This IRB Protocol Review form is made available to Investigators so they may see what IRB members need to find in order to approve research protocols.

**Do not complete this form and do not submit it to the IRB.**

LECOM Institutional Review Boards
Protocol Review Form

Instructions. Please complete this entire form to document the IRB's consideration of all criteria for approval. If an item is not applicable to this protocol, please mark it "Not Applicable," do not leave it blank.

If the protocol requires approval at a convened IRB meeting, this completed form will be distributed to IRB members with the protocol in advance of the meeting. If this is eligible for expedited review, the IRB Chairperson may approve the protocol based on your review or may refer it to the convened IRB.

**Protocol Number:** _____

**Protocol Title:** _____

**Principal Investigator:** _____

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**Reviewer:** _____

**Date:** _____

☐ LECOM IRB #1 (internal LECOM IRB)

☐ LECOM IRB #4 (hospital consortium IRB)

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| **I. "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. **Does this study present no more than minimal risk of harm to human subjects?** | ☐ Yes | ☐ No |

| **II. Eligibility for "Expedited Review"** | | |
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| **A.** Only minimal risk studies are eligible for **"Expedited Review."** Did you assess this study as presenting no more than minimal risk in Section I, above? | ☐ Yes | ☐ No |
| **B.** If you answered "**No**" to Part A, the study is not eligible for expedited review; **please skip the rest of Sections II and III, and proceed to Section IV.** | | |
| **C.** Are **all** research activities involved in this project in one or more of the categories listed below? | ☐ Yes | ☐ No |

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| ☐ | 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.) |
| ☐ | 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. |
| ☐ | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: 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; **or**,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. |
| ☐ | Prospective collection of biological specimens for research purposes by noninvasive means.<br>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 |
| ☐ | 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.)<br>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. |
| ☐ | 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). |
| ☐ | Collection of data from voice, video, digital, or image recordings made for research purposes. |
| ☐ | 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. |

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| **D.** If you answered "**No**" to Part C, the study is not eligible for expedited review; **please skip the rest of Section II and Section III, and proceed to Section IV**. If you answered "**Yes**" to Part C, please identify all of the categories of research activities utilized in this protocol by checking the box(es) next to each applicable activity above. | |
| **E.** Do you recommend that the protocol be reviewed via the expedited process or would you prefer to refer it to the convened IRB at a meeting? | ☐ Expedited<br>☐ Full IRB |

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| **III.** If the protocol achieves approval via the expedited process, do you recommend that it be required to undergo continuing review on an annual basis? | ☐ Yes<br>☐ No |

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| **IV. Risks to subjects are minimized** (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (2) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes. | ☐ Met – research design is appropriate, no unnecessary exposure to risks, procedures already needed for non-research purposes being utilized whenever appropriate.<br><br>☐ Not Met |
| **Please summarize ways in which risks to subjects are minimized; whenever possible, please reference page numbers in the protocol where these procedures are described:** | |
| **Please identify any changes to the protocol that should be required to ensure that risks to subjects are minimized:** | |

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| **V. 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.<br>• Do not consider risks or benefits of thereapies that subjects would receive even if not in the research<br>• Do not consider long-range effects of applying knowledge gained in the study | ☐ Met – the anticipated benefits of this study to the subjects and/or the importance of the knowledge expected to result outweigh the risks of harm to the subjects<br><br>☐ Not Met |
| **Please summarize risks to subjects, any expected benefits to individual subjects, and the importance of the knowledge expected to be gained; whenever possible, please reference page numbers in the protocol where these risks and benefits are described:** | |
| **Please identify any changes to the protocol that should be required to ensure that risks are reasonable:** | |

