AUA IRB#2 Application Form 2014

American University of Armenia | Հայաստանի Ամերիկյան Համալսարան

AMERICAN UNIVERSITY OF ARMENIA

INSTITUTIONAL REVIEW BOARD # 2
COMMITTEE ON CLINICAL RESEARCH

SCHOOL OF PUBLIC HEALTH

40 Baghramian Ave.,
Yerevan, Armenia, 0019
Phone (374060) 61 25 61/ FAX (374060) 61 25 66

APPLICATION FORM

PLEASE PRINT OR TYPE. INCOMPLETE FORMS WILL NOT BE PROCESSED

Principal Investigator
(Name, degree)
(Must be a faculty member)

Department:

Phone:

Email:

Co-Investigator(s):
(Name(s), degree(s))

Student Investigator:
(Name, degree)

Project Title:

Proposed Start Date (MM/DD/YYYY)

Anticipated Duration of Research

Study Subjects:
(Check all that apply)

- ☐ Males
- ☐ Females
- ☐ Children (under 12 yrs. of age)
- ☐ Adolescents (12-17 yrs. of age)
- ☐ Pregnant Women/Fetuses
- ☐ Elderly (over 65 years)
- ☐ Prisoners
- ☐ Patients
- ☐ Normal Volunteers
- ☐ Students
- ☐ Employees of study sites
- ☐ Cognitively Impaired
- ☐ No subjects—existing data or specimens

Type of Study:
(Check all that apply)

- ☐ Clinical Trial
- ☐ Community Trial
- ☐ Survey
- ☐ In-depth Interview
- ☐ Focus Group Discussions
- ☐ Experiment
- ☐ Secondary Data Analysis
- ☐ Program/ Project Evaluation
- ☐ Case Control Study
- ☐ Longitudinal Study
- ☐ Record Review
- ☐ Course Activity
- ☐ Other

Indicate the items below which apply to your research
(Check all that apply)

- ☐ FDA approved drug(s)
- ☐ Armenian Drug and Medical Technology Agency (ADMTA) approved drug(s)
- ☐ FDA approved device(s)
- ☐ Armenian Drug and Medical Technology Agency (ADMTA) approved device(s)
- ☐ FDA approved biologics (e.g., vaccine(s))
- ☐ Armenian Drug and Medical Technology Agency (ADMTA) approved biologics (e.g., vaccine(s))
- ☐ Investigational New Drug (IND)
- ☐ _____IND Sponsor
- ☐ _____IND Number
- ☐ Approved drug being used for an unapproved use
- ☐ Investigational New Device (INE)
- ☐ _____INE Sponsor
- ☐ _____INE Number
- ☐ Approved device being used for an unapproved use
- ☐ Not applicable
- ☐ Other

Participant risk

Does this study involve biologic toxins?

- ☐ Yes
- ☐ No

Does this study involve infectious agents?

- [ ] Yes
- [ ] No

Is radiation used in this study?

- [ ] Yes
- [ ] No

If Yes, what form of radiation?

- [ ] X-ray
- [ ] Radiation therapy
- [ ] Radioisotopes
- [ ] Other

Is it beyond standard of care?

- [ ] Yes
- [ ] No

Is information recorded in such a manner that subjects can be identified from information provided directly or through identifiers linked to the subjects?

- [ ] Yes
- [ ] No

Does the research deal with sensitive aspects of the subject's behavior; sexual behavior, alcohol use or illegal conduct such as drug use?

- [ ] Yes
- [ ] No

Could the information recorded about the individual if it became known outside of the research place the subject at risk of criminal or civil liability?

- [ ] Yes
- [ ] No

Could the information recorded about the individual if it became know outside of the research damage the subject's financial standing, reputation, or employability?

- [ ] Yes
- [ ] No

Do you consider this research: (Check one)

- [ ] Greater than minimal risk?
- [ ] Minimal risk?
- [ ] No risk?

Minimal Risk *is a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as a part of routine physical examination.*

If you consider this proposal to merit expedited or exempt status, indicate the justification below (check all that apply)

- [ ] Secondary analysis of a previously approved dataset
- [ ] Research is purely for a course assignment and poses no risk
- [ ] Protocol has already been reviewed and approved by another IRB

Consent Process: (Check all that apply)

- ☐ Written
- ☐ Oral
- ☐ Armenian language
- ☐ English language
- ☐ Russian language
- ☐ Other language
- ☐ None

SUBMIT ELECTRONIC FILE OF THE ENTIRE APPLICATION/THESIS PROPOSAL TO THE AUA IRB HUMAN PARTICIPANTS ADMINISTRATOR,
Dr. Kristina Akopyan, Room 410W, email auairb@aua.am.

