenses** | Appropriate Licenses (Dental, Medical) are present and current for Principal Investigator and all sub-investigators listed on the 1572.  |[ ] [ ] [ ]   |
| **Investigator Brochures / Package Inserts** | Investigator Brochures are present, current, and available for investigational products. Documentation of IRB submission is present (if applicable).Package inserts are present, current, and available for approved drugs. Documentation of IRB submission is present (if applicable). |[ ] [ ] [ ]   |
| **1572** | A 1572 (for IND studies) is present and complete.The form is current, accurate, and signed by the PI. |[ ] [ ] [ ]   |
| **Financial Disclosure Forms (IND/IDE)** | Financial disclosure forms for all key personnel are present (if applicable). |[ ] [ ] [ ]   |
| **Sponsor Correspondence** | Documentation of correspondence between the site and sponsor is present and current. |[ ] [ ] [ ]   |
| **Internal Correspondence** | Documentation of internal correspondence is present and current.  |[ ] [ ] [ ]   |
| **Final Reports** | The Final Report to the IRB is present (if applicable).The Final Report to the sponsor is present (if applicable). |[ ] [ ] [ ]   |
| **Notes to File** | Relevant study-specific notes to file / numbered memos are present. |[ ] [ ] [ ]   |
| **Delegation of Responsibilities Log** | The Delegation of Responsibilities Log is present and current for all individuals authorized to make entries in study records or participate in protocol execution. |[ ] [ ] [ ]   |
| **Subject Code List** | The Subject Code List is present. This is a list that links patient names to subject IDs. (It often exists in a secured location separate from the remainder of the study file.) |[ ] [ ] [ ]   |
| **Site Screening and Enrollment Log** | The Site Screening and Enrollment Log is present and up-to-date. |[ ] [ ] [ ]   |
| **Investigational Product** | Investigational Product Accountability Records are present, accurate, and current. Records reconcile with current IP inventory. (Records must be able to link batch numbers to subjects.)Instructions (protocol-specific MOP) for the storage, mixing, and handling of Investigational Product are present, or their location is specified and easily accessible.Randomization list and decoding procedures for Masked Investigational Product are present.Investigational Product Temperature Logs are present, or their location is specified and easily accessible.Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers of all test articles (if open-label study) are present and current. |[ ] [ ] [ ]   |
| **Laboratory Normals and Accreditations** | Laboratory certifications and accreditations are present for U.S. labs. (CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.) If not a U.S. lab, appropriate certificates of qualification for the lab are present. If not present, a statement is present explaining the reason and a description of the standard being used. Approvals from collaborating Research Laboratories are present. Current and historical Normal Ranges for all protocol-required tests are present. This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. |[ ] [ ] [ ]   |
| **Specimen Tracking Logs** | Specimen Tracking Logs or Retention Records are present, or their location is specified and easily accessible.  |[ ] [ ] [ ]   |
| **Unanticipated Problems (UPs)** | All UPs are identified and reported according to protocol and IRB requirements. |[ ] [ ] [ ]   |
| **Serious Adverse Events (SAE) and Other Safety** | All SAEs that have been reported to NIDCR/CROMS and the IRB are present. Copies of all study issue “Dear Doctor” letters are present. Copies of all IND Safety Reports are present. |[ ] [ ] [ ]   |
| **Protocol Deviations** | All Protocol Deviations are present, and all relevant deviations that have been reported to the IRB according to IRB requirements.  |[ ] [ ] [ ]   |
| **Monitoring Visit Logs and Associated Visit Documents** | Monitoring Visit Logs and associated visit documentation are present. (Site Initiation, Interim Monitoring, Close-out) |[ ] [ ] [ ]   |
| **Study-specific Procedures / Manual of Procedures** | Current and historical study-specific procedures or the Manual of Procedures (MOP) are present and clearly identifiable as current or historical. |[ ] [ ] [ ]   |
| **Sample Case Report Forms (CRF) / eCRF(s)** | If data are captured on paper CRFs, a blank copy of each approved version is present and easily identifiable as current or historical. |[ ] [ ] [ ]   |

**Section 9: Outcome measures**

**Question to the PI:** Have any presentations, publications and/ or posters been completed from data collected in this study?

