INSTITUTIONAL REVIEW BOARD

APPLICATION FORM

Principal Investigator: Mr. …….., ScD, Prof.

Phone: +374 …….

Email: ……..

Co-Investigator(s):

Student Investigator:

Project Title: ……PROJECT

Proposed Start Date: ……., 2016
Anticipated Duration of Research: 3 (three) years

Address for correspondence:

…….. Yerevan, Armenia
Phone: +374
Fax: +374 …….

Population: Proposed Inclusion Criteria

(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
- ☐ Cognitively Impaired

Type of Study:

(Check all that apply)

☐ Survey

☐ In-depth Interview

☐ Focus Group Discussions

☐ Experiment

☐ Secondary Data Analysis

☐ Program/Project Evaluation

☐ Clinical/Community Trial

☐ Case Control Study

☐ Longitudinal Study

☐ Record Review

☐ Course Activity

☐ Other

Participant risk

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, 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 known 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

Name of Contact Person (if applicable) Telephone#

Signature of Principal Investigator Date

Name of PROJECT

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RESEARCH PLAN

1. RESEARCH QUESTION ADDRESSED BY THIS PROPOSAL

.....

The principle goal of the ..... Project () is the .....

Then, will be possible to evaluate .....

The project will help to understand to what extent the ..... Furthermore, it will identify the most common type of health-relevant variations in ……. This will allow developing refined diagnostics tests optimally tailored to ……..

The long-term goals of this project are:

- deepen our understanding of the .....;
- achieve a new level in Armenian healthcare through finding the optimal ways to improve population health and providing more efficient medical assistance;
- promote the development of biomedicine and modern medical and gene technologies in the Republic of Armenia thus increasing the competitiveness of medical services in the region;
- advance science and education ensuring the needed constant stream of qualified specialists in the high technology sector

These goals will be achieved by establishing ……

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 aim/research questions provided earlier)
- Study duration

- Study population, sample size, inclusion and exclusion criteria, gender, age, and locale. On greater than minimal risk, 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)
- 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)
- Methods of intervention
- Methods for dealing with adverse events and reporting those to IRB. Methods for dealing with illegal, reportable activities (i.e. abuse)

4. RISK/BENEFIT

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

- A description of risks, physical/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.

Risks

The measurements used here are standard techniques used in many studies in the medical, biological, and epidemiological literature and incorporate no risk to the donors. The blood sampling procedures pose a risk of slight pain and/or bruising. Donor may also feel lightheaded and there is a slight risk of fainting. The blood collection will be performed by a trained physician. Moreover, at least one more investigator or technician will be present at all times. All investigators will have previous experience in studies involving blood sampling and they will be very familiar with unintended effects in the frame of blood sampling. If a medical emergency occurs, the investigators will initially give a donor first aid and then contact the nearest physician. All blood samples will be taken individually. Thus a donor will be individually monitored so that intervention can be done rapidly.

Benefits

……..

……

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 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
- Why the particular subject was contacted
- Procedures to be used if