Investigator Initiated Research Checklist
Good Clinical Practice (GCP) Guidance
UHCMC Center for Clinical Research and Technology

Researchers should be fully aware of their obligations and responsibilities required by University Hospitals Case Medical Center (UHCMC) and the UHCMC IRB and applicable regulatory agencies prior to conducting research. This checklist provides a summary of researcher responsibilities pertinent to data and document management in accordance with Good Clinical Practice (GCP) Guidance.

Yes	No	N/A	GCP E6 4.1	Researcher Qualifications and Agreements
☐	☐	☐	4.1.1	As the researcher, are you qualified by education, training, and experience to assume responsibility for the proper conduct of the trial? The researcher 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 researcher, 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 researcher, are you aware of Good Clinical Practice guidance and the applicable regulatory requirements?
☐	☐	☐	4.1.4	As the researcher, 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 researcher, 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	GCP E6 4.2	Adequate Resources
☐	☐	☐	4.2.1	As the researcher, 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 researcher, do you have sufficient time to properly conduct and complete the trial within the agreed trial period?
☐	☐	☐	4.2.3	As the researcher, 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 researcher, can you 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?

Yes	No	N/A	GCP E6 4.3	Medical Care of Trial Subjects
☐	☐	☐	4.3.1	As the researcher, can you ensure a qualified physician (or dentist, when appropriate), either yourself or a sub-investigator for the trial, will be responsible for all trial-related medical (or dental) decisions?

☐	☐	☐	4.3.2	As the researcher, 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 researcher should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.
☐	☐	☐	4.3.3	As the researcher, 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 researcher, will you make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights?

Yes	No	N/A	GCP E6 4.4	Communication with the IRB
☐	☐	☐	4.4.1	As the researcher, do you have written and dated approval from the IRB for the research application, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects?
☐	☐	☐	4.4.2	As the researcher, did you provide the IRB with a current copy of the Investigator's Brochure? If the Investigator's Brochure is updated during the trial, you must provide a copy of the updated Investigator's Brochure to the IRB.
☐	☐	☐	4.4.3	As the researcher, did you provide the IRB with all documents subject to review according to the IRB's requirements?

Yes	No	N/A	GCP E6 4.5	Compliance with the IRB-Approved Research Application
☐	☐	☐	4.5.1	As the researcher, will you conduct the research in compliance with the research protocol that was given approval by the IRB? As the researcher, you must sign the research application to confirm agreement.
☐	☐	☐	4.5.2	As the researcher, can you ensure that you will not implement any deviation from the IRB-approved research protocol without prior review and documented approval from the IRB of a modification? If necessary to eliminate an immediate hazard to research subjects, a researcher may deviate from the IRB-approved research application without prospective IRB approval.
☐	☐	☐	4.5.3	As the researcher, will you document and explain any deviation from the approved protocol that occurs without prospective IRB approval?
☐	☐	☐	4.5.4	As the researcher, if you deviate from the IRB-approved research protocol to eliminate an immediate hazard(s) to research subjects without prospective IRB approval, will you submit an amendment and report the deviation to the IRB?

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Yes	No	N/A	GCP E6 4.6	Investigational Product(s)
☐	☐	☐	4.6.1	As the researcher, will you take responsibility for investigational product(s) accountability at the research site(s)?
☐	☐	☐	4.6.2	As the researcher, will you assign some or all of your duties for investigational product(s) accountability at the research site(s) to an appropriate pharmacist or another appropriate individual who is under your supervision?
☐	☐	☐	4.6.3	As the researcher, will you, or a designee you have appointed, maintain records of the product's delivery to the research site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s)? These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and research subjects. Researchers should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.
☐	☐	☐	4.6.4	As the researcher, will you ensure that the investigational product(s) will be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s)?
☐	☐	☐	4.6.5	As the researcher, will you ensure that the investigational product(s) are used only in accordance with the IRB-approved research application?
☐	☐	☐	4.6.6	As the researcher, 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	N/A	GCP E6 4.7	Randomization Procedures and Unblinding
☐	☐	☐		As the researcher, 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	N/A	GCP E6 4.8	Informed Consent of Trial Subjects
☐	☐	☐	4.8.1	As the researcher, 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 researcher must have the IRB's written approval of the written informed consent form and any other written information to be provided to subjects.

