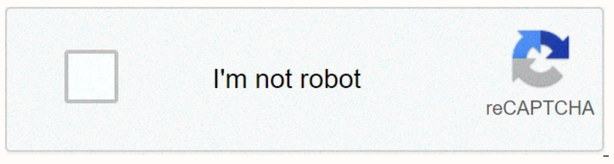

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Ich gcp guidelines for informed consent

4.1 Investigator's Qualifications and Agreement 4.1.1 The Investigator(s) must be qualified by education, training and experience to assume responsibility for the proper conduct of the trial, must meet all qualifications specified by the applicable regulatory requirement(s), and provide proof of such qualifications through the up-to-date course Vita and/or other relevant document requested by the sponsor, IRB/IEC. and/or regulatory authority(ies)4.1.2 the investigator should be well acquainted with the proper use of the investigative product(s), as described in the protocol, in the brochure of the current investigator, in product information and in other information sources.4.1.3 provided by the sponsor should be aware of the investigator, and must comply with, GCP and applicable regulatory requirements. 4.1.4 Monitoring and auditing by investigator/institution sponsor must be permitted, and inspected by appropriate regulatory authority(s). 4.1.5 The investigator should maintain a list of properly qualified persons to whom the investigator has delegated important test-related duties. 4.2 Adequate Resources 4.2.1 The Investigator should be able to demonstrate (e.g., on the basis of retrospective data) an ability to recruit the required number of suitable subjects within the agreed recruitment period. 4 Investigator must have sufficient time to conduct and complete the trial properly within the agreed trial period. 4.2.3 The investigator should have sufficient number of qualified staff and adequate facilities for an unexpected period of trial to be conducted appropriately and safely for an unexpected period of trial. 4.2.4 The investigator should ensure that all persons assisting in the trial are adequately informed about the protocol, protocol. Check products, and their test-related duties and functions. ADDENDUM4.2.5 Investigator is responsible for monitoring any person or party whom the investigator delegates to the duties and functions related to the trial conducted at the test site. 4.2.6 If the investigator/institution retains the services of any person or party to perform duties and functions relating to the trial, the investigator/institution must ensure that this person or party is qualified to perform those trial-related duties and functions and must implement procedures to ensure the integrity of test-related duties and functions and generate any data. 4.3 Medical Care of Test Subjects 4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or deputy investigator for the trial, should be responsible for all test-related medical (or dental) decisions. 4.3.2 During and after the participation of a subject in a test, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events including medically significant laboratory values related to the test. The investigator/institution should A subject when intercurrent illness (es) requires medical care from which the investigator becomes aware. 4.3.3 It is recommended that the investigator inform the primary doctor of the subject about the involvement of the subject in the examination if the subject is the primary physician and if the subject is being communicated to the primary doctor. 4.4.3 3.4 Although no subject is obliged to give its due(s) for premature withdrawal from the test, the investigator must make reasonable efforts to ascertain the cause(s) with fully respecting the rights of the subject fully with IRB/IEC 4.4.1 before starting the trial, The investigator/institution should have written and dated approval/favourable opinion from IRB/IEC for testing protocol, written informed consent form, consent form update, subject recruitment procedures (e.g., advertisement), and any other written information to be provided to the subjects 4.4.2 As part of the written application for IRB/IEC of the Investigator/Institute, the investigator/institution should provide IRB/IEC along with the current copy of the brochure of the investigator. If the investigator's brochure is updated during the trial, the investigator/institution should supply a copy of the brochure of the updated investigator on IRB/IEC.4.4.3, the investigator/institution should provide all documents under review to the IRB/IEC. 4.5 Compliance with Protocol 4.5.1 The investigator/institution must conduct the trial in compliance with the protocol agreed by the sponsor and, if necessary, by the regulatory authority and which was approved/favourably given by the IRB/IEC. The investigator/institution and sponsor must sign the protocol, or an optional contract, to ratify the agreement. 4.5.2 Any deviation from the investigator should not apply, or the change of protocol without agreement by the sponsor and prior review and the approval/favorable opinion document from IRB/IEC of an amendment, In addition to eliminating an immediate threat(s) to test subjects where necessary, or when the change(s) involve only military or administrative aspects of the test (e.g., changes in monitor(s), changes to telephone number(s) 4.5.3 the investigator, or the person nominated by the investigator, should document and interpret any deviation from the approved protocol. 4.5.4 May enforce deviation or change from investigator, protocol to eliminate immediate threat(s) to test subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the deviations or changes in force, the reason for this, and, if appropriate, the proposed protocol amendment(s) should be submitted: (a) to the IRB/IEC for review and approval/favourable opinion, to the sponsor for the (b) agreement and, if necessary, to the Regulatory Authority(ies) to (c). 