American University of Health Sciences
Institutional Review Board

1600 East Hill Street, Building #1, Signal Hill, CA 90755
: Phone (562) 988-2278 : Fax (562) 988-1791.
Dr. Okezie Aruoma, IRB E-mail address: irb@auhs.edu

REQUEST FOR IRB REVIEW

This form must be submitted with proof of completion of the National Institute of Health course on working with human subjects. The course is free and takes about two hours. It can be found at http://phrp.nihtraining.com/users/login.php

Protocol and Study Information				
Date Submitted to IRB:	Program ☐ School of Nursing ☐ School of Pharmacy ☐ School of Biomedical Sciences ☐ University Extension Program ☐ Other _____			
Principal Investigator:	Research Advisor (if any):			
Proposal Title				
Number of Subjects			Age Range	
Total	Male	Female	From	To

Investigator Information		
	Name	Department
Co-Investigator		
Co-Investigator		
Co-Investigator		
Co-Investigator		
Co-Investigator		

IRB applications should be sent to the IRB committee via email, to the current chair of the committee, Dr. Okezie Aruoma, IRB E-mail address: irb@auhs.edu

If email is impractical, the forms should be sent in triplicate by snail mail or in-house interoffice mail to the
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Part A:

Application Status
The final determination of application status will be made by the IRB committee.

☐ Full Review
(Project involves invasive procedures or other medical or therapeutic interventions)

☐ Expedite Review
(Project does not involve invasive procedures or other medical or therapeutic interventions. Generally include interviews, review of existing data such as chart reviews or data collected in previous studies, or passive observations)

Full or Expedite Reviews require annual recertification.

☐ Exempt
(Project fits the Federal criteria outline in the IRB instructions, or surveys)
Exempt status can only be determined by the IRB committee. Exempt studies do not require annual recertification, unless changes are made to the research methods.

Concise Statement of Proposed Research with Details of Human Subjects Use Aspect

Describe within the space below, **in layman's terms**, what is to be done so that a realistic estimate of the risks to the subjects and the benefits of the project can be assessed. If, in addition to this concise statement, an extensive description of the project has been drafted, please attach.

The inclusion of females and members of minority groups and their sub-populations must be addressed in the development of the research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group. Provide a rationale for each selection of such subjects. Your proposal should contain a description of the proposed outreach programs for recruiting females and minorities as participants.

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Part B:

Answer the following questions:

1. Are human subjects involved in the proposed study? ☐ Yes ☐ No

   If yes:

   a. Are the human subjects healthy volunteers? ☐ Yes ☐ No

   b. Are the subjects under medical or therapeutic treatment? ☐ Yes ☐ No

   c. What is the age range of the subjects? From: ____ To: ____

   d. How many subjects will be studied at this site? (approximate estimate if definite number is not known) _____

   e. Of the subjects studied, how many will be females? _____

   f. Of the subjects studied, how many will be from minority groups? _____

   g. Are the subjects capable of understanding the nature of the study ☐ Yes ☐ No

   h. What is the population source of the subjects to be studied? _____

   _____

   i. Are the subjects' inpatients? ☐ Yes ☐ No

   j. Are you the subject's attending physician and/or therapist? ☐ Yes ☐ No

   k. How long will each subject be in the study? _____

   If more than a year, study will have to be recertified in one year.

   l. At what intervals will each subject be seen?_____

2. Will any of the following classes of subjects be involved in the proposed study?

   Minors (if yes assent form may be required) ☐ Yes ☐ No

   Incompetents ☐ Yes ☐ No

   Compromised Mental Status ☐ Yes ☐ No

   Females ☐ Yes ☐ No

   Pregnant Women ☐ Yes ☐ No

   Fetuses ☐ Yes ☐ No

   Fetal Tissue ☐ Yes ☐ No

Minorities ☐ Yes ☐ No

Prisoners ☐ Yes ☐ No

3. Are human tissues, biological fluids or products (feces, mucus, etc.) involved in the study? ☐ Yes ☐ No

If yes,

a. What tissues, fluids or products are involved?

b. Are the tissues, fluids or products being collected solely for the purpose of the study? ☐ Yes ☐ No

c. Are extra quantities (more than needed for routine tests) of the above being collected? ☐ Yes ☐ No

d. Are the above to be removed from a cadaver? ☐ Yes ☐ No

e. Are the above to be removed during a surgical ☐ Yes ☐ No procedure?

f. Are the above to be obtained during routine non-operative procedures? ☐ Yes ☐ No

4. Does the study involve a drug? *If yes: ☐ Yes ☐ No

a. Is this a marketed drug? ☐ Yes ☐ No

If yes, is the study being initiated by a physician or a drug company?

b. Is this an investigational drug or is the study intended to support an application for marketing permit? ☐ Yes ☐ No

c. In what phase of the study is the drug?

d. What is the dose range of the drug to be used?

e. Have there been untoward reactions to the drug? ☐ Yes ☐ No

What tissues or organ systems were involved in these reactions?

