







Los Angeles County Public Health, Ambulatory Care Network and Health Services Administration Institutional Review Board (IRB) 313 N. Figueroa St., Room 127

Los Angeles, CA 90012

Phone: (213) 288-8675 Email: irb@ph.lacounty.gov

http://publichealth.lacounty.gov/irb/

## **APPLICATION FOR EXEMPT REVIEW (CHECKLIST NOT NEEDED)**

1. Title of project	2. Date Application Prepared	
2. Principal Investigator: Name, degree		
3. Telephone		
5. DPH/DHS Liaison if applicable: Name, department or	organization and title	
6. Contact person/study coordinator		
7. Telephone	8. Email	
9. Funding source(s) (check all that apply)		
Federal, state, government (name of agency)		
Commercial County commitment of in-kind reso	ources No specific budget – funding out of operating expenses	
Other (explain)		
10. Total amount of funding \$		
11. New proposal Amendment (IRB approval #		
12. Source of subjects		
13. Sample: Size Age group		
Children Adults ≥ 18		
14. Form of consent (include script if applicable)		
Written Verbal consent Embedded consent in	n instrument	
Other (explain)		
15. Describe how your study addresses community-eng	aged research needs and involves the community in the research	
plan and conduct of the study including how the fin	idings will be disseminated to the community	

Please include with this application:

Request for Exempt Review HIPAA Individual Authorization or Waiver Request if applicable

Protocol summary (project aim, study design and methodology including recruitment method, consent procedures and script, explanation of how privacy and confidentiality of subjects will be protected and data collection instruments)

Certificate of IRB or Human Subjects Protection training (PI, co-PI, study coordinator and research personnel dealing with data collection or analysis)

## Principal Investigator's assurance and signature

Signature certifies that the Principal Investigator understands and accepts the following obligations to protect the rights and welfare of subjects in this study.

- I recognize that as the Principal Investigator it is my responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform with the IRB approved protocol, IRB requirements/policies, and all applicable HHS/FDA regulations.
- I recognize that it is my responsibility to ensure that valid informed consent/assent has been obtained from all research subjects or their legally authorized representatives.
- I will inform the IRB of any unanticipated adverse event or injury immediately after it becomes known that a subject suffered an adverse event/injury.
- I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject in which case the IRB will be notified as soon as possible.
- I will maintain all required research records and recognize the IRB is authorized to inspect these records.
- I will inform the IRB immediately of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.
- I will not enter subjects on the study before IRB approval.
- I will inform the IRB immediately if I become aware of any violations of HHS regulations (45 CFR 46), FDA regulations (21CFR5r0.56) or IRB Policies and Procedures for the protection of human subjects.
- I understand that failure to comply with all applicable HHS/FDA regulations, IRB Policies and Procedures and the provisions of the protocol as approved by the IRB may result in suspension or termination of my research project, notification of appropriate governmental agencies by the IRB, and/or suspension of my freedom to present or publish results.

PRINCIPAL INVESTIGATOR' S NAME	DATE	SIGNATURE	
PRINCIPAL DPH OR DHS LIAISON if applicable	DATE	SIGNATURE	
PROGRAM DIRECTOR'S/DIVISION CHIEF'S NAME	DATE	SIGNATURE	
Key Personnel (name and role):			
NAME	ROLE		