For Official Use Only:
AUHS IRB Log #: _____ Date: _____

Institutional Review Board

REQUEST FOR IRB REVIEW

Date Submitted:			
Title of Research Project:	**Comorbidities of Diabetes and Hypertension in a Cohort of Homeless Population in Long Beach, CA**		
Principal Investigator/ Project Director:	Department:	Principal Investigator/ Project Director:	Department:
Co-Principal Investigator:	Department:	Co-Principal Investigator:	Department:
Co-Investigator:	Department:	Co-Investigator:	Department:
Co-Investigator:	Department:	Co-Investigator:	Department:

Projected Duration of Research:	Project Start Date:	Grant affiliation (if none, put "NA")
Other organizations and/or agencies, if any involved in the study: American University of Health Sciences Foundation		

REQUIRED DOCUMENTATION FOR ALL PROJECTS

I. Project Information:

1. Project Activity Status:
   - ☐New Project
   - ☐ Periodic Review of Continuing Project
   - ☐ Revision to Previously Approved Project

2. This project involves American University of Health Sciences students:
   - ☐ Yes
   - ☐ No

3. Human Subjects from the following populations will be involved in this study:
   - ☐ Minors
   - ☐ Mentally Disabled
   - ☐ Elderly
   - ☐ Prisoners
   - ☐ Homeless
   - ☐ None of the above

4. Total number of subjects to be studied:

II. 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?
      ☐ Yes ☐ No treatment?
   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, ☐ Yes ☐ No, nature of the study?
   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 ☐ NA
   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 ☐ NA
   c. Are extra quantities (more than needed for routine tests) of the above being collected?
      ☐ Yes ☐ No ☐ NA
   d. Are the above to be removed from a cadaver?
      ☐ Yes ☐ No ☐ NA

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

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

4. Does the study involve a drug?
☐ Yes ☐ No ☐ NA

If yes:

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

c. In what phase of the study is the drug?
☐ Yes ☐ No ☐ NA

d. What is the dose range of the drug to be used?
☐ Yes ☐ No ☐ NA

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

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

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

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

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?
   ☐ Yes ☐ No ☐ NA

   If yes:
   a. Is the procedure entirely new, new to this institution, or routine?
      ☐ Yes ☐ No ☐ NA
   b. Have there been untoward reactions to this procedure?
      ☐ Yes ☐ No ☐ NA
      What tissues or organ systems were involved in these reactions? _____
   c. Will placebo procedures be used in the study?
      ☐ Yes ☐ No ☐ NA
   d. Will routine procedures customarily employed for this disease be denied the subject?
      ☐ Yes ☐ No ☐ NA

All applicants must answer the following questions:

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

   a. May the study contribute directly to the subject's health or welfare?
      ☐ Yes ☐ No ☐ NA
   b. May the study provide health benefits for mankind?
      ☐ Yes ☐ No ☐ NA
   c. Are the subjects paid for entering the study?
      ☐ Yes ☐ No ☐ NA
      What is the amount and source of the funds? $_____ Source _____
   d. Are other inducements going to be made to recruit subjects?
      ☐ Yes ☐ No ☐ NA
      If yes, explain:
8. Are all parties in the project protected?
   ☐ Yes ☐ No
9. Are consent forms to be used?
   ☐ Yes ☐ No
   a. Does the investigator have the needed insurance coverage?
      ☐ Yes ☐ No ☐ NA
   b. Is AUHS covered by its Insurance under the conditions of the project?
      ☐ Yes ☐ No ☐ NA
10. Have provisions been made for the subject's care in case of an untoward reaction?
    ☐ Yes ☐ No ☐ NA

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

FINANCIAL COMPENSATION FOR SERVICES

1. 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.

III. Project Description

Describe **in layman's terms** the scientific significance and goals of the study, including background and references. (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document. How much time will be required of each subject? Describe procedures to which humans will be subjected. What is the number of subjects that would be required to meet the study goals?

a. Specific aims (no more than 300 words)

b. Background (no more than 800 words)

c. Significance (no more than 500 words)

d. Study design/Methodology (no more than 1000 words)

e. Potential risks and benefit (Describe the potential risks and direct/indirect benefits to subjects and /or target population as well as procedures for minimizing the risks (no more than 200 words)

f. Describe the inclusion and exclusion criteria for subject entry or for use of data/tissues

IV. **Precautions** (What steps will be taken to ensure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?

V. **Confidentiality and privacy of data** (Describe the procedures to maintain confidentiality and privacy be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc) The procedures to maintain confidentiality and privacy. The vulnerable groups that may be encountered in the subject population, with emphasis on additional protections that will be put into place to ensure that the rights and welfare of such groups are protected.

VI. **Consent** (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject). How the capacity to consent will be assessed for all subjects?

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented (except in case of immediate hazards to the subject).
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.
- If the IRB requires modifications in the project prior to approval, the IRB will notify the PI(s) who can then make changes and resubmit application for final approval.

I certify that the protocol and method of obtaining informed consent as approved by the Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

Principal Investigator (s) Signature Albert Ngo	Date	Co-Investigator/Student Signature (if appropriate)	Date

FOR OFFICE USE ONLY	
Signature of IRB Chair	Date
IRB Chair: Check appropriate box: Returned for additional information ☐ Returned for revisions ☐ Approved ☐ Approved with modifications ☐ Denied ☐	

Type of Review (as determined by IRB): ☐ Exempt ☐ Expedited ☐ Full Review

FOR EXEMPT PROJECTS

Charts 1-11 Charts to Determine Exemptions to IRB process can be found in the hyperlink below.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html