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| **VI. Selection of subjects is equitable,** taking into account the purpose of the research, the setting in which it will be conducted, and the special problem of research involving subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. | ☐ Met – Subject selection is equitable; neither unduly burdens vulnerable populations nor unduly benefits privileged groups. Compensation if any, is not so excessive as to be coercive.<br><br>☐ Not Met |
| **Please summarize subject selection/recruitment methods and relevant characteristics of anticipated subjects. Please reference page numbers in the protocol where recruitment procedures and subject characteristics are described:** | |
| **Please identify any changes to the protocol that should be required to ensure that selection of subjects is equitable:** | |

| **VII. Will children be subjects of this research activity?** ☐ **Yes** ☐ **No** |
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| **If "Yes", please also complete and attach the "Research Involving Children" review form.** |

| **VIII. Waiver or Alteration of Informed Consent** | | | |
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| **A.** Is the investigator requesting waiver of the requirement for informed consent, or omission of some of the required elements of consent, or alteration of some or all of the required elements of consent? | ☐ YES | ☐ NO | |
| **B. Criteria for Waiver or Alteration of Informed Consent.** If you answered "Yes" to Part A, please address the criteria for a waiver or alteration below. If you answered "No" to Part A, please proceed to Section IX. | | | |
| The research involves no more than minimal risk to the subjects (must agree with the answer to Section I.) | ☐ YES | ☐ NO | |
| The waiver will not adversely affect the rights and welfare of the subjects | ☐ YES | ☐ NO | |
| The research could not practicably be carried out without the waiver or alteration | ☐ YES | ☐ NO | |
| If the research involved using identifiable private information or identifiable biospeciments, the research could not be practicably carried out without using such information or biospecimens in an identifiable format. | ☐ YES | ☐ NO | ☐ N/A |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation | ☐ YES | ☐ NO | ☐ N/A |
| Use this space to provide any needed explanation regarding the above responses. If an alteration rather than a complete waiver is requested, please explain the nature of the alteration. | | | |

**NOTE: Throught the remainder of this form, whenever the terms "subject" or "prospective subject" are used in the context of informed consent, they include a subject's or prospective subject's legally authorized representative.**

| **IX. Informed Consent Process** | | |
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| **A**. Unless a complete waiver of the informed consent requirement was requested, does the protocol provide a process for obtaining informed consent from each prospective subject? | ☐ YES | ☐ NO |
| **B.** Does the informed consent process provide the prospective subject with sufficient opportunity to discuss and consider whether or not to participate? | ☐ YES | ☐ NO |
| **C.** Does the informed consent process minimize the possibility of coercion or undue influence? | ☐ YES | ☐ NO |
| **D.** Is the information provided to the prospective subject in language that is understandable to the prospective subject (i.e. reading level, lack of specialized jargon, subject's fluency in the language, etc.)? | ☐ YES | ☐ NO |
| **E.** Is the prospective subject provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate? | ☐ YES | ☐ NO |
| **F. If you answered "No" to any of items A through E, please explain the deficiencies below.** | | |
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| **X.** If some or all subjects are likely to be vulnerable to coercion and undue influence, additional safeguards have been included in the study design to protect the rights and welfare of these subjects. (If a complete waiver of informed consent was requested, answer "N/A"). | ☐ Yes | ☐ No | ☐ N/A |
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| **If "Yes", please summarize these safeguards and please reference the page numbers in the protocol where they are described.** | | | |
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| **XI. Documentation of Informed Consent** (if a complete waiver of informed consent was |
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| requested, answer "N/A" to Part A, below). | | | |
| **A.** Is the investigator requesting waiver of the requirement that informed consent be documented? | ☐ Yes | ☐ No | ☐ N/A |
| **B.** If you answered "Yes" to Part A, skip the rest of Section XI and proceed to Section XII. If you answered "N/A" to Part A, skip directely to Section XIII. | | | |
| **C.** Informed consent will be documented by:<br>☐ Signature of the subject on a consent form containing all required elements of informed consent, a copy of which is provided to the subject; or,<br>☐ Signature of the subject on a short-form consent form stating that required elements have been presented orally to subject and that the concise overview (described in Section XIII.A.) was provided before any other information). | | | |
| **D**: If the short-form consent form is to be used, are all of the requirements listed below met: | | | |
| The protocol includes a written summary of what is to be said to the subject | ☐ YES | ☐ NO | |
| The protocol provides for a witness to the oral presentation | ☐ YES | ☐ NO | |
| The witness will sign both the short-form consent and the written summary | ☐ YES | ☐ NO | |
| The person actually obtaining the consent will sign the written summary | ☐ YES | ☐ NO | |
| Copies of both the short-form consent and the written summary will be provided to the subject. | ☐ YES | ☐ NO | |

