|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **NA** | **Investigator Qualifications and Agreements 4.1** |
|  |  |  | **4.1.1 As the investigator, are you qualified by education, training, and experience to assume responsibility for the proper conduct of the trial? The investigator should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).** |
|  |  |  | **4.1.2 As the investigator, are you thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information, and in other information sources provided by the sponsor?** |
|  |  |  | **4.1.3 As the investigator, are you aware of Good Clinical Practice guidance and the applicable regulatory requirements?** |
|  |  |  | **4.1.4 As the investigator, are you aware that you must permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies)?** |
|  |  |  | **4.1.5 As the investigator, are you aware that you must maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties?** |
| **Yes** | **No** | **NA** | **Adequate Resources 4.2** |
|  |  |  | **4.2.1 As the investigator, are you able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period?** |
|  |  |  | **4.2.2 As the investigator, do you have sufficient time to properly conduct and complete the trial within the agreed trial period?** |
|  |  |  | **4.2.3 As the investigator, do you have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely?** |
|  |  |  | **4.2.4 As the investigator, are all persons assisting with the trial adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions?** |
| **Yes** | **No** | **NA** | **Medical Care of Trial Subjects 4.3** |
|  |  |  | **4.3.1 As the investigator, can you ensure that a qualified physician (or dentist, when appropriate), who is an investigator or a subinvestigator for the trial, will be responsible for all trial-related medical (or dental) decisions?** |
|  |  |  | **4.3.2 As the investigator, can you ensure that adequate medical care is provided to a subject for any adverse events (including clinically significant laboratory values) related to the trial, both during and following a subject's participation in a trial? The investigator should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.** |
|  |  |  | **4.3.3 As the investigator, will you inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed?** |
|  |  |  | **4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, as the investigator, will you make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights?** |
| **Yes** | **No** | **NA** | **Compliance with the IRB-Approved Protocol 4.5** |
|  |  |  | **4.5.2 As the investigator, you will not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval from the IRB of an amendment? If necessary to eliminate an immediate hazard to research subjects, an investigator may deviate from the IRB-approved research application without prospective IRB approval.**  |
|  |  |  | **4.5.3 As the investigator, will you document and explain any deviation from the approved protocol that occurs without prospective IRB approval?**  |
|  |  |  | **4.5.4 As the investigator, if you deviate from the IRB-approved research application to eliminate an immediate hazard(s) to research subjects without prospective IRB approval, will you submit a modification and explain the deviation to the IRB, to the sponsor for agreement and, if required, to the regulatory authority(ies)?**  |
| **Yes** | **No** | **NA** | **Investigational Product(s) 4.6** |
|  |  |  | **4.6.5 As the investigator, will you ensure that the investigational product(s) are used only in accordance with the IRB-approved research application?**  |
|  |  |  | **4.6.6 As the investigator, will you, or a designee you have appointed, explain the correct use of the investigational product(s) to each subject? Will you, or a designee you have appointed, periodically check that each subject is following the instructions properly?**  |
| **Yes** | **No** | **NA** | **Randomization Procedures and Unblinding 4.7**  |
|  |  |  | **As the investigator, will you follow the trial's randomization procedures, if any? Will you ensure that the code is broken only in accordance with the IRB-approved research application? If the research is blinded, will you promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s)?**  |
| **Yes** | **No** | **NA** | **Informed Consent of Trial Subjects 4.8** |
|  |  |  | **4.8.1 As the investigator, will you comply with the applicable regulatory requirement(s) and adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki in obtaining and documenting informed consent? Prior to the beginning of the research study, the investigator must have the IRB's written approval of the written informed consent form and any other written information to be provided to subjects.**  |
|  |  |  | **4.8.10 As the investigator, will you ensure that, the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:*** **The subject’s responsibilities.**
* **The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.**
* **That the monitor(s), auditor(s), IRB, and the regulatory authority(ies) will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject’s legally acceptable representative is authorizing such access.**
* **The approximate number of subjects involved in the trial.**
 |
| **Yes** | **No** | **NA** | **Records and Reports 4.9** |
|  |  |  | **4.9.1 As the investigator, will you ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports?**  |
|  |  |  | **4.9.2 As the investigator, will you ensure that data reported on the CRF derived from source documents are consistent with the source documents? If there are any discrepancies, they should be explained.** |
|  |  |  | **4.9.3 As the investigator, will you ensure that any change or correction to a CRF will be dated, initialed, and explained (if necessary) and will not obscure the original entry (i.e., an audit trail should be maintained)? This applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. As the investigator, you should retain records of the changes and corrections.**  |
|  |  |  | **4.9.4 As the investigator, will you maintain the research documents as required by the applicable regulatory requirement(s)? The investigator should take measures to prevent accidental or premature destruction of these documents.**  |
|  |  |  | **4.9.5 As the investigator, will you ensure that essential documents will be retained until at least 3 years have elapsed since the formal discontinuation of clinical development of the investigational product? If required by the applicable regulatory requirements or by an agreement with the sponsor, these documents may need to be retained for a longer period. It is the sponsor’s responsibility to inform the investigator as to when these documents no longer need to be retained.**  |
|  |  |  | **4.9.6 As the investigator, will you ensure that the financial aspects of the study are documented in an agreement between yourself and the sponsor?**  |
|  |  |  | **4.9.7 As the investigator, will you make available for direct access all requested research-related records upon request of the monitor, auditor, IRB, or regulatory authority?**  |
| **Yes** | **No** | **NA** | **Safety Reporting 4.11** |
|  |  |  | **4.11.2 As the investigator, will you report adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol?**  |
|  |  |  | **4.11.3 As the investigator, will you supply the sponsor and the IRB with any additional requested information for reported deaths (e.g., autopsy reports and terminal medical reports)?** |
| **Yes** | **No** | **NA** | **Premature Termination or Suspension of a Trial 4.12** |
|  |  |  | **4.12.1 As the investigator, if you terminate or suspend research without prior agreement of the sponsor, will you inform the sponsor and the IRB? The investigator should provide the sponsor and the IRB with a detailed written explanation of the termination or suspension.**  |
|  |  |  | **Comments** |
|  |  |  | **Any Additional Comments:** |