This form is for completion by IRB Members only.

It is provided to prospective research investigators for informational purposes only, so that investigators may see what IRB members must “find” before a protocol may be approved.

It is hoped that this information will help investigators to design their research protocols in conformity with IRB standards and Federal regulations (and will lead to quicker approval with fewer modifications required in order to secure approval).

Please **do not** complete and return this form with your protocol.

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LECOM IRB Protocol Review Form

Protocol Number: _____

Protocol Name: _____

Principal Investigator: _____

Reviewer: _____

Primary Reviewer ☐ **Secondary Reviewer** ☐

Date: _____

Instructions. Please complete this entire form to document the IRB's consideration of all criteria for approval required by LECOM's Federalwide Assurance for the Protection of Human Subjects of Research. If an item is not applicable to this protocol, please mark it "Not Applicable," do not leave it blank. Attach additional sheets if needed.

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

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 encourntered in daily life or during the performance of routine physical or psychological examinations or tests. **Is this a "minimal risk" study?**	☐ Yes	☐ No

II. 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. ☐ 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:	

III. 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. • Do not consider risks or benefits of thereapies that subjects would receive even if not in the research • 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 ☐ 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:	

IV. Selection of subjects is equitable, taking into account the purpose of the research, the setting in which it will be conducted, and special concerns for research involving vulnerable populations (children, prisoners, mentally disabled individuals, pregnant women, and economically or educationally disadvantaged individuals). Additional safeguards are in place for potentially vulnerable subjects to avoid coercion and undue influence.	☐ 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. ☐ 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:	

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

VI. Informed Consent		
	Yes	**No**
1. Did the Investigator request a waiver of the informed consent requirement? If **Yes**, complete Section IX, below, and skip the remainder of this table.		
2. Did the Investigator request a waiver to exclude or alter any of the required elements of informed consent? If **Yes**, indicate N/A in this table for all items for which waiver is requested and complete Section IX.		
3. Did the Investigator request a waiver of the documentation of informed consent?		

4. 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** to the prospective subjects?

	Page # (if Yes)	**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			
Are all of the required basic elements of informed consent (A through P, above) either "Yes" or "Not Applicable"?			

* Refer to your answer to the "minmal risk" question on the first page of this form..

One or more of the following **additional elements of 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.	**Appropriate and already included**	**Appropriate but, not yet included**	**Not needed**
Q. 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			
R. Anticipated circumstances in which the subject's participation may be terminated by the investigator without regard to the subject's consent			
S. Any consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject			
T. Any additional costs to the subject that may result from participation in the research			
U. 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			
V. The approximate number of subjects involved in the study			
Are all additional elements of informed consent either already included in the consent process or not needed for this particular study?	☐ **Yes**	☐ **No**	

VII. Are the elements of informed consent written in a manner that they can be understood by the prospective subjects? (i.e. appropriate reading level, avoidance of specialized jargon, etc.). If "No", identify areas of concern below.	☐ **Yes**	☐ **No**

VIII. The consent process may not include any "exculpatory language" (i.e. any language through which the subject or the representative is made to waive or appear to waive any of the subject's rights or releases or appears to release the investigator, the sponsor, the institutions, or its agents from liability for negligence). Does the consent form or script contain any exculpatory language? If "Yes", please detail below.	**☐ Yes**	**☐ No**

IX. Complete this section only if the Investigator requested a waiver of the requirement for informed consent or if the Investigator requested to alter or waive any of the elements of informed consent (i.e. if you answered "Yes" to either Question VI.1. or VI.2., above).

	YES	**NO**
The research involves no more than minimal risk to the subjects (must agree with the answer to Question I. on first page)		
The waiver will not adversely affect the rights and welfare of the subjects		
The research could not practicably be carried out without the waiver or alteration		
Whenever appropriate, the subjects will be provided with additional pertinent information after participation		

Use this space to provide any needed explanation regarding the above responses.

X. Documentation of Informed Consent	**Check the one that applies**
1. Written consent form signed by the subject (or legally authorized representative) and embodying the required elements of informed consent	
2. Short-form consent form signed by subject stating that required elements have been presented orally to subject (or legally authorized representative)	
If #2 is checked:	
Procedure must specify a witness to the consent process ☐ Yes ☐ No	
Protocol includes written summary for IRB approval of what is to be said at consent process ☐ Yes ☐ No	
Procedure must specify that witness signs short form consent and copy of written summary ☐ Yes ☐ No	
Subject (or representive) must be given copy of summary and copy of short form consent ☐ Yes ☐ No	
3. The Investgator has requested a waiver of the requirement to document informed consent.	
Either A or B, below must be met for the waiver to be granted.	
A. 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. ☐ Yes ☐ No	
B. 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. ☐ Yes ☐ No	
If waiver request is approved, should investigator be required to provide subjects with a written statement describing the research? ☐ Yes ☐ No	

XI. 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.

XII. Does this project require IRB review more often than annually? (i.e. uncertain or high level of risk, novel techniques, etc.)	☐ Yes	☐ No	
XIII. 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	
XIV. If needed, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?	☐ Yes	☐ No	☐ N/A
XV. 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 XII or XIII and any "No" responses to XIV or XV, above.			

XVI. Please describe any additional revisions that should be required prior to approval that are not reflected elsewhere on this form.

XVII. Complete this section only if the Investigator requested a waiver or alteration of the HIPAA Authorization requirement.		
	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.		

XVIII. CITI Training		
	YES	**NO**
Does the submission include documentation that the Principal Investigator completed CITI training for Principal Investigators within the past two 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 two years?		
List any members of the project staff for whom documentation of training was not provided:		

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LECOM IRB 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)