Name of Contact Person (if applicable)	Telephone #
Signature of Principal Investigator	Date

American University Of Armenia

Institutional Review Board # 2
School of Public Health
COMMITTEE ON CLINICAL RESEARCH

NEW RESEARCH PROJECT

RESEARCH PLAN

The following items should be covered in no more than six typed pages in 12-point type and presented in the following consecutive order:

1. RESEARCH QUESTION ADDRESSED BY THIS PROPOSAL:

2. RATIONALE for RESEARCH:

- Motivation for research (Problem)
- Summary of related research (Background - shortly describe clinical data, ongoing experiences related to the procedures, drug or device, and any other applicable information that justifies the research)
- Importance of proposed work (Aim)

3. METHODS:

- Study design and rationale for that design (must relate to the stated aims/research questions provided earlier).
- Study duration
- Study population, sample size, inclusion and exclusion criteria, gender, age, locale (provide justification for single gender or group). On greater than minimal risk studies, provide a justification for the sample size. Recruitment process – explain how the participants will be identified for the study (if research topic is sensitive, describe how the risks to the potential participants will be minimized)
- If applicable, information and justification of blinding and not blinding
- If applicable, information and reasons the participants will not receive regular care or current therapy
- If applicable, justification for non-treatment or placebo group
- Explanation of treatment failure, removal criteria of the participants
- Discuss options to therapy when participation stops prematurely or when study ends
- Procedures involving the subjects of the research: Distinguish procedures which are a part of routine care from those which are part of the study (when applicable)

    Provide information on will physicians refer subjects, will referring physicians receive any incentives to recommend subjects for study participation, (if yes describe the incentive)
- Provide information on the frequency, duration and place of contacts between research team and the participants
- Briefly describe data analysis plan
- Questionnaire/Interview Instrument (when applicable): If the study includes an instrument, a copy is to be appended to this application. If the instrument is in the developmental stages, provide an outline of the types of questions to be asked and the expected date of completion and submission to the IRB.
- Drugs/devices/vaccines under the study

If the study includes drug: provide the rationale for deciding the drug and dose, its names (generic, trade), name of its manufacturer, information on its indication(s) as well as FDA- and/or Armenian Drug and Medical Technology Agency (ADMTA)-approval of the drug for the indication described in the protocol;
if not-FDA or ADMTA- approved, an Investigational New Drug (IND) provide name of the IND, information on manufacturer, who (sponsor, investigator) holds the IND#, describe your procedures for the management and control of the IND; as well as submit the Investigator's Drug Brochure.

If the study includes device: provide its name, name of its manufacturer, information on its indication(s) as well as FDA- and/or Armenian Drug and Medical Technology Agency (ADMTA)-approval of the device for the indication described in the protocol;
if not-FDA or ADMTA-approved, an Investigational Device (IDE) indicate its category (category A: Experimental/ Investigational; Innovative device, not previously approved or category B: Non-experimental/Investigational; Proven Technology, new application), provide name of the IDE, name of its manufacturer, information on who (sponsor, investigator) holds the IND#; describe your procedures for the management and control of the IND; as well as submit Investigator's Drug Brochure.

- Facility/facilities where the study will be conducted
- Possible sources of health information (physician records, hospital records, billing records, laboratory results, biologic or tissue samples, radiology results, interviews/surveys/questionnaires, etc)
- Detailed treatment information, including protocols and evidence-based practice
- Methods for dealing with adverse events and reporting those to IRB. Methods for dealing with illegal, reportable activities (i.e. child abuse)
- Describe safety monitoring plan the research team will rely on during the study – by whom monitoring should be conducted and how often?*

***Data and Safety Monitoring Plan (DSMP)** is a description of a system of how each clinical trial monitor the progress and participants' safety, report the adverse events and guarantee compliance to the study protocol.

4. RISK/BENEFIT:

The study will be reviewed by the IRB committee to determine if there is a favorable risk/benefit ratio. They need the following information:

- A description of risks (major and minor, physical and non-physical, legal (associated with confidentiality) and financial) to the study subjects. A description of measures that will be taken to minimize risks and deal with the anticipated results. Methods for reporting unexpected deviations from the study.
- A description of the level of research burden (including inconvenience to subjects)
- A description of how subjects may benefit from participation as well as the significance and likelihood of benefit to others. If there are no benefits from participation to subjects, state so.

