

**STUDY COMPLIANCE CHECK LIST**

**Use as the front page of the Study Regulatory Binder**

**SUDY TITLE:** \_\_\_\_\_

<b><u>A. Study Preparation</u></b>	<b><u>Comments</u></b>	<b>Coordinator</b>		<b>PI</b>	
		<b>Signature</b>	<b>Date</b>	<b>Signature</b>	<b>Date</b>
1. <b><u>Responsibility of PI:</u></b> I agree to assume the following responsibilities: a. Understanding of protocol and agreeing to conduct study in accordance of investigational plan, good clinical practice, applicable local, state, and federal regulations. b. Provide administrative oversight for the sub-investigators, coordinators, regulatory and budgeting staff participating in this study. c. Follow the study procedures as outlined in the protocol and to follow sponsor and IRB requirements. d. Sign and date all required documents after reviewing for accuracy and oversights. e. Implement all future study amendments in a timely fashion.					
2. <b><u>Training and Personnel:</u></b> a. PI and coordinator to attend the investigator meeting and complete all required training. If the Sub-I attends the investigator meeting, PI still has to be familiar with what was discussed and complete all required training. b. Everyone listed on the site delegation log needs training on the protocol, and the trainer and trainee has to be documented. c. All investigators doing study-related procedures are listed on the 1572. d. Personnel are trained in electronic data transfer/other technology for study. e. Sponsor site initiation visit is performed before enrollment.					
3. <b><u>Protocol Review:</u></b> a. Protocol procedures, inclusion/exclusion criteria, amendments, screening tools, and all aspects of study are reviewed before beginning enrollment. b. Informed consent (ICF) will contained most recent amendment changes. c. Source documents reflect the most recent protocol and amendments.					
4. <b><u>Drug Storage:</u></b> a. Study drugs are stored in a secure manner (locked cabinet) in accordance with sponsor and IRB requirements. b. If study drug has to be refrigerated, it will be transported from office to subject in an insulated cooler with a frozen ice pack to ensure a stable temperature. If study drug can be at room temperature, it will be hand carried in its original box/container. c. Temperature logs are updated as required per the IRB or sponsor.					

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<b><u>B. Screening-Enrollment (To be done after Screening 1<sup>st</sup> subject)</u></b>	<b><u>Comments</u></b>	<b>Coordinator</b>		<b>PI</b>	
		<b>Signature</b>	<b>Date</b>	<b>Signature</b>	<b>Date</b>
<p>1. <u>Screening:</u></p> <ul style="list-style-type: none"> <li>a. Referral source is documented for follow-up care.</li> <li>b. Relevant present and past medical/social history is reviewed and documented prior to enrolling subject. Current medications are reviewed and documented.</li> <li>c. Screening labs-test results are reviewed &amp; signed by investigator before enrollment.</li> <li>d. Source documents generated by our unit have to be reviewed to ensure accuracy and reflect protocol and amendment changes. Sponsor may review source documents if necessary.</li> </ul>					
<p>2. <u>Study Entry Criteria:</u></p> <ul style="list-style-type: none"> <li>a. Subject must meet all inclusion criteria and no exclusion criteria, including screening lab and test results, <u>before</u> enrollment to assure subject's safety.</li> <li>b. Waiver from the sponsor is required for enrollment outside of study criteria, and the waiver must be submitted to IRB.</li> <li>c. In some cases, it may be up to PI's discretion regarding enrollment. PI's clinical judgment and sponsor communication will be documented.</li> </ul>					
<p>3. <u>Obtaining Informed Consent and Research Authorization:</u></p> <ul style="list-style-type: none"> <li>a. Subject will be given most recently approved IRB-stamped informed consent (ICF) and Research Authorization (RA) to review, with most recent amendment changes.</li> <li>b. PI and/or coordinator will review ICF and RA with the subject.</li> <li>c. Subject will be given the opportunity to ask questions and receive answers.</li> <li>d. Subject will sign most recent, approved, ICF and RA before any study-related procedures are done.</li> <li>e. Subject and coordinator will sign the appropriate signature/date lines. If PI did not obtain the ICF, PI must sign ICF within 2 weeks.</li> <li>f. Subject will be given a copy of the signed ICF and RA.</li> <li>g. The process of obtaining ICF and RA should be documented.</li> <li>h. Subject requiring a legal representative to sign ICF has to be pre-approved by IRB and sponsor.</li> </ul>					
<p>4. <u>Protocol Procedures:</u></p> <ul style="list-style-type: none"> <li>a. All protocol procedures, sponsor's documentation requirements, and case report forms are followed.</li> <li>d. Documentation is complete to reflect protocol compliance.</li> <li>e. All investigators doing study-related procedures are listed on 1572.</li> <li>f. Investigator who performs the study-related procedure, not the coordinator, will sign source document and will interpret results.</li> </ul>					

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<b><u>C. Compliance Review (To be done after Enrolling 1<sup>st</sup> subject)</u></b>	<b><u>Comments</u></b>	<b>Coordinator</b>		<b>PI</b>	
		<b>Signature</b>	<b>Date</b>	<b>Signature</b>	<b>Date</b>
<p>1. <b><u>Protocol Review after Enrollment:</u></b></p> <p>a. After enrolling the <u>first</u> subject, PI and coordinator will review the inclusion/exclusion criteria, source documents, procedures, data entry, and all aspects of protocol of this subject to ensure compliance.</p> <p>b. Deviation to protocol for Industry-Sponsored Study has to be pre-approved by the sponsor. IRB will be notified if protocol deviation may affect subject safety.</p>					
<p>2. <b><u>Sponsor Review:</u></b></p> <p>a. After enrollment of <u>first or second</u> subjects, request the sponsor to come in a timely manner for a site monitor visit to ensure protocol compliance.</p> <p>b. PI and/or coordinator will work with sponsor to ensure accuracy of electronic data collection and in agreement of source documents.</p> <p>c. Coordinator will ask for preliminary verbal feedback during the site visit, to avoid delaying correction of any problems.</p> <p>d. Coordinator will ask for written feedback of site visit ASAP and file the response in the regulatory binder.</p>					
<p>3. <b><u>Response to Monitor Visit:</u></b></p> <p>a. PI and coordinator will incorporate all sponsor-initiated changes and fulfill all sponsor requests in a timely manner.</p> <p>b. All outstanding queries will be completed by next monitoring visit.</p>					
<p>4. <b><u>Periodic Protocol Review:</u></b></p> <p>a. PI and coordinator will hold periodic reviews to ensure study compliance.</p> <p>b. All documents are signed &amp; dated on day of review. Back-dating is <u>not</u> allowed.</p> <p>c. Subject will be reconsented if there is a change of study risk in the Informed Consent <u>or</u> the sponsor request to reconsent the subjects.</p> <p>d. Update site delegation log for personnel (add or remove).</p> <p>e. PI will ensure accuracy of electronic data and in agreement of source documents.</p>					
<p>5. <b><u>Voluntary Suspension:</u></b></p> <p>a. Voluntary suspension, if any, will be reported to the IRB within 72 hours to 5 business days, depending on requirement, using an Unanticipated Problem Involving Risks to Subjects and Others (UPIRTSO) form.</p>					
<p>6. <b><u>Deviations Identified by this Check List:</u></b></p> <p>a. Protocol deviations will be reported to sponsor &amp; IRB within 10 business days.</p> <p>b. Any deviations identified by this check list will be corrected and the sponsor and/or IRB will be notified if needed within 10 business days.</p>					