TU-IRB-Form 03-B
INVESTIGATOR GOOD CLINICAL PRACTICE (GCP) CHECKLIST

Investigators should be fully aware of their obligations and responsibilities required by the Institutional Review Board (IRB) and National Committee on Biomedical Ethics (NCBE) prior to conducting research. This checklist provides a summary of investigator responsibilities pertinent to data and document management in accordance with Good Clinical Practice (GCP) Guidance.

Yes	No	N/A	4.1	**Investigator Qualifications and Agreements**
☐	☐	☐	4.1.1	Are you qualified to be responsible for the proper conduct of the research?
☐	☐	☐	4.1.2	Are you familiar with the appropriate use of the investigational medicine in the Investigator's Brochure provided by the sponsor?
☐	☐	☐	4.1.3	Are you aware of Good Clinical Practice guidance?
☐	☐	☐	4.1.4	Are you aware that you must permit monitoring and auditing by appropriate regulatory authority?
☐	☐	☐	4.1.5	Are you aware that you must maintain a list of your research team members?
Yes	**No**	**N/A**	**4.2**	**Adequate Resources**
☐	☐	☐	4.2.1	Are you able to recruit the required number of participants into your study within the time allowed by the IRB?
☐	☐	☐	4.2.2	Do you have sufficient time to properly conduct and complete the trial within the time allowed by the IRB?
☐	☐	☐	4.2.3	Do you have adequate number of qualified staff and adequate resources to conduct the research properly and safely?
☐	☐	☐	4.2.4	Can you ensure that all your team members are adequately informed about the protocol and their duties?
Yes	**No**	**N/A**	**4.3**	**Medical Care of Study** participant**s**
☐	☐	☐	4.3.1	Can you ensure that you or a sub-investigator will be responsible for all research-related medical decisions?
☐	☐	☐	4.3.2	Can you ensure that adequate medical care is provided to a participant in case of any adverse events?
☐	☐	☐	4.3.3	Will you record in the participant 's medical record about their participation in the research?
☐	☐	☐	4.3.4	Will you fully respect the research participants' rights?
Yes	**No**	**N/A**	**4.4**	**Communication with the IRB**
☐	☐	☐	4.4.1	Do you have a current IRB approval letter?
☐	☐	☐	4.4.2	Did you provide the IRB with a current copy of the Investigator's Brochure (for Clinical Trials only)?
☐	☐	☐	4.4.3	Did you provide all documents to review according to the IRB's requirements?
Yes	**No**	**N/A**	**4.5**	**Compliance with the IRB-Approved Research Application**
☐	☐	☐	4.5.1	Will you conduct the research in compliance with the protocol approved by the IRB?
☐	☐	☐	4.5.2	Can you ensure that you will not implement any change in your research without prior review and approval from the IRB?
☐	☐	☐	4.5.3	Will you document and explain any deviation from the approved protocol that may occur?
☐	☐	☐	4.5.4	If you deviate from your research to eliminate an immediate hazard, will you explain the deviation to the IRB?

Yes	No	N/A	4.6	Interventional and Investigational Product(s)/Devices – For Clinical Trials ONLY
☐	☐	☐	4.6.1	Will you take responsibility for interventional/investigational product/device, and accountability?
☐	☐	☐	4.6.2	Will you assign all of your duties for interventional/investigational, product/device, accountability at your organization to the CTU pharmacist?
☐	☐	☐	4.6.3	Will you, or your designee, maintain records of the product's/device's delivery your organization?
☐	☐	☐	4.6.4	Will you ensure that the interventional/investigational, product/device, will be stored and in accordance with the applicable regulatory requirement(s) and as specified by the sponsor (if applicable)?
☐	☐	☐	4.6.5	Will you ensure that the interventional/investigational product(s)/device(s) are used only in accordance with the IRB-approved research protocol?
☐	☐	☐	4.6.6	Will you, or your designee, explain the correct use of the interventional/investigational product(s)/device(s), to each participant? Will you, or a designee you have appointed, periodically check that each participant is following the instructions properly?
Yes	**No**	**N/A**	**4.7**	**Randomization Procedures and Unblinding**
☐	☐	☐		Will you follow the study's randomization procedures? Will you ensure that the code is broken only in accordance with the IRB-approved research application?
Yes	**No**	**N/A**	**4.8**	**Informed Consent of Study participants**
☐	☐	☐	4.8.1	Will you use the IRB's written informed consent form as approved prior to the beginning of the research?
☐	☐	☐	4.8.2	Will you ensure that you will revise the written informed consent form, whenever important new information becomes available, whenever that may be relevant to continuing participant 's consent?
☐	☐	☐	4.8.3	Will you ensure that neither you nor the research staff will coerce or unduly influence a participant to participate or to continue to participate in the research?
☐	☐	☐	4.8.4	Will you ensure that none of the oral and written information concerning the research waives any legal rights, or releases the investigator, the institution, or the sponsor (if applicable) from liability for negligence?
☐	☐	☐	4.8.5	Will you ensure that you, or a designee, will fully inform the participant or, if the participant is unable to provide informed consent, the participant 's legal representative, of all pertinent aspects of the research?
☐	☐	☐	4.8.6	Will you ensure that the language used in the oral and written information about the research, including the consent form, will be understandable to the participant or the participant 's legal representative?
☐	☐	☐	4.8.7	Will you ensure that you, or a designee, will provide the participant or the participant 's legal representative ample time to decide whether or not to participate in the research?
☐	☐	☐	4.8.8	Will you ensure that the written consent form is signed and dated by the participant or by the participant 's legal representative, and by the person who conducted the informed consent discussion prior to a subject's participation in any research procedures?
☐	☐	☐	4.8.9	Will you ensure that, if a participant is unable to read an impartial witness will be present during the entire informed consent discussion?
☐	☐	☐	4.8.10	Will you ensure that, the written informed consent form provided to participants should include explanations of the following: • That the study involves research. • The purpose of the study. • The study treatment(s) and probability for random assignment to each treatment (if applicable). • The study procedures to be followed, including all invasive procedures (if

