The purpose of this checklist is to provide support for IRB members reviewing research. This checklist must be completed and retained for all studies being reviewed.

Criteria for Approval of Research in compliance with 45CFR46.111 and 21CFR.56.111: (All must be "Yes" or "N/A") (Applies to initial, continuing, modifications that alter risk or research decision making, convened, and expedited reviews)

☐ Yes ☐ No Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

☐ Yes ☐ No ☐ N/A Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if no such procedures)**

☐ Yes ☐ No Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

☐ Yes ☐ No Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)

☐ Yes ☐ No ☐ N/A When the research involves more than minimal risk to subjects, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if no more than minimal risk)**

☐ Yes ☐ No There are adequate provisions to protect the privacy of subjects.

☐ Yes ☐ No There are adequate provisions to maintain the confidentiality of data.

☐ Yes ☐ No ☐ N/A Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. **("N/A" if no vulnerable subjects)**

☐ Yes ☐ No Informed consent will be sought from each prospective subject or Legally Authorized Representative (LAR), in accordance with, and to the extent required by:

☐ CONSENT PROCESS ☐ WAIVER OR ALTERATION ☐ Permanently closed to enrollment

☐ Yes ☐ No Informed consent will be appropriately documented, in accordance with, and to the extent required by:

☐ CONSENT PROCESS ☐ WAIVER OR ALTERATION ☐ Permanently closed to enrollment

---

Consent Process

☐ Yes ☐ No ☐ N/A The investigator will obtain the informed consent of the subject or LAR.

☐ Yes ☐ No ☐ N/A Consent will be obtained only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.

☐ Yes ☐ No ☐ N/A Consent will be obtained only under circumstances that minimize the possibility of coercion or undue influence.

Information to be given to the subject or LAR will be in language understandable to the subject or LAR.

☐ Yes ☐ No ☐ N/A The information to be given to the subject or LAR does not include any exculpatory language through, which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Additional Considerations (May Be "Yes" or "No")

☐ Yes ☐ No Is Continuing Review required? Possible reasons for continuing review are: 1) Required by other applicable regulations (e.g., FDA), 2) The research involves topics, procedures, or data that may be considered sensitive or controversial; 3) The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability; 4) An investigator has minimal experience in research or the research type, topic, or procedures; and/or 5) An investigator has a history of noncompliance.

If yes, describe the reason:

☐ Yes ☐ No Does the research involve more than minimal risk to subjects? Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If no, select below under which IRB Expedited Review category or categories the research should be approved. Check *all* that apply.

Category #1 ☐	Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b)Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
Category #2 ☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
Category #3 ☐	Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
Category #4 ☐	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
Category #5 ☐	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
Category #6 ☐	Collection of data from voice, video, digital, or image recordings made for research purposes.
Category #7 ☐	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
Category #8 ☐	Continuing review of research previously approved by the convened IRB as follows: where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.
Category #9 ☐	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

General requirements for informed consent in compliance with 45CFR46.116(b); 45CFR46.116(c); 21CFR50.25(a); 21FCR56(b). All required and all appropriate additional elements must be disclosed and documented) ***Required: (*Starred elements can be omitted if there are none. Check the box to indicate completion, if missing, leaving the box blank .***

Yes	No	N/A	
☐	☐	☐	A statement that the study involves research.
☐	☐	☐	An explanation of the purposes of the research.
☐	☐	☐	An explanation of the expected duration of the subject's participation.
☐	☐	☐	A description of the procedures to be followed.
☐	☐	☐	Identification of any procedures, which are experimental.*
☐	☐	☐	A description of any reasonably foreseeable risks or discomforts to the subject.*
☐	☐	☐	A description of any benefits to the subject or to others, which may reasonably be expected from the research.*
☐	☐	☐	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
☐	☐	☐	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.*
☐	☐	☐	For FDA-regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records.
☐	☐	☐	For research involving more than minimal risk an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
☐	☐	☐	For research involving more than minimal risk an explanation as to whether any medical treatments are available if injury occurs and, if so,what they consist of, or where further information may be obtained.
☐	☐	☐	An explanation of how to contact the research team for questions, concerns, or complaints about the research.
☐	☐	☐	An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
☐	☐	☐	An explanation of whom to contact in the event of a research-related injury to the subject.
☐	☐	☐	A statement that participation is voluntary.
☐	☐	☐	A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
☐	☐	☐	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
☐	☐	☐	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional: (Include when appropriate.)

Yes	No	N/A	
☐	☐	☐	A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
☐	☐	☐	A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
☐	☐	☐	Anticipated circumstances under which subject's participation may be terminated by the investigator without regard to the subject's consent.
☐	☐	☐	Any additional costs to the subject that may result from participation in the research.
☐	☐	☐	The consequences of a subject's decision to withdraw from the research.
☐	☐	☐	Procedures for orderly termination of participation by the subject.
☐	☐	☐	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
☐	☐	☐	The approximate number of subjects involved in the study.
☐	☐	☐	The amount and schedule of all payments.

Required for Clinical Trials:

Yes	No	N/A	
☐	☐	☐	The approval/favorable opinion by the IRB.
☐	☐	☐	The probability for random assignment to each treatment.
☐	☐	☐	The subject's responsibilities
☐	☐	☐	When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
☐	☐	☐	The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
☐	☐	☐	When there is no intended clinical benefit to the subject, a statement to this effect.
☐	☐	☐	A statement that monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
☐	☐	☐	If the results of the trial are published, the subject's identity will remain confidential.

Reviewer Comments:

Please use the textbox below to provide additional comments or to elaborate on items that are missing or otherwise don't address the criteria:

Decision:

Please use the "Review Status" field in the Novelution Approval Form to mark your final decision selecting from the below:

a) Modifications Needed for Admin Review: IRB staff may approve after reviewer comments have been addressed

b) Modifications Needed for Member Review: reviewer comments must be addressed and changes sent back to reviewer

c) Modifications Needed for Convened Review: if the revisions requested are for a project undergoing Full Board Review

d) Referred to Convened Meeting: if this project should be referred to Full Board for review, contact the IRB Office

e) Approved: project can go forward as is