_____

*If study involves an investigational drug/agent, the sponsor's investigator drug brochure must accompany this form.

f. Will a placebo be used in this study? ☐ Yes ☐ No

g. Is this a double blind study? ☐ Yes ☐ No

h. Will the subject be denied other drugs customarily employed for this disease? ☐ Yes ☐ No

i. I am familiar with the "Formulary and Regulations Governing Drugs" at the Division at which the study is being conducted. ☐ Yes ☐ No

5. Does the study involve a device? ☐ Yes ☐ No

a. Is the device FDA approved? ☐ Yes ☐ No

b. If yes, please provide documentation.

c. If no, is this a significant risk device? ☐ Yes ☐ No

d. If yes, please provide IDE # _____

or

Has the 30-day waiting period expired? ☐ Yes ☐ No

or

Has the FDA waived requirement for an IDE? ☐ Yes ☐ No

If either Numbers 4 or 5 have been answered yes, then the investigator must attach a specific list of parameters to be monitored and the frequency of monitoring. This may be a copy of a list supplied by the sponsor.

The Investigator must also report any untoward reaction to the IRB or its Officers after its occurrence within two working days.

6. Does the study involve a diagnostic or therapeutic procedure? If yes: ☐ Yes ☐ No

a. Is the procedure entirely new, new to this institution, or routine? ☐ Yes ☐ No

b. Have there been untoward reactions to this procedure? ☐ Yes ☐ No

What tissues or organ systems were involved in these reactions? _____

c. Will placebo procedures be used in the study? ☐ Yes ☐ No

d. Will routine procedures customarily employed for this disease be denied the subject? ☐ Yes ☐ No

All applicants must answer the following questions:

7. Will the subjects personally benefit from the study? ☐ Yes ☐ No

a. May the study contribute directly to the subject's health or welfare? ☐ Yes ☐ No

b. May the study provide health benefits for mankind? ☐ Yes ☐ No

c. Are the subjects paid for entering the study? ☐ Yes ☐ No

What is the amount and source of the funds? $_____ Source _____

d. Are other inducements going to be made to recruit subjects? ☐ Yes ☐ No

If yes, explain:

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8. Are all parties in the project protected? ☐ Yes ☐ No

   a. Are consent forms to be used? ☐ Yes ☐ No

   b. Does the investigator have the needed insurance coverage? ☐ Yes ☐ No

   c. Is AUHS covered by its Insurance under the conditions of the project? ☐ Yes ☐ No

   d. Have provisions been made for the subject's care in case of an untoward reaction? ☐ Yes ☐ No

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IMPORTANT

Protocols will be delayed if the following items are not submitted along with this form:

Attachments:
1. Consent Form
2. IND Form – If applicable
3. Indemnification Letter – If Drug Company sponsored protocol
4. Contractual Agreement – If Protocol is sponsored by an external source

9. **FINANCIAL COMPENSATION FOR SERVICES**

   a. Are the services and/or tests associated with this study billable to the patient or third party payers? ☐ Yes ☐ No

   If no, please describe below how these costs will be recovered.

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Part C:

All applicants must answer the following eight questions.

Please address the following questions regarding your project. Answer as briefly as possible, but in detail. Refer to the IRB Instructions for further detail.

Remember that some reviewers are not specialists in your field. Word your answer so that an educated layperson will be able to understand your study. Use a separate page(s) for each question.

1. Who will the subjects be and how will they be selected
   Include copies of all recruitment material such as flyers. All recruitment material must include the Program's name, the purpose of the study, and contact information for the IRB office.

2. Where will the research be performed? Who will be your approved supervisor?

3. What precisely will be done with the subjects? Describe in reasonable detail. If a questionnaire will be used, please enclose a copy.

4. How will subject anonymity and confidentiality be guaranteed?

5, Will the project require subjects to be uninformed, misled or misinformed in any way (e.g. sham treatment, placebo effects).

   If yes, discuss the rationale for this approach and what measures are being taken to remove the deception at the earliest possible moment.
   .

6. In your judgment, will the project involve discomfort, stress or risk to the subject?

7. If a written consent form will be obtained from the subjects, please attach a copy. If your project is a survey, please attach the cover letter and questionnaire. Generally, surveys will not require a separate consent form. All consent forms are required to include the name and address of the Dr. Okezie Aruoma, IRB E-mail address: oaruoma@auhs.edu, 1600 East Hill Street, Building #1, Signal Hill, CA 90755 Phone (562) 988-2278

8. What benefits may there be to the subject(s) and/or society? If there are risks involved do the benefits outweigh the risks? Please explain.

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DATE:_____

TO: Members of the Institutional Review Board for the Protection of Human Subjects

SUBJECT: APPROVAL OF RESEARCH PROPOSAL INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR:

PROJECT TITLE:

The subject application is attached for your review. Please indicate your action thereon by signing in one of the spaces below.

1. CERTIFICATION
I hereby certify that in my judgment the proposal complies with AUHS policy on the Protection of Human Subjects.

Committee Member Date

2. CLARIFICATION
Further information or clarification is requested as follows:

Committee Member Date

3. DISAPPROVAL
In my judgment, the proposal does **NOT** meet the appropriate standards because:

Committee Member Date

The attached material is submitted for review and approval to the AUHS Institutional Review Board for the Protection of Human Subjects.

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of Advisor Date