4.6 Investigation Product(s) Checks Product(s) Rests with Test Site(s) for Accountability Where permission/institution is required, the investigator/institution should assign some or all duties of the investigator/institution for investigation product(s) accountability at the test site to an appropriate pharmacist or any other suitable person who is under the supervision of the investigator/institution. 46.3 The investigator/institution and/or a pharmacist or other suitable person, designated by the investigator/institution, must maintain records of the distribution of the product to the test site, inventory on site, use by each subject, and return to the alternative nature of sponsor or unused product(s). These records must include dates, quantities, batch/serial numbers, expiration dates (if applicable), and unique code numbers assigned to the check product(s) and test subjects. Investigators must maintain records that adequately harmonise all check product(s) of the document that subjects were provided doses specified by the protocol and received from the sponsor. 4.6.4 The probe product(s) should be stored as specified by the sponsor (see 5.13.2 and 5. The check for each subject should explain the correct use of the product(s) and check, at appropriate intervals for testing, that each subject is following the instructions properly. 4.7Randomization procedures and random processes of unblinding investigator testing must follow, if any, and must ensure that the code is broken only according to protocol. If the trial is blind, the investigator should immediately explain to the document and sponsor any premature unblinding (for example, accidental avling, abliding) due to a serious adverse event of the investigation product(s). 4.8 In obtaining informed consent and documenting the consent of the test subjects 4.8.1, the investigator must comply with the applicable regulatory requirement(s), and adhere to the GCP and ethical principles that are their origins in the Helsinki Declaration. Prior to the start of the trial, the investigator should have a favourable opinion of the written acceptance/written informed consent form of IRB/IEC and any other written information to be provided to the subjects. 4.8.2 Any other written information provided to the written informed consent form and subjects should be revised whenever important new information becomes available which is relevant to the consent of the subject. Any revised written informed consent form, and written information should obtain the approval/favorable opinion of IRB/IEC in advance of use. The legally admissible representative of the subject or subject must be informed in time If new information becomes available that may be relevant to the subject's desire to continue participation in the test. The communication of this information must be documented. 4.8.3 Neither investigator, nor test staff, must force or unnecessarily influence a subject to participate or continue to participate in a trial. 4.8.4 None of the oral and written information relating to the trial, including the written informed consent form, shall include any language that appears to waive the legally admissible representative of the subject or subject or to waive any legal rights, or that the liability for communiqués or negligence appears to release the investigator, institution, sponsor, or their agents. 4.8.5 Person named by investigator, or investigator, The subject should be fully informed or, if the subject is unable to provide informed consent, the subject should be incomprehension for the legally accepted representative of the subject, the information written by IRB/IEC and all relevant aspects of the trial including approval/favourable opinion, the language used in oral and written information about the trial, including written consent form, as non-technical as practical and legally accepted representative and impartial witness of the subject or subject where may be applied. 4.8.7 Before receiving the informed consent, the person named by the investigator, or investigator, the legally accepted representative of the subject or subject, should provide sufficient time and opportunity to inquire about the details of the trial and take a decision to participate in the trial. All questions about the test must be answered to the satisfaction of the legally acceptable representative of the subject or subject. 4.8.8 Prior to the participation of a subject in the trial, the written informed consent form must be signed and personally dated by the legally accepted representative of the subject, and by the person who held the informed consent discussion. 4.8.9 If a subject is unable to read or if a legally accepted representative is unable to read, an impartial witness must be present throughout the informed consent discussion. Following the written informed consent form and any other written information provided to the subjects, the legally admissible representative of the subject or subject is read and explained, and the legally accepted representative of the subject or subject has verbally consented to the subject's participation in the trial and, if able to do so, the witness must sign and personally date the consent form. By signing the consent form, the witness certifies that the information in the consent form and any other written information was accurately explained, and apparently deemed by, the legally acceptable representative of the subject or subject, and that Consent was freely granted by a legally acceptable representative of the subject or subject. 