1 PURPOSE

1.1. This guidance outlines the additional obligations of investigators conducting research subject to ICH-GCP.

2 GUIDANCE

2.1. Investigator's Qualifications and Agreements

2.1.1. The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, 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, and/or the regulatory authority(ies).

2.1.2. The investigator should be 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.

2.1.3. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

2.1.4. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

2.1.5. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

2.2. Adequate Resources

2.2.1. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

2.2.2. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

2.2.3. The investigator should 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.

2.2.4. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

2.3. Medical Care of Trial Subjects

2.3.1. A qualified physician (or dentist, when appropriate), who is an investigator or a sub investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

2.3.2. During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

2.3.3. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the

check, at intervals appropriate for the trial, that each subject is following the instructions properly.

2.7. Randomization Procedures and Unblinding

2.7.1. The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should 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).

2.8. Informed Consent of Trial Subjects

2.8.1. In obtaining and documenting informed co.3 (nd)-(T)-5.5 ()-8 (o.3 (nd)-b)-12.3 (l)3.2 (-6.3 (uc)-8 (t)

2.8.10.18. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated

2.8.10.19. The expected duration of the subject's participation in the trial

2.8.10.20. The approximate number of subjects involved in the trial

2.8.11. Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a cooesupda (d w).1 73unded atai siitte2.8.10. PrWun io p (m)-12.3 4 (i)3.3ci. hieeidu(

pseW nBT9 - Tw 9.96 -0 0 9.96 172.8 685.92 T8172.8 685.-80f