Combined Informed Consent and HIPAA Authorization Guidance:

- **Study Title:** Title of the study must match the title provided on the IRB application.

- **Principal Investigator:** Provide the name of the principal investigator.

- **Sponsor:** If applicable, provide the name of the sponsor funding the research study. If there is no funding, list "None". If Ohio State is the recipient of a sub-award, both the sub-award and primary award entities are to be listed. If there is internal funding, list "The Ohio State University". If internal funding is from a primary federal award, then this should be listed.

- **Key Information About This Study:** Lengthy and/or complex consent documents must begin with a concise and focused summary of the key information that is most likely to help the participants decide whether or not to participate in the study, and to encourage discussion about the pros and cons of research participation. The following items may be addressed in this summary: the purpose of the research, the expected duration, and the research procedures to be followed; the most important risks or discomforts (i.e., highest frequency or greatest severity); the reasonably expected benefits; and appropriate alternative procedures or courses of treatment. Other additional information may be needed based on the study design and the intended subject population.

  Note: Information listed here need not be repeated later in the consent form unless that information is necessary to help ensure the consent remains understandable to the subject.

1. **Explanation of the study (Why is this study being done?):** Provide a brief non-technical explanation of the purposes of the research. Explain why the subject is being asked to participate in the study (e.g., you are being asked to participate in this research study because…).

2. **Number of participants in the study (How many people will take part in this study?):** Include approximate number of participants; if multi-center, include total study number and number expected at Ohio State.

3. **Study procedures (What will happen if I take part in this study?):** Provide a complete description of procedures, including the order in which they occur, and specifically identify and distinguish any procedures that are experimental or being performed solely for research purposes. Describe what the participant will be expected to do using lay language and fully explain any medical terms or abbreviations.

4. **Duration of participation (How long will I be in the study?):** Provide expected duration, including frequency of re-contact and follow-up, of the participant's participation. Ensure that the proposed duration is realistic for the procedures to be performed.

5. **Study withdrawal (Can I stop being in the study?):** Indicate that the subject may choose to discontinue participation without penalty or prejudice.

   Note: Standard language is provided on the consent template.

   Explain potential outcomes of a participant's decision to withdraw from the research. If applicable, insert the following language and describe the procedures for orderly termination, explaining why the tests, visits, etc. are necessary for the participant's welfare:

   You may be asked to follow certain procedures or undergo additional testing to safely leave the study.

   If applicable, also insert the following language and explain anticipated circumstances under which the subject's participation may be terminated:

   There may also be reasons why your study participation can be stopped without your consent.

   Note: Do not state that the investigator may withdraw participants if they do not follow study procedures, as participants are not in a position to know all of the study procedures.

   Regarding participant withdrawal from FDA-regulated clinical trials, explain the following:

   - According to FDA regulations, data collected about the participant up to the time of withdrawal remains part of the study data and may not be removed
   - Participants may be asked if they wish to provide informed consent for continued follow-up and data collection subsequent to their withdrawal from the interventional portion of the study (Note: Distinguish between previous study-related interventions and the continued follow-up of associated clinical outcomes, and address the maintenance of privacy and confidentiality of the participant's data.)
   - Data collected about the participant prior to withdrawal may be reviewed by the researcher and research team (including review of public records, such as survival status) even if the participant does not provide consent to continued follow-up.

6. **Description of the risks (What risks, side effects or discomforts can I expect from being in the study?):** Provide a description of any reasonably foreseeable risks or discomforts. Explain the likelihood and seriousness of the risks, including potential physical, social, economic, psychological, and legal harms. Describe the precautions that will be taken to minimize the risks.

   When appropriate (e.g., for studies involving investigational drugs), include a statement that the particular treatment or procedure may involve risks to the participant (or embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable. If drugs or devices are being studied, ensure that the risks described are based on the protocol, investigator's brochure, package labeling and/or previous research reports.

When appropriate (e.g., for studies involving genetic testing), include the following language:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- *Health insurance companies and group health plans may not request your genetic information from this research.*
- *Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.*
- *Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

When appropriate, for research involving biospecimens, address whether the research will (if known) or might include whole genome sequencing.

Note: Standard language is provided on the consent template.

7. Description of the benefits (What benefits can I expect from being in the study?): Provide a description of any benefits to the participant or to others that may reasonable to expect from the research, distinct from benefits subjects may receive if not participating. Consider potential benefits that may accrue to science or society in general as a result of the planned research. Assess the likelihood of benefits based on the protocol and ensure they are realistic for the research. Do not overstate potential benefits.

If applicable, insert the following language when no direct benefits to participants are expected:

You will not benefit directly from participating in the study.

Note: Describe any payments to participants in the incentives (Will I be paid for taking part in this study?) section.

8. Alternatives (What other choices do I have if I do not take part in the study?): Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Include the full range of available options for the participant.

Also state that participants may choose not to participate without penalty or loss of benefits.

Note: Standard language is provided on the consent template.

9. **Additional costs to participants (What are the costs of taking part in this study?):** Explain any additional costs to the subject that may result from participation in the research. When medical care is delivered in the context of the study, distinguish between costs of procedures performed for research purposes and those performed as part of standard care.

   If applicable, insert the following language when there will be no additional costs to participants:

   There will be no additional costs to participate in the study.

10. **Description of the incentives provided (Will I be paid for taking part in this study?):** Explain payments or other incentives to participate, including amount and schedule of payments. Compensation should be pro-rated (e.g., per visit) and not contingent upon study completion.

    If payments will be offered, also state that payments are considered taxable income.

    Note: Standard language is provided on the consent template.

    If payments will not be offered, delete standard language from the consent template and insert the following language:

    You will not be paid to participate in the study.

    When appropriate, address whether participants' biospecimens (even if identifiers are removed) may be used for commercial profit and whether or not participants will share in this profit.

11. **Compensation/medical treatments for injury (What happens if I am injured because I took part in this study?):** Explain any compensation or medical treatments available if injury occurs. Use non-exculpatory language to describe the availability of compensation. Include any information regarding whether participants or their insurance companies will be billed for any costs.

    Note: When funds have not been set aside for compensation, use the standard language provided on the consent template.

    When compensation for injury will be provided by the sponsor, also insert the following language:

{Insert sponsor's name}, *the study sponsor, plans to pay for necessary medical treatment not covered by your insurance if you are injured by the drugs or devices being studied or any procedures required by the study, as described above in this consent form. The sponsor does not plan to pay for treatment or other complications or illness that did not result from your study participation, or for injuries that result from your failing to follow instructions given to you by the researcher or study doctor.*

12. **Participants' rights (What are my rights if I take part in this study?):** State that subjects do not give up any personal legal rights by agreeing to participate. The following statements must also be included: participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; subjects may discontinue participation at any time without penalty or loss of benefits; and any significant new findings developed during the course of the research that may relate to subjects' willingness to continue participation will be provided.

    Note: Standard language is provided on the consent template.

13. **Future use of de-identified information and/or biospecimens (Will my de-identified information (and biospecimens) be used or shared for future research?):** For research that involves the collection of identifiable private information or identifiable biospecimens, explain if there might be future use or sharing of the information or biospecimens even if identifiers are removed.

    Note: Standard language is provided on the consent template.

14. **Confidentiality of records (Will my study-related information be kept confidential?):** Add the following to the standard language on the consent template: A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. Do not interchange the terms "confidential," "anonymous," and "de-identified." Discuss the disposition of participants' records following conclusion of the research.

    When appropriate address whether clinically relevant research results, including individual research results, will or will not be returned to participants. Note: Standard language is provided on the consent template.

    For applicable clinical trials, also state that participant information from studies involving drugs, biologics, or devices will be entered into the publicly available databank at ClinicalTrials.gov.

    Note: Standard language is provided on the consent template.

15. **HIPAA Authorization (HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES):** In general, the language provided

should not be changed. Study specific information should be provided for the following sections:

- **I. What information may be used and given to others?** List the information to be accessed in a specific and meaningful manner. Add and delete bullets as applicable.
- **III. Who might get this information?** List every known non-Ohio State person, class of persons, or organization [include specific names of the sponsor, collaborators, study monitor (CRO, SMO), healthcare providers, persons or organizations that analyze health information for the study, data safety monitoring boards, etc..] that may create, disclose, receive, and/or use the information in connection with the study. If information will not be disclosed outside of The Ohio State University, insert "None" under "Other." Note: if a person(s) or organization is not listed on the form, they may not create, disclose, receive, or use PHI in connection with the study.
- **VI. When will my permission end?** If the authorization will not expire, delete the sentence "This permission will be good until *[date]*." If there is a specific date on which authorization expires, provide an end date and delete the paragraph that begins "There is no date at which […]."

16. **Contact Information (Who can answer my questions about the study?):** Provide contact information for the principal investigator and/or research staff for questions, concerns, or complaints about the study and for information about the availability of compensation or medical treatments. The person(s) listed should be knowledgeable about the research. As appropriate, provide provisions for emergency or after-hours contact.

    Note: Add information to the standard language on the consent template. If no physical interventions are planned, investigators can remove the "If you are injured […]" contact line.

    Provide contact information for the appropriate HIPAA privacy officer.

    Note: Add information in the space provided. If the research involves the use of medical records from Ohio State's University Wexner Medical Center insert (where applicable) the contact and address: HIPAA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, OH 43201. If the research solely involves the use of personal health records at sites other than The Ohio State University Wexner Medical Center clinics or health care facilities (for example, College of Dentistry and Dental Faculty Practice, College of Optometry, Nisonger Center, Younkin Success Center, Psychological Services Clinic, The Ohio State University Speech-Language-Hearing Clinic), insert the name and address of the appropriate Privacy Contact for the center, school, clinic, or practice group. If unknown, contact the director of the health center, school, clinic, or practice group or the Office of Legal Affairs at (614) 292-0611 for the contact and address of the applicable Privacy Contact. See HIPAA Privacy Officer List for the current list of privacy officers and contact information.

    Provide ORRP contact information for questions about participant rights and as a contact not part of the study team for participant concerns or complaints about the research. Include area code or international dialing codes for phone or fax numbers.

    Note: Standard language is provided on the consent template.

When appropriate, include one or more of the following elements:

- A statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable (e.g., in studies involving investigational drugs or devices)
- A statement that the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable, if the participant is or may become pregnant (e.g., in studies involving drugs or devices used in pregnant women or women of childbearing potential for which the safety profile in pregnancy is unknown)
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent (Note: Circumstances must be specific and may not include "If you do not follow study procedures," as participants are not in a position to know all of the study procedures)
- Consequences of a participant's decision to withdraw from the research (e.g., in studies involving interventions for which stopping the intervention would have adverse consequences if not monitored or replaced by another treatment)
- Procedures for orderly termination of participation (e.g., when in best interest of participants and specified in study procedures)