5. DISCLOSURE/CONSENT PROCESSES:

Any kind of contact with human beings selected as research participants requires a prior disclosure/consent process.

A good consent is one that truly informs, is not coerced; one in which the individual has the opportunity to ask questions and get answers and one in which the individual has the opportunity to think about whether or not s/he really wants to do this; meaning that there is, ideally, a period of time between the initial request and the signing on and that the amount of time for deciding is proportionate to the level of risk involved. The expectation is that all research plans include details regarding consent.
All disclosure/consent forms should contain the title of the study, name of the principal investigator, date of submission, page number on each page as well as the following items:

- Purpose
- Who is doing the study (include mention of AUA)
- Why the particular Subject was contacted
- Procedures to be used if subject agrees to participate
- Experimental nature of the procedures (if applicable)
- Risk/discomfort (including time factor)
- Benefit or lack of benefit
- How confidentiality will be maintained
- Alternatives to participation
- Voluntary nature of the study Right to withdraw at any time
- Who to contact if subject has questions about the study

- Written consent must include date and be signed by the study subject. If oral consent is to be obtained, a written rationale and text must be provided. A description of the system of documentation of oral consent is to be included. If children, a copy of the Assent Form is to be included - varies with age. (See attached sample consent statement and guidelines for assent.)

- If an advance letter and/or solicitation by telephone is to be used in lieu of or in addition to the consent process, justification must be provided for the use of this procedure; specify at what point in the study this letter/ phone call will be introduced to potential subjects and by whom. Advance letters and "scripts" of the disclosure to be made by telephone must be submitted with the application for IRB approval.

- Copies of the consent form should be submitted at this time in all languages that will be used. A complete English translation of the consent form must be provided.

- Any request to waive consent must be accompanied by a justification
for this waiver. (See Children's Assent Section on waivers for minors.) If the study involves collection of data on individuals, but without actual contact, such as in a record review and consent will not be obtained, details regarding confidentiality and location of stored data must be addressed in Item 6 below.

- If the study is a clinical trial the following items must also be addressed in the consent form:
  - Detailed treatment information
  - Special procedures
  - Patient responsibilities and safeguards

6. CONFIDENTIALITY ASSURANCES:

Describe the methods for safeguarding the confidentiality of the study data and/or the measures for protecting the anonymity and/or confidentiality of the research subjects. Include a description of plans for record keeping, location of the data

- Data security
- Person responsible and telephone number
- Who will have access to the data
- Plans for disposal of the data upon completion of the study
- If applicable, why personal identifiers (signature on the written consent form is considered as an identifier) are collected or planned to be stored. Do the research team plan to destroy identifiable data and in which time frame and the methods?

Tips for data protection

- The physical transport of the data and data containing portable devices (tablets, USB flash drives etc) should be minimized.
- Encryption of the electronic data is welcomed, especially when kept on portable devices or to be transferred via internet.
- Identifiable data transfer in physical and/or electronic form should be minimized.

7. COLLABORATIVE AGREEMENTS:

Provide letters of agreement from collaborators (donors, subcontractors, etc) and IRB approval from the collaborator's respective site of operation.

American University Of Armenia

Institutional Review Board # 1
School of Public Health

GUIDE FOR DEVELOPING THE CONSENT FORM

Consent form explanations for research projects must be typed. If continuation pages are necessary, the explanation may be continued on a plain sheet of paper. Additional pages should be clearly numbered and should contain both the title of the project and the name of the principal investigator typed at the top of the page(s).
The explanation should be written as if the investigator were speaking to the subject: avoid use of the First person. It is preferable to have the explanation written in second or third person in language appropriate to the reading level of the study population. The Committee requires that consent documents be written at no more than an 8th grade reading level or a reading level appropriate for the population being studied The reading level of your consent statement can be checked with one of the available computer programs such as WordPerfect 6.1 Grammatik. (Grammatik, View, Statistics, Readability). In the interest of simplicity, use separate consent forms for subject subgroups

Please use paragraph headings to organize the form.

TITLE OF RESEARCH PROJECT
EXPLANATION OF RESEARCH PROJECT

PURPOSE OF STUDY:
Explain that this is a research project.
Explain the purpose of the research project.
Explain that the research is being conducted by AUA.
Explain why/how the subject/patient was selected for the study
Inform him/her why he/she is being asked to participate in the study.