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| **XII. Waiver of Documentation of Informed Consent.** | | | |
| **A.** To approve the waiver of documentation of informed consent, the IRB must find one of the three circumstances below. Please mark which one applies. | | | |
| ☐ | The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern. | | |
| ☐ | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. | | |
| ☐ | Subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternate mechanism for documenting that informed consent was obtained. | | |
| **B.** If waiver request is approved, should investigator be required to provide subjects with a written statement describing the research? | | ☐ YES | ☐ NO |

| **XIII. General Criteria for Information Provided in Consent Process** | | |
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| **A.** Does the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding why one might or might not want to participate in the research? | ☐ YES | ☐ NO |
| **B**. Is the concise and focused presentation of key information organized and presented in a way that facilitates comprehension? | ☐ YES | ☐ NO |
| **C.** Does the informed consent as a whole present information in sufficient detail related to the research and is it organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates prospective subject's understanding of the reasons why one might or might not want to participate? | ☐ YES | ☐ NO |
| **D.** Is the informed consent free of any exculpatory language through which the subject is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence? | ☐ YES | ☐ NO |
| **E. If you answered "No" to any of items A through D, please explain the deficiencies below.** | | |
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| **XIV. Informed Consent** Does the informed consent process (i.e. either the consent form or the written summary if a "short form" consent form is to be used) provide each of the following **basic elements of informed consent** and the necessary additional elements of informed consent to the prospective subjects? | | | |
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| | **Page #** | **No** | **N/A** |
| A. A statement that the study involves research | | | |
| B. An explanation of the purposes of the research | | | |
| C. The expected duration of the subject's participation | | | |
| D. A description of the procedures to be followed | | | |
| E. Identification of any procedures which are experimental | | | |
| F. A description of any reasonably foreseeable risks or discomforts | | | |
| G. A description of any benefits to the subject, or others, which may reasonably be expected from the research | | | |
| H. Disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject | | | |
| I. Description of extent, if any, to which confidentiality of records identifying the subject will be maintained | | | |
| J. Information on who to contact in the event of a research related injury | | | |
| K. Information on who to contact for answers to questions about the research | | | |
| L. Information on who to contact for answers to questions about the research subjects' rights | | | |
| M. A statement that participation is voluntary and that refusal to participate will result in no penalty and no loss of benefits to which the subject is otherwise entitled | | | |
| N. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled | | | |
| O.For research involving greater than minimal risk, an explanation as to whether there is any compensation available if injury occurs and, if so, what it consists of or where further information may be obtained | | | |
| P. For research involving greater than minimal risk, an explanation as to whether there are any medical treatments available if injury occurs and, if so, what they consist of or where further information may be obtained | | | |
| Q. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: **Either,** 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 resereach studies or distributed to another investigator for future research studies without additional informed consent, **or,** 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. | | | |
| **Are all of the required basic elements of informed consent (A through Q, above) either "Yes" or "Not Applicable"?** | | | |

| One or more of the following **additional elements of** | **Appropriate** | **Appropriate** | **Not** |
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| **informed consent** must be included when appropriate to the circumstances of the research. Please identify which are needed and, if needed, whether they are already included. | **and already included** | **but, not yet included** | **needed** |
|---|---|---|---|
| R. A statement that the particular treatment or procedure may involve risks to the subject (or to the fetus or embryo if the subject is or may become pregnant) which are currently unforeseeable | | | |
| S. Anticipated circumstances in which the subject's participation may be terminated by the investigator without regard to the subject's consent | | | |
| T. Any consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject | | | |
| U. Any additional costs to the subject that may result from participation in the research | | | |
| V. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation in the study will be provided to the subject | | | |
| W. The approximate number of subjects involved in the study | | | |
| X. A statement that the subject's biospecimens (even if identifiers are removed) might be used for commercial profit and whether the subject will or will not share in the commercial profit. | | | |
| Y. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. | | | |
| Z. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) | | | |
| **Are all additional elements of informed consent either already included in the consent process or not needed for this particular study?** | ☐ **Yes** | ☐ **No** | |