**Section 10: Education & Training**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Self-Audit Review Questions** | **Yes** | **No** | **N/A** | **Comments** |
| **CITI Human Subjects Training** | **Did all members of the research team have up to date CITI Human Subjects Training on file?** |[ ] [ ] [ ]   |
| **HIPAA 101** | **Did all members of the research team complete HIPAA 101 training?**Please note, all workforce members at the Medical School are required to complete HIPAA online training. If training has been completed through BJC, it is a good practice to keep a copy of that training on file for your research team members. |[ ] [ ] [ ]   |
| **Good Clinical Practice**  | **Did all members of the research team have completed GCP training?** *\*Please review Washington University’s Policy on Good Clinical Practice Training:* * + Washington University requires all faculty, staff, students, or other personnel engaged in the conduct, oversight, or management of *clinical trials* (*as defined by the NIH’s definition of a clinical trial*) to complete training in Good Clinical Practice (GCP) every 3 years: <https://research.wustl.edu/good-clinical-practices/>
* Email ovcrinfo@wustl.edu​ with questions concerning the Education in Good Clinical Practices Policy, and your message will be forwarded to the appropriate office(s).
 |[ ] [ ] [ ]   |

**Section 11: Multi-Site Management Issues**

**Summary of Multi-Site Management Findings [if applicable]**

***[Separate findings by site]***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Self-Audit Review Questions** | **Site #1** | **Site #2** | **Site #3** | **Site #4** | **Site #5** | **Comments** |
| **Protocol**  | A current and IRB approved copy of the Protocol is on file. All previous versions of the Protocol are on file.Signed versions of the protocol signature page are available for each version of the Protocol.Any lapses have been documented properly. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Consent Document(s)** | A current and IRB approved copy of the Consent Document is on file.All previous versions of the Consent Document are on file. Any lapses have been documented properly. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Local Regulatory Approvals** | All local, state, and/or special authorizations related to the protocol are maintained and up-to-date. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Federal Wide Assurances (FWA)** | Current Federal Wide Assurance and IRB Registration documents for governing regulatory bodies (e.g., IRB), issued from OHRP, are present and include expiration dates. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **IRB Membership** | The IRB Roster or Membership composition is on file and has been updated annually. If the IRB does not provide a roster, Official IRB documentation is present stating that names are not released. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **IRB Approvals** | The initial IRB Approval for the Protocol and the Consent Document(s) is present.Continuing Review Approval(s) are present. (Annually)IRB Approvals for information given to study subjects are on file. (Advertisements, Recruitment Scripts, Subject Information Materials)Periodic Reports are present (if applicable).Approvals for any protocol/consent/assent amendments are present. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Curricula Vitae (CVs) or Biosketches** | Current CVs or biosketches are present for Principal Investigator and all sub-investigators listed on the 1572. For non-IND studies, CVs should be dated any time on or after the start of the study. For IND studies, CVs should be updated every 2 years. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Licenses** | Appropriate Licenses (Dental, Medical) are present and current for Principal Investigator and all sub-investigators listed on the 1572.  | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Investigator Brochures / Package Inserts** | Investigator Brochures are present, current, and available for investigational products. Documentation of IRB submission is present (if applicable).Package inserts are present, current, and available for approved drugs. Documentation of IRB submission is present (if applicable). | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **1572** | A 1572 (for IND studies) is present and complete.The form is current, accurate, and signed by the PI. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Financial Disclosure Forms (IND/IDE)** | Financial disclosure forms for all key personnel are present (if applicable). | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Sponsor Correspondence** | Documentation of correspondence between the site and sponsor is present and current. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Internal Correspondence** | Documentation of internal correspondence is present and current.  | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Final Reports** | The Final Report to the IRB is present (if applicable).The Final Report to the sponsor is present (if applicable). | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Notes to File** | Relevant study-specific notes to file / numbered memos are present. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Delegation of Responsibilities Log** | The Delegation of Responsibilities Log is present and current for all individuals authorized to make entries in study records or participate in protocol execution. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Subject Code List** | The Subject Code List is present. This is a list that links patient names to subject IDs. (It often exists in a secured location separate from the remainder of the study file.) | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Site Screening and Enrollment Log** | The Site Screening and Enrollment Log is present and up-to-date. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Investigational Product** | Investigational Product Accountability Records are present, accurate, and current. Records reconcile with current IP inventory. (Records must be able to link batch numbers to subjects.)Instructions (protocol-specific MOP) for the storage, mixing, and handling of Investigational Product are present, or their location is specified and easily accessible.Randomization list and decoding procedures for Masked Investigational Product are present.Investigational Product Temperature Logs are present, or their location is specified and easily accessible.Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers of all test articles (if open-label study) are present and current. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Laboratory Normals and Accreditations** | Laboratory certifications and accreditations are present for U.S. labs. (CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.) If not a U.S. lab, appropriate certificates of qualification for the lab are present. If not present, a statement is present explaining the reason and a description of the standard being used. Approvals from collaborating Research Laboratories are present. Current and historical Normal Ranges for all protocol-required tests are present. This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Specimen Tracking Logs** | Specimen Tracking Logs or Retention Records are present, or their location is specified and easily accessible.  | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Unanticipated Problems (UPs)** | All UPs are identified and reported according to protocol and IRB requirements. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Serious Adverse Events (SAE) and Other Safety** | All SAEs that have been reported to NIDCR/CROMS and the IRB are present. Copies of all study issue “Dear Doctor” letters are present. Copies of all IND Safety Reports are present. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Protocol Deviations** | All Protocol Deviations are present, and all relevant deviations that have been reported to the IRB according to IRB requirements.  | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Monitoring Visit Logs and Associated Visit Documents** | Monitoring Visit Logs and associated visit documentation are present. (Site Initiation, Interim Monitoring, Close-out) | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Study-specific Procedures / Manual of Procedures** | Current and historical study-specific procedures or the Manual of Procedures (MOP) are present and clearly identifiable as current or historical. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |
| **Sample Case Report Forms (CRF) / eCRF(s)** | If data are captured on paper CRFs, a blank copy of each approved version is present and easily identifiable as current or historical. | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A |  |