PROCEDURES:

Describe the sample size and inclusion/exclusion criteria. State the procedures to be used if the subject agrees to participate in the study. Specify the approximate total duration of the subject's time to participate, approximate time required for each activity, and any plans to contact the subject more than once or for possible follow-up studies.

If the study involves a survey, describe the type of information to be collected; specify if the questions are personal or of a sensitive nature (e.g. personal finances, psychological or emotional experiences, sexual habits, marital and/or family situations, alcohol or illegal drug use, etc.). For studies involving clinical procedures, briefly explain the study design; describe the examinations and tests in which the subject will participate (e.g. venipuncture-specify the number, amount of blood to be drawn in household measures such as tsp, cup, etc.). Explain how treatment groups will be assigned. If treatment assignments are determined by randomization, the process should be defined for subjects; i.e. either by drawing a card or number, or by flipping a coin.

RISKS/DISCOMFORTS:

Describe all major and minor risks (physical, psychological, social) and their anticipated frequency as well as any research related inconveniences.

BENEFITS:

State potential benefits of participation for the subject, **Do Not Overstate Benefits - Be Realistic**. If a subject will not benefit from participation, clearly state so. State the possible general benefit for science or for other subjects with similar diseases or for the population, at large, if applicable.
Outline remuneration amount and payment procedures, including penalties for failure to complete the study (if applicable). There may be situations where a patient or research subject is known to possess materials (blood or tissue specimens) having unique characteristics thought to have commercial value. If the specimen are obtained for research purposes and expected to be commercialized into a marketable product, subjects must be informed of the commercial objective prior to deciding whether to donate the sample for a study.

ALTERNATIVES TO PARTICIPATION: (May be omitted for normal volunteer studies)

Explain realistic alternatives to participation; specifically, state what treatment will be offered or recommended if subject declines to participate.

CONFIDENTIALITY:

Describe the procedures for protecting the confidentiality of the information collected from the subject. Specify who will have access to the data; how and when personal identifiers will be destroyed. It is suggested that you include the following language in all consent forms except where subjects are strictly anonymous. "Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible". If there is reason to suspect that the data may be of interest in a legal proceeding, the references to "limits of the law" should be amplified. If a Certificate of Confidentiality* has been issued to protect the data from subpoena, include this information in the consent form.

VOLUNTARINESS:
Explain the voluntary nature of the study.
Explain that not joining the study or withdrawing from the study at any time will jeopardize job or medical care already available (if applicable).

WHOM TO CONTACT:
For questions regarding the study list the name and telephone number of the person in charge of the study. For international studies, a local name and phone number should be included.
Include a statement that if the subject wants to talk to anyone about the research study because they feel they have not been treated fairly or think they have been hurt by joining the study they should contact the American University of Armenia at (374 060) 61 25 61.

American University Of Armenia

Institutional Review Board # 1
School of Public Health

CONSENT FORM TEMPLATE

Title of Research Project:

_____
Explanation of Research Project:

It is your decision whether or not to be in this study. You can stop being in this study at any time. Whether or not you are in the study will not affect your job. You should ask the person in charge listed below any questions you may have about this research study. You should ask him/her questions in the future if you do not understand something about the study. The researchers will tell you anything new they learn that they think will affect you.
If you want to talk to anyone about this research study you should call the person in charge of the study, **[NAME]** at **[NUMBER and/or e-mail]**. The person in charge of the study will answer your questions.

If you agree to be in this study, please sign your name below.

_____
Subject's signature (including children, when applicable)

_____
Witness to Consent Procedures*

_____
Signature of Investigator

_____
Date

* Optional unless subject is illiterate, or unable to sign.

Note: Signed copies of this consent form must be a) retained on file by the Principal Investigator, b) given to the participant, and c) put in the patient's medical records (when applicable).

American University Of Armenia

Institutional Review Board # 1
School of Public Health

PARENATAL CONSENT/CHILD ASSENT GUIDELINE

The policy guiding the Committee on Human Research states that parental or guardian consent must be obtained for almost all studies involving children. In addition, the assent of children aged five years and older also must be obtained. The Committee recognizes that the formulation of assent procedures and forms for children is difficult. We suggest different approaches for each of the four age ranges.

1. Children younger than 5 years: A simple oral explanation of the study should be offered to the child before study-related procedures are conducted. For a blood drawing study for example: "We have to draw some blood for [simple concept of study]. That means you will feel a little needle stick. It will only hurt for a minute. Your mother (or father) will be with you the whole time.