				applicable). • The participant's responsibilities (if applicable). • Those aspects of the study that are experimental (if applicable). • The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant. • The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks (if applicable). • The compensation and/or treatment available to the participant in the event of study-related injury (if applicable). • The anticipated prorated payment, if any, to the participant for participating in the study (if applicable). • The anticipated expenses, if any, to the participant for participating in the study (if applicable). • That the participant 's participation in the study is voluntary and that the participant may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the participant is otherwise entitled. You will make a reasonable effort to ascertain the reason, while fully respecting the participant's rights. • That the monitor(s), the auditor(s), the IRB/LEC, and the regulatory authority(ies) will be granted direct access to the participant 's original medical records for verification of clinical trial procedures and/or data (if applicable), without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant 's legally acceptable representative is authorizing such access. • That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential. • That the participant or the participant 's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant 's willingness to continue participation in the study (if applicable). • The person(s) to contact for further information regarding the study and the rights of study participant s, and whom to contact in the event of study-related injury (if applicable). • The foreseeable circumstances and/or reasons under which the subject's participation in the study may be terminated (if applicable). • The expected duration of the subject's participation in the study. • The approximate number of participant s involved in the study.
☐	☐	☐	4.8.11	Will you ensure that, prior to enrolling in the research, the participant or the participant's legal representative will receive a copy of the signed and dated consent form?
☐	☐	☐	4.8.12	Will you ensure that when research includes vulnerable populations, the participant will be given the opportunity to sign and personally date the written informed consent?
☐	☐	☐	4.8.13	Will you ensure that your research will be conducted in participants who can personally give consent and who sign and date the written informed consent form?
Yes	**No**	**N/A**	**4.9**	**Records and Reports**
☐	☐	☐	4.9.1	**For Clinical Trials**: Will you ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the data collection sheets and in all required reports?
☐	☐	☐	4.9.2	**For Clinical Trials**: Will you ensure that data reported on the CRF (paper or electronic) as derived from source documents are accurately consistent with the source documents?
☐	☐	☐	4.9.3	**For Clinical Trials**: Will you ensure that any change or correction to a CRF (paper or electronic) will be dated, initialed, and explained?

☐	☐	☐	4.9.4	Will you maintain the research documents as required by the NCBE regulations?
☐	☐	☐	4.9.5	Will you ensure that your research documents will be retained for a minimum of 2 years after study closure or longer if required by the IRB?
☐	☐	☐	4.9.6	**For Clinical Trials**: Will you ensure that the financial aspects of the study are documented in the Clinical Trial Agreement (CTA) between yourself and the sponsor?
☐	☐	☐	4.9.7	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**	**4.10**	**Progress Reports**
☐	☐	☐	4.10.1	Will you submit written summaries of the research status to the IRB as per NCBE regulations?
☐	☐	☐	4.10.2	Will you promptly provide written reports to the sponsor (if applicable), the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the research, and/or increasing risks to participants?
Yes	**No**	**N/A**	**4.11**	**Safety Reporting (For Clinical Trials Only)**
☐	☐	☐	4.11.1	Will you immediately report all serious adverse events (SAEs) to the sponsor, and the IRB?
☐	☐	☐	4.11.2	Will you report adverse events and/or laboratory abnormalities to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol?
☐	☐	☐	4.11.3	Will you supply the sponsor and the IRB with any additional requested information in case of reported death?
Yes	**No**	**N/A**	**4.12**	**Premature Termination or Suspension of a Study (For prospective interventional studies)**
☐	☐	☐	4.12.1	If the study is prematurely terminated or suspended for any reason, will you promptly inform the study participants, assure appropriate resumption of needed therapy and follow-up for the participants, and inform the regulatory authority(ies)?
☐	☐	☐	4.12.2	In case you terminate or suspend research without prior agreement of the sponsor, will you inform the sponsor and the IRB?
☐	☐	☐	4.12.3	If the sponsor/funding agency terminates or suspends a study, as the investigator, will you promptly inform the IRB and provide a detailed written explanation of the termination or suspension?
☐	☐	☐	4.12.4	If the IRB terminates or suspends its approval of your research, will you notify the sponsor/funding agency and provide the sponsor/funding agency with a detailed written explanation of the termination or suspension?
Yes	**No**	**N/A**	**4.13**	**Final Report(s) by Investigator**
☐	☐	☐		Upon completion of the research, as the investigator, will you inform the IRB and provide a summary of the research results, and provide any reports required by the NCBE?

Investigator Acknowledgement

By signing below you acknowledge that: you have read and understood the GCP guidelines and you will conduct this Human Research or trial in accordance with requirements of GCP.

Investigator signature	Date