☐	☐	☐	4.8.2	As the researcher, will you ensure that the written informed consent form and any other written information to be provided to subjects will be revised whenever important new information becomes available that may be relevant to the subject's consent? Any revised consent form and other written information provided to subjects must receive the IRB's approval in advance of use. The subject or the subject's legally authorized representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the research, and the communication of this information should be documented.
☐	☐	☐	4.8.3	As the researcher, will you ensure that neither you nor the research staff will coerce or unduly influence a subject to participate or to continue to participate in the research?
☐	☐	☐	4.8.4	As the researcher, will you ensure that none of the oral and written information concerning the trial, including the written informed consent form, contains any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence?
☐	☐	☐	4.8.5	As the researcher, will you ensure that you, or a designee you have appointed, will fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the research including the written information and the approval by the IRB?
☐	☐	☐	4.8.6	As the researcher, will you ensure that the language used in the oral and written information about the research, including the consent form, will be as non-technical as practical and will be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable?
☐	☐	☐	4.8.7	As the researcher, will you ensure that you, or a designee you have appointed, will provide the subject or the subject's legally authorized representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the research? All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.
☐	☐	☐	4.8.8	As the researcher, will you ensure that the written consent form is signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion prior to a subject's participation in any research procedures?
☐	☐	☐	4.8.9	As the researcher, will you ensure that, if a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness will be present during the entire informed consent discussion? After the written informed consent form, and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.
☐	☐	☐	4.8.11	As the researcher, will you ensure that, prior to participation in the research, the subject or the subject's legally acceptable representative will receive a copy of the signed and dated consent form and any other written information provided to the subject. During a subject's participation in the research, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated revised consent form and a copy of any updates to the written information provided to subjects.

☐	☐	☐	4.8.12	As the researcher, will you ensure that when research (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the research with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject will be informed about the research to the extent compatible with the subject's understanding and, if capable, the subject will be given the opportunity to sign and personally date the written informed consent?
☐	☐	☐	4.8.15	As the researcher, will you ensure that in emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally authorized representative, if present, will be requested? When prior consent of the subject is not possible, and the subject's legally authorized representative is not available, enrollment of the subject requires measures described in the research application and/or elsewhere, with documented IRB approval to protect the rights, safety, and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally authorized representative must be informed about the research as soon as possible and consent to continue and other consent as appropriate (see 4.8.10 above) should be requested.

Yes	No	N/A	GCP E6 4.9	Records and Reports
☐	☐	☐	4.9.1	As the researcher, 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 researcher, 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 researcher, 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 researcher, you should retain records of the changes and corrections.
☐	☐	☐	4.9.4	As the researcher, will you maintain the research documents as required by the applicable regulatory requirement(s)? The researcher should take measures to prevent accidental or premature destruction of these documents.
☐	☐	☐	4.9.5	As the researcher, 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 researcher as to when these documents no longer need to be retained.
☐	☐	☐	4.9.6	As the researcher, 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 researcher, 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	GCP E6 4.10	Progress Reports
☐	☐	☐	4.10.1	As the researcher, will you submit written summaries of the research status to the IRB annually, or more frequently if requested by the IRB?
☐	☐	☐	4.10.2	As the researcher, will you promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the research, and/or increasing risks to subjects?

Yes	No	N/A	GCP E6 4.11	Safety Reporting
☐	☐	☐	4.11.1	As the researcher, will you immediately report all serious adverse events (SAEs) to the sponsor, except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting? The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the research subjects rather than by the subjects' names, personal identification numbers, and/or addresses. As the researcher, you should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the IRB and regulatory authority(ies).
☐	☐	☐	4.11.2	As the researcher, 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 researcher, 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	GCP E6 4.12	Premature Termination or Suspension of a Trial
☐	☐	☐		As the researcher, if the trial is prematurely terminated or suspended for any reason, will you promptly inform the trial subjects, assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), inform the regulatory authority(ies)?
☐	☐	☐	4.12.1	As the researcher, if you terminate or suspend research without prior agreement of the sponsor, will you inform the sponsor and the IRB? The researcher should provide the sponsor and the IRB with a detailed written explanation of the termination or suspension.
☐	☐	☐	4.12.2	If the sponsor terminates or suspends a trial, as the researcher, will you promptly inform the IRB and provide a detailed written explanation of the termination or suspension?
☐	☐	☐	4.12.3	If the IRB terminates or suspends its approval of your research, will you notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension?

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Yes	No	N/A	GCP E6 4.13	Final Report(s) by Investigator
☐	☐	☐		Upon completion of the research, as the researcher, will you inform the IRB and provide a summary of the research results, and provide any reports required by the regulatory authority(ies)?

Investigator Certification
As the Principal Investigator, I understand the requirements as summarized in this document and will follow Good Clinical Practices while conducting research associated with the protocol "insert title". **Investigator Signature:** _____ **Date:**_____
Office of Research Compliance and Education (ORCE) Verification of Completion of Education Session **ORCE Staff Signature:** _____ **Date:** _____
List Individuals Present for Education Session: