Consent Form Instructions and Guidance

OVERALL GUIDANCE FOR USING THE TEMPLATE:

1. Remove yellow highlighted text from the draft before submitting to the IRB for review.
2. To the extent possible, use the unhighlighted text as presented; however, adaptations are permissible as needed to accurately and clearly convey information that potential participants can understand.
3. To the extent possible, maintain the major headings and subheadings and elaborate/delete as appropriate to the study.
4. Use age-appropriate lay language (8th grade reading proficiency for adults) to define and describe complex technical and medical terms and procedures. CoPilot can be helpful in decreasing complex technical language.
5. When adapting the template to the study, ensure that the draft document maintains the required elements of consent, which can be found in OHRE SOP 1101, section 2.5.
6. Specimen Storage addendum instructions begin on page 9.

Main Consent Form

CONSENT FORM SECTION	INSTRUCTIONS/GUIDANCE
HEADER	One form may be used for multiple populations, i.e., Adult, Parent Permission/Adolescent Assent, Parent/Child Participants. You may wish to add a group sub-title such as "Control Group" or "Phase 1 – Interviews" to the 'Participants' line. **Control Group Participants** The version date should be updated with each change to the consent form to allow for proper consent tracking. Best practice is to update the file name with the version and/or version date with each update.
KEY INFORMATION	This section is only required for consent forms that are more than 5 pages in length (excluding signature lines). Use the prompts to provide a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This section should be a succinct description of the 1) purpose, 2) key procedures and their main risks, 3) expected time commitment, and 4)

	potential for benefit. You do not need to list every risk or side effect but should include a list that comprises the most common and most severe. You do not need to list details of the study visits but indicate if all visits are on site and/or remote. Distinguish between a direct benefit (e.g., improvement in symptoms such as X, Y from therapeutic or intervention research) and a possible indirect benefit (e.g., talking about/reflecting on an experience may lead to a better understanding of oneself). For uneven benefit across groups, e.g., If you are assigned to receive the investigational drug and it works as intended, you may experience some improvement in your symptoms such as X, Y but this cannot be guaranteed. If there is no potential direct benefit, state the benefit to society. It is essential that participants are fully informed (1) about the 'investigational' (or 'experimental') nature of research that studies the safety or effectiveness of a new drug or device and (2) when an FDA-approved medication is being studied for a purpose for which it is not FDA approved. It is also important that language used to describe the purpose is not overly assuring that the drug is safe or effective (for example, considering using terms such as 'well tolerated' rather than safe), and that the meaning of 'investigational' is explained. For example: The purpose of this research is to study if the investigational drug X is well-tolerated and helps reduce symptoms of Y in adults with type-1 diabetes. Investigational means the drug is not approved by the U.S. Food and Drug Administration (FDA) ***OR*** Investigational means the drug is not approved by the U.S. Food and Drug Administration (FDA) for the purposes it is being studied in this research. You may include illustrations, videos, and other novel approaches. You may include direct benefit, if any, and may mention potential compensation if not over-emphasized. Use the text prompts, as provided. However, the prompts may be re-organized to emphasize the most important elements for a particular study.

STUDY DESCRIPTION	In simple language, provide background information that guides the reader to an understanding of the scientific knowledge gap that the study seeks to address. Explain the main research question(s) to be addressed. You may mention, but do not overstate, the longer-term potential applications/benefits of the research to society. For example, the purpose of this study is to learn more about how differences in blood sugar levels affect brain activity. This information may eventually help researchers develop new strategies for treating diabetes. Continue to refer to the investigational nature of the drug(s) or device(s) being studied. Indicate the reason someone is being asked to participate. For example, they have a particular diagnosis, they represent a particular group of people (e.g., college students emergency responders, regular exercisers). The regulations require the "disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject." Examples include supportive care for some terminally ill patients, joining another research study that offers the potential for direct benefit, or receiving the intervention outside of the research as part of clinical care. Indicate the planned total enrollment number and if this number is only at UNC or across multiple institutions, including UNC.
REASONS TO NOT BE IN THE STUDY	List reasons that are recognizable to the potential participant. Avoid listing reasons that are beyond the participant's immediate knowledge, e.g., specific laboratory values This section can be challenging to understand if it includes highly technical or medical eligibility criteria that are not common knowledge to potential participants. It is important that this section focuses the participant's attention on key factors they would easily be able to identify as pertaining to them, so they

	might quickly recognize a reason or reasons they should exit the consent process. For example, someone is likely to know if they currently use high blood pressure medication, have received a prior diagnosis of cancer, or had a seizure event; they would know if they were not willing to refrain from caffeine consumption during the study or to allow researchers to review their medical record. On the other hand, someone would not likely know their blood glucose level, or their cancer sub-type or grade, or what the medical term neutropenia means. If the Sponsor requires all eligibility criteria to be listed, complex technical or medical terms must be explained in lay language. If the research risks include harm to a pregnant person or their fetus, include the second paragraph. [As applicable] If you are planning to become pregnant in the next [insert the number of weeks, months, or years as applicable to this study], you should not join the study. [As applicable] If you agree to be in the study and sign this consent form, the study team will do an in-depth assessment to be sure you are eligible to participate. If they find any reason you are not eligible, they will let you know.
RESEARCH PROCEDURES AND RISKS	For studies with multiple visits and procedures, it is HIGHLY RECOMMENDED to include a Time and Events Schedule/Table in this section or as an addendum to this form. Throughout this section, it is recommended that you organize the information in order of highest to lowest risk, e.g., invasive before noninvasive, sensitive before nonsensitive. This prioritization may help a concerned person choose an off-ramp during the consent process, sooner rather than later.

	Describe and explain each study intervention or treatment, including the investigational status of any drugs or devices; include randomization and blinding procedures, as applicable. Describe the risks of each intervention or treatment. Describe each study procedure, what it involves, why it is being done, how long it will last, how often (at what visits) it will be done, and what risks are associated with it. Refer to the Common Procedures and Risks document for suggested descriptions. For lengthy/complex activities, consider using bullets and sub-headings rather than long narrative text. Consider including a Table of Events or include as an appendix to the Informed Consent Form. You can find a template in the Procedures and Risks document. For optional procedures, describe them here or in a separate consent document, and delete any text that is not relevant. For optional studies that use a separate consent document, substitute this statement for the above: There are optional activities that will be explained to you later in a separate document. You will not be excluded from this study if you choose not to participate in these optional activities.
RISKS TO PREGNANCY	This section should clearly state the risks to a fetus if the participant or participant's partner is pregnant or becomes pregnant during the study, the requirement to use effective birth control, and immediate notification to the researcher if they suspect pregnancy.
RISKS TO A NURSING CHILD	Describe any specific effects, if known, from human studies. Consider describing effects from animal studies. If a drug study, include the time period after stopping the study drug.
ALTERNATIVES TO PARTICIPATION	Should be included for all studies where an intervention is the focus of the research.
COMPENSATION	It is important to differentiate reimbursement for study-related costs, such as transportation/parking or overnight accommodations, and incentive

	payments. When incentives are offered, they should be described, including amount, schedule for receipt, and any proration for partial study completion. For minors, if reimbursements and/or incentive payments are given to the parent instead of the participant, this should be clearly stated. For older minors, it is appropriate to consider incentive payments for both the participant and the parent. For younger minors, non-monetary gifts may be appropriate.
COSTS	List the additional tests/visits/procedures to be performed for research purposes only. Describe who will be responsible for paying the cost of research tests, procedures, visits, etc. that are not standard-of-care. Be sure to indicate who will pay for the pregnancy tests. • Clearly explain what the likely costs will be for participation in this research study and who will be responsible for those costs e.g. "… billed to you and/or your insurance." Or "… paid by the sponsor." • Describe specific items or procedures that may/may not be covered. Include clinic or diagnostic fees, transportation, and parking fees (if known). • Address clearly who will be responsible for the payment of the costs of standard treatment in the research study, e.g., "These costs will be billed to you or your insurance carrier." If reimbursement is provided for transportation, parking, meals, or accommodations, please explain these as upfront costs that will be reimbursed later and how and when that will be done.
RESEARCH INJURIES	There are 2 options, both of which are scripted and should be used as written. One option is for studies without a commercial sponsor; the other is for studies with a commercial/industry sponsor. The second one may not be revised without prior approval from the Clinical Research Compliance Office, as this ensure congruence between the consent form and the contract with the industry sponsor.
NEW INFORMATION DURING THE STUDY	For studies that involve imaging (e.g., CT, MRI), include one of two statements related to the likelihood of incidental findings of an abnormality. This section of the consent form will be auto-populated by indicating in the IRBIS application that incidental findings are likely or unlikely.

PRIVACY AND CONFIDENTIALITY PROTECTIONS	• Describe how records will be secured. • Describe who will have access to individually identifiable data and how access will be restricted. • Describe whether names or ID numbers will be used (if codes or numbers are assigned, describe how the linkage file will be secured). • When using an interpreter, describe how you will help ensure that the bilingual interpreter will maintain confidentiality. • Describe what will be done with audio and video recordings, including plans for storage during use, how long the recordings will be kept after transcription, and a reminder that participants can request not to be recorded, if that is true for the study. Edit the bulleted list of confidentiality protections as needed.
HIPAA AUTHORIZATION	Do not alter this section unless indicated.
REVIEW OF YOUR INFORMATION	Tailor this section to the particular oversight for your study. Delete any organizations that do not apply to your study.
CERTIFICATE OF CONFIDENTIALITY	Use one of the two descriptions provided. Delete the other. Typically, the briefer description is used for international studies.
STOPPING MY PARTICIPATION	This section is important for informing participants about the reasons they may be withdrawn as well as the steps they should take if they wish to withdraw themselves, so that early departures from the study do not introduce added risk (for example, abrupt cessation of drug treatment without proper downward titration). Modify the first paragraph as needed to explain the consequences of a subject's decision to withdraw and the procedures that will be followed for the orderly termination of participation.
FUNDING/STUDY SPONSOR	It is important for participants to be informed when an external entity is sponsoring the study, and whether the sponsor or investigators have any conflicts of interest to be disclosed. Modify this section only if there is a Conflict of Interest Management Plan that needs to be disclosed. Insert the language provided by the Conflict of Interest Office.

QUESTIONS ABOUT THE STUDY	DO NOT ALTER THIS SECTION
QUESTIONS ABOUT YOUR RIGHTS	DO NOT ALTER THIS SECTION
AGREEMENT TO PARTICIPATE	To document assent of an adolescent: The adolescent should sign as Research Participant. The parent(s) should sign the Parent section. To document assent of an individual with impaired decisional capacity: The participant should sign as Research Participant. Their representative should sign as LAR. Witness signature lines: Should be included in all consent forms for unanticipated enrollment of individuals with low literacy, visual impairment, physical condition affecting the ability to sign, or witness for non-English individual when a Short Form Consent is used.

Optional Specimen Collection/Storage Addendum

PURPOSE OF THE BIOBANK	State the type and amount of specimens to be collected. Describe purpose for the specimen collection and storage and what you hope to learn from the stored samples. Provide a specific description of the research to be conducted with the specimens if known.
RESEARCH PROCEDURES AND RISKS	Provide specific details about how the specimen will be collected, including frequency and size/amount.
STORAGE AND FUTURE USE	Address specific areas about how the sample will be used and stored: Provide a clear description of the operation of the specimen biobank, such as: Where will the specimen be stored? Who will have access to the link? When will the specimens be destroyed? If applicable, please describe how clinical or study data will be linked to the specimens for future use. Inform subjects of conditions under which data and specimens will be released to other investigators. Insert any contract, grant or agreement language related to specimen ownership or modify the following boilerplate.
RESEARCH RESULTS	Will populate depending on application responses.
PRIVACY AND CONFIDENTIALITY	Include protection of identifiable data. Describe methods to be used: coding, etc. Describe how the records will be secured. Include who may have access to the records, if names will be used, or if there will be ID numbers only, and a linkage file.
GENETIC INFORMATION	DO NOT ALTER THIS SECTION

	Unless you are certain that future research will not include genetic analysis, retain this section. Note that if this section is not included, the IRB cannot provide Institutional Certification for studies that intend to produce genetic results.
RESEARCH INJURIES	Will populate based on application responses.
WITHDRAWING YOUR SPECIMENS	Will populate based on application responses.
COMPENSATION	Complete based on whether compensation will be provided for the optional collection.