**Section 12: Miscellaneous**

[Insert any additional findings]

**Section 13: Best Practices**

**Guidance on Best Practice for the Execution of Informed Consent/Assent**

Please review the following ***best practices*** for obtaining informed consent/assent:

* Execute the most current consent/assent document(s).
	+ Printing directly from myIRB can ensure that the most recent version of the consent form is used.
	+ If using a verbal consent or assent process, it is best practice to document this in the research record.
		- This would include, but is not limited to, recording the date of conversation, the participant’s response and the research team member who obtained verbal consent/assent in the research record.
			* However, if documentation of consent was waived because signed consent would be the only record linking the participant to the research, and the principal risk would be potential harm from a breach in confidentiality, consent should **not** be documented.
* Participants must personally complete all sections of the consent form except the PI/Designee section.
	+ The research team **may not** complete components of the consent reserved for the participant (answerable items, printed names, dates etc.).
	+ It is good practice to have the research team member verify that the consent was fully executed during the consent process and conversation.
		- If a participant makes a mistake, it is best practice to have the participant personally correct the mistake and initial and date the correction.
		- Attaching a note to file if you or one of your team notices something is missing (such as a date), is a good idea, but the note to file must also be signed and dated.
	+ If any answerable item is left blank in the consent form, you must treat the answer as if the participant said “no”.
		- It is best practice to record participant’s responses to answerable items. This helps to ensure the appropriate actions are taken in accordance with their indicated responses.
* When dealing with vulnerable populations, please be sure to contact HRPO for guidance on different approaches for obtaining consent.
* It is best practice to use ink when signing the consent documents. Pencil should not be used as signatures can fade or rub off over time.
* Any changes to the content in the consent document or changes to the consent process **must** be approved by HRPO prior to use/implementation.
* All participants must receive a copy of the fully executed and signed consent document.
	+ It is a good practice to document that this was completed.

**Guidance on Best Practice for Study Documentation/Implementation**

Please review the following ***best practices*** for study documentation:

* The research record should contain documentation of each participant’s study involvement. This would include, but is not limited to, participant enrollment status, dates of completed assessments, and complete or incomplete study interventions, questionnaires, and/or assessments.
	+ With hardcopy study documentation, any item not completed should be lined through, initialed and dated.
		- It is not a good practice to document information on post-it notes.
			* Consider creating a source document to capture study information.
		- It is also a good practice to document why a record is incomplete or an assessment could not be obtained.
		- Attaching a note to file or documenting in a running note missing items, dates, incomplete questions, missing assessments, etc., is another way to document why a record is incomplete, but the note to file entry must also be signed and dated.
	+ With electronic study documentation, consider creating a data field to capture any general notes about why study interventions were not completed or were partially complete
* Study interventions as outlined in the myIRB application (including any attached protocols) should be followed without deviation.
	+ Any modifications or deviations from the protocol (no matter how minor) should be approved by HRPO prior to implementation.
	+ It is also important that the attached protocol is consistent with the myIRB application.
* All questionnaires, scales, and/or interviews executed by participants must be approved by HRPO prior to implementation.
* Hardcopy source documents/data collections forms should contain at the very least participant ID and study visit date on each loose page.
	+ It is suggested that this be documented on each loose page in case the files are ever separated.
* Research team members should document each task they perform.
	+ This can be done by creating designated data fields or sections on the data collection forms for PI/Designee signature and date (or initials and date).
	+ It is also important that the designated signature sections are completed to the fullest extent.