2. Children between the ages of 5-12 years: Informed voluntary assent should be obtained without pressure from parents or investigators. The IRB application should include an example of the explanation to be offered to the child. Assent from the child should be solicited in the presence of a parent, and the parental consent form should include the following statement from the investigator: "This project has been explained to my child in my presence, in language he/she can understand. He/she has been encouraged to ask questions both now, and in the future, about the research study."

3. Children between the ages of 12-16 years: Investigators may choose to handle the consent/assent requirements for this group in one of two ways. They may either submit a consent form that is written at a level simple enough for both parent and child to read meaningfully (i.e. about a 6th grade reading level) or they may choose to submit a consent form for parents and a separate consent form for the child to read and sign. If a consent form is designed for both the parent and the child, the form should be signed by each of them after the study has been explained. An assent form should be written as simply as possible and cover the following points:

- what the study is about
- why he/she qualifies for the study
- the voluntary nature of the study
- what procedures will be done?
- potential benefits potential risks
- assurance that s/he will be treated the same whether or not s/he agrees to join the study
- invitation to ask questions
- assurance that s/he may withdraw from the study after discussing it with his/her parents.

4. Children between the ages of 16 and 18 years: Consent form must be written in language that is easily understandable for both the parents and adolescent child. A separate assent form need not be used. The parent and the child must sign the consent form.
Note: Under exceptional circumstances and with strong justification, adolescents may provide consent without parental consent for studies involving no more than minimal risk.

DEFINITIONS:

"Children" - persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. The age of majority typically is 18 years: The exception to the 18 year-old cutoff is an "emancipated minor".
"Emancipated Minors" - include those persons who are not living with a parent and who are financially independent from the parent. Pregnant adolescents who seek prenatal care, and those who seek medical care (without the parent's knowledge) for a sexually transmitted disease are also considered exceptions when the research relates to clinical care.
"Assent" - means that child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.
"Parent" -means the child's biological or adoptive parent.
"Guardian"- means an individual under applicable State or local law to consent, on behalf of a child, to general medical care.

CHECKLIST FOR CONSENT DOCUMNET

Does this Consent Form contain EACH element, if appropriate:

1. The study involves research

☐ Yes
☐ No
☐ NA

2. An explanation of the purposes of the research

☐ Yes
☐ No
☐ NA

3. That study is being conducted by the American University of Armenia and the [Name of the Principal Investigator/Donor]

☐ Yes
☐ No
☐ NA

4. An explanation of how selected for the study

☐ Yes
☐ No
☐ NA

5. An explanation of why selected for the study

☐ Yes
☐ No
☐ NA

6. The expected duration of the subject's participation

☐ Yes
☐ No
☐ NA

7. A description of the procedures to be followed

☐ Yes
☐ No
☐ NA

8. Identification of any procedures which are experimental

☐ Yes
☐ No
☐ NA

9. A description of any benefits to the subject or to others which may reasonably be expected from the research

☐ Yes
☐ No
☐ NA

10. A description of any reasonably foreseeable risks or discomforts to the subjects

☐ Yes
☐ No
☐ NA

11. A disclosure of appropriate alternative procedures or courses of treatment if any.

☐ Yes
☐ No
☐ NA

12. A statement that participation is voluntary

☐ Yes
☐ No
☐ NA

13. A statement that the subject can withdraw at any time and will not affect any benefits that they would normally receive or they will not be penalized for withdrawing from the study.

☐ Yes
☐ No
☐ NA

14. The consequences of a subject's decision to withdraw from the study.

☐ Yes
☐ No
☐ NA

15. A statement under which the subject’s participation may be terminated by the investigator, where appropriate.

☐ Yes
☐ No
☐ NA

16. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained

- ☐ Yes
- ☐ No
- ☐ NA

17. An explanation of whom to contact for information about the research study itself [name and phone number for primary investigator]

- ☐ Yes
- ☐ No
- ☐ NA

18. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights

- ☐ Yes
- ☐ No
- ☐ NA

19. For research involving more that minimal risk, a statement that AUA does not have a program to provide compensation any injuries or bad effects which may be incurred by the subject which are not the fault of the investigator.

- ☐ Yes
- ☐ No
- ☐ NA

20. Language is understandable and written at the eighth-grade level and in no smaller than 12-point type. If not written at 8th grade level, please provide at what reading level the consent form was written

- ☐ Yes
- ☐ No
- ☐ NA

Additional notes

Please attach to the application the consent forms, questionnaires and guides in Armenian and English and other related to your research documents e.g. official letters, script forms.

Completed by ☐