4.8.10 Both informed consent discussion and written informed consent form and any other written information to be provided to the subjects must include explanations of the following: (a) that involves test research. (b) Purpose of testing. (c) Possibility of trial treatment(s) and random work for each treatment. (d) All invasive procedures including testing procedures should be followed. (e) Responsibilities of the subject. (f) The aspects of the test which are experimental. (g) Reasonably foreseeable risks or inconveniences to the subject and when applicable, to the fetus, fetus or nursing infant. (h) Reasonably expected profit. When there is no intended clinical benefit for this subject, the subject must be made aware of this. (i) Course of alternative procedure or treatment which may be available for the subject, and their significant potential benefits and risks. (j) Compensation and/or treatment to the subject in case of trial related injury. (k) Anticipated processed payment, if any, on the subject to participate in the trial. (l) Anticipated expenditure, if any, on the subject to participate in the trial. (m) That the participation of the subject in the test is voluntary and the subject may, at any time, refuse to participate or withdraw from the trial, without any penalty or loss of profit, which the subject is otherwise entitled to. (n) that the Monitor(s), Auditor(s), IRB/IEC, and the Regulatory Authority (IES) shall 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 applicable laws and regulations and that, by signing a written informed consent form, a legally acceptable representative of the subject or subject is authorizing such access. (O) The records identifying the subject shall be kept confidential and not made publicly available to the extent permitted by applicable laws and/or regulations. If the results of the test are published, the identity of the subject will remain confidential. (P) If the information becomes available, the legally accepted representative of the subject or subject shall be informed in time which may be relevant to the subject's desire to continue participation in the trial. (q) Contacting the person for more information about the rights of test and test subjects and who to contact in case of test related injury. (r) Under the foreseeable circumstances and/or reasons under which the participation of the subject in the trial can be terminated. (c) Required period of participation of the subject in the examination. (t) The approximate number, subject or subject of the subjects involved in the 4811 test before participating in the trial is legally admissible Signed and dated written consent form and the subjects must obtain a copy of any other written information provided. During the participation of a subject in the trial, the legally admissible representative of the subject or subject should receive a copy of the signed and dated consent form update and a copy of any amendment to the written information provided to the subjects. 4.8.12 When a clinical trial (therapeutic or non-therapeutic) involves subjects which may only be enrolled in the trial with the consent of the legally accepted representative of the subject (e.g., minors, or patients with severe dementia), the subject must be informed about the trial to an extent consistent with the understanding of the subject matter and, if competent, the subject must sign and date of personally written informed consent. In addition to 4.8.13 as described in 4.8.14, a non-therapeutic test (i.e. a test that has no anticipated directed clinical benefit), should be conducted in subjects that personally consent and which sign and date the written informed consent form. 4.8.14 Non-clinical trials may be conducted in subjects with the consent of a legally accepted representative provided the following conditions are met: (a) The objectives of the trial cannot be fulfilled through trial in subjects that may give personally informed consent. (b) The foreseeable risks for subjects are low. (c) The negative impact on the well-being of the subject is minimized and minimized. (d) Trial by law is not prohibited. (e) Approval/favourable opinion of IRB/IEC on inclusion of such subjects is clearly sought and this aspect has been incorporated in the written approval/favourable opinion. Such tests, unless an exception is justified, must be conducted in patients with a disease or condition for which the test product is intended. The subjects in these tests must be monitored particularly closely and withdrawn if they appear to be unnecessarily distressed. 48.15 In emergencies, when prior consent of the subject is not possible, the consent of the legally admissible representative of the subject should, if at present, be requested. When prior consent of the subject is not possible, and a legally acceptable representative of the subject is not available, the nomination of the subject should require the protocol with approval/favourable opinion documented by the IRB/IEC and/or the measures described elsewhere in order to protect the rights, safety and well-being of the subject and ensure compliance with the regulatory requirements in force. The legally admissible representative of the subject or subject should be informed of the trial as soon as possible and consent and other consent (see 4.8.10) should be requested to continue as appropriate. 