

## UAB Investigator Checklist ICH-Good Clinical Practice (GCP) Guidance

The UAB IRBs and OSP operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. GCP standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the UAB IRBs and OSP do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The UAB IRBs comply with most aspects of ICH-GCP, and the UAB policies, procedures, and forms require investigators to comply with most ICH-GCP guidance. **Listed below are the additional investigator responsibilities that are required when the study is being conducted to comply with ICH-GCP guidance.**

Yes	No	N/A	Investigator Qualifications and Agreements 4.1
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.1.3 As the investigator, are you aware of Good Clinical Practice guidance and the applicable regulatory requirements?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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)?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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	N/A	Adequate Resources 4.2
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
Yes	No	N/A	Medical Care of Trial Subjects 4.3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?

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Yes	No	N/A	Compliance with the IRB-Approved Research Application 4.5
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>4.5.1 As the investigator, will you conduct the research in compliance with the research application that was given approval by the IRB? As the investigator, you must sign the research application to confirm agreement.</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>4.5.2 As the investigator, you will not implement any deviation from, or changes of the protocol <b>without agreement by the sponsor</b> 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.</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>4.5.3 As the investigator, will you document and explain any deviation from the approved protocol that occurs without prospective IRB approval?</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>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, <b>to the sponsor for agreement and, if required, to the regulatory authority(ies)?</b></b>
Yes	No	N/A	Investigational Product(s) 4.6
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>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?</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>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?</b>
Yes	No	N/A	Randomization Procedures and Unblinding 4.7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>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)?</b>
Yes	No	N/A	Informed Consent of Trial Subjects 4.8
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>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.</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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: <ul style="list-style-type: none"> <li>• <b>The subject's responsibilities.</b></li> <li>• The alternative procedure(s) or course(s) of treatment that may be available to the subject, <b>and their important potential benefits and risks.</b></li> <li>• <b>The approximate number of subjects involved in the trial.</b></li> </ul>

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Yes	No	N/A	Records and Reports 4.9
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.9.5 As the investigator, will you ensure that essential documents will be retained until at least 2 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.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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	N/A	Safety Reporting 4.11
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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	N/A	Premature Termination or Suspension of a Trial 4.12.1
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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.

UAB IRB Protocol # \_\_\_\_\_

Signature of Principal Investigator \_\_\_\_\_

Date \_\_\_\_\_