| **XV. Revisions to Consent Process. Please describe any additional changes to the consent process that the IRB should require prior to approval of the protocol, particularly any that would meaningfully add to the protection of the rights and welfare of the subjects.** |
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| **XVI. Does this project require IRB review more often than annually?**<br>**(i.e. uncertain or high level of risk, novel techniques, etc.)** | ☐ Yes | ☐ No | |
| **XVII. Does this project require verification from someone other than the investigator regarding whether material changes have occurred since the last review (i.e. based on investigator's prior history, diffusion of responsibilities among principal investigator and others, etc.)?** | ☐ Yes | ☐ No | |
| **XVIII. If needed, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?** | ☐ Yes | ☐ No | ☐ N/A |
| **XIX. If needed, does the research plan make adequate provision to respect the privacy of subjects and to maintain confidentiality of data?** | ☐ Yes | ☐ No | ☐ N/A |
| **Please state your recommendation regarding any "Yes" responses to XVI or XVII and any "No" responses to XVIII or XIX, above.** | | | |
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| **XX. Please describe any additional revisions that should be required prior to approval that are not reflected elsewhere on this form.** |
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| **XXI. Complete this section only if the Investigator requested a waiver or alteration of the HIPAA Authorization requirement.** | | |
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| | **YES** | **NO** |
| Is there an adequate plan to protect health information identifiers from improper use and disclosure? | | |
| Is there an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so)? | | |
| Would it be practical to obtain authorizations from the subjects? | | |
| Would it be practical to conduct the research project without access to the subjects' protected health information? | | |
| Use this space to provide any needed explanation regarding the above responses. | | |

| **XXII. CITI Training** | | |
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| | **YES** | **NO** |
| Does the submission include documentation that the Principal Investigator completed CITI training for Principal Investigators within the past three years? | | |
| Does the submission include documentation that **all** project staff (co-investigators, research assistants, student researchers, etc.) completed CITI training appropriate to their roles within the past three years? | | |
| List any members of the project staff for whom documentation of training was not provided: | | |

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# Review Form for Research Involving Children

1. Does the research activity present no more than minimal risk of harm to the children?

   ☐ Yes (go to Question #2)

   ☐ No (go to Question #3)

2. Does the research activity make adequate provision for soliciting the assent of the children and the permission of their parents or guardians?

   ☐ Yes – Research is approvable if requirements applicable to all protocols are also met

   ☐ No – Protocol must be modified to include provisions for assent and permission prior to approval

3. Is the greater than minimal risk of harm to the children presented by either (A) an intervention or procedure that **holds out the prospect of direct benefit to the individual subject**, or (B) by a monitoring procedure that **is likely to contribute to the subject's well-being**?

   ☐ Yes (go to Question #4)

   ☐ No (go to Question #5)

4. Are **all** of the following true?

   A. The risks are justified by the anticipated benefits to the subjects,
   B. The relationship of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and,
   C. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

   ☐ Yes – Research is approvable if requirements applicable to all protocols are also met

   ☐ No – ☐ If "A" or "B" is not true, research activity is not approvable
   ☐ If "C" is not true, protocol must be modified to include needed provisions

5. If the greater than minimal risk of harm to the children is presented either by (A) an intervention or procedure that **does not hold out the prospect of direct benefit to the individual subject,** or (B) by a monitoring procedure that **is not likely to contribute to the subject's well-being**, then are **all** of the following true?

   A. The risk represents a minor increase over minimal risk,
   B. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations,
   C. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and,
   D. Adquate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

   ☐ Yes – Research is approvable if requirements applicable to all protocols are also met

   ☐ No – ☐ If "A", "B", or "C" is not true, research activity is not approvable
   ☐ If "D" is not true, protocol must be modified to include needed provisions

6. If the research activity was found to be approvable at either Question #2 or Question #4, is the permission of one parent, rather than both parents, sufficient?

   ☐ Yes, the permission of one parent is sufficient

   ☐ No, permission must be obtained from both parents (unless one is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)