4.9 Record and ReportsADDENDUM4.9.0 The investigator/institution must maintain adequate and accurate source documents and test records including all relevant comments on each of the test subjects of the site. origin The reason, legible, contemporary, original, must be precise and complete. Changes to source data must be detected, the original entry should not be obscured, and should be explained if necessary (for example, through an audit mark). 4.9.1 The investigator should ensure the accuracy, completeness, validity and timeliness of the data reported to the sponsor in the CRF and in all necessary reports. 4.9.2 Data reports on CRF, which are obtained from source documents, must conform to source documents or discrepancies must be explained. 4.9.3 Any changes or corrections to the CRF must be dated, initiated, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail must be maintained); This applies to both written and electronic changes or corrections (see 5.18.4(n)). Sponsors must provide guidance to designated representatives of investigators and/or investigators on making such improvements. Sponsors should have written procedures to assure that changes or corrections to CRFs made by the sponsor's designated representatives are documented, required, and endorsed by the investigator. The investigator must maintain records of changes and improvements. 4.9.4 The investigator/institution must retain the test documents specified in the documents required for conducting the clinical trial (see 8)) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents. 4.9.5 The required documents should be retained at least 2 years after final approval of final approval of the marketing application in ICH field and unless there are any pending or considered marketing applications in the ICH area or at least 2 years have passed since the formal discontinuation of clinical development of the investigating product. These documents must be retained for a long period of time, however if required by applicable regulatory requirements or an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution when these documents need to be retained (see 5.5.12) 4.9.6 The financial aspects of the trial must be documented in an agreement between the sponsor and the investigator/institution. 4.9.7 At the request of the Monitor, the Auditor, IRB/IEC, or regulatory authority, the investigator/institution should provide all requested test related records for direct access. 4.10 Progress Reports4.10.1 The investigator should submit a written summary of the test status to the IRB/IEC annually, Or more often, if requested by IRB/IEC.4.10.2 the investigator should provide written report to the sponsor, IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes is significantly affecting the conduct of the trial, and/or increase the risk to the subjects. 4.11 Safety Reporting4.11.1 All Serious Adverse Events (SAEs) In addition to those SAEs, the sponsor may be immediately informed that the protocol or other document (e.g., the investigator's brochure) identifies as not requiring immediate reporting. The report must be followed immediately after a detailed, written report. Immediate and follow-up reports should identify subjects by unique code numbers assigned to test subjects instead of subjects name, personal identification number, and/or address. The investigator should also comply with the applicable regulatory requirement(s) relating to reporting of unexpected serious adverse drug reactions in the protocol as important for regulatory authority (IES) and IRB/IEC/4.11.2 adverse events and/or laboratory abnormal identities. The security assessment must be communicated to the sponsor in accordance with the reporting requirements and within the period specified by the sponsor in the time protocol. 4.11.3 For reported deaths, the investigator must sponsor and supply the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports. 4.12 Premature termination or suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should immediately notify the test subjects, assure appropriate medical and follow-up action for subjects and, where required by the applicable regulatory requirement(s), should notify the Regulatory Authority (ies). Further: 4.12.1 If the investigator concludes or suspends a trial without prior agreement of the sponsor, the investigator must inform the institution where applicable, and the investigator/institution should immediately inform the sponsor and IRB/IEC, and provide a detailed written account of the termination or suspension to the sponsor and IRB/IEC. 4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should immediately notify the institution where applicable and the investigator/institution should immediately notify the IRB/IEC and provide a detailed written explanation of termination or suspension to IRB/IEC. 4.12.3 If IRB/IEC terminates or suspends its approval/approval, IRB/IEC suspends its approval. A trial-friendly opinion (see 3.1.2 and 3.3.9), the investigator should inform the institution where applicable and the investigator/institution should immediately inform the sponsor and provide the sponsor with a detailed written explanation of termination or suspension. 4.13 On completion of the trial by the final report(s) investigation, the investigator, where applicable, should inform the institution; The investigator/institution should provide the Regulatory Authority (IES) with a summary of the test result and any necessary report to the IRB/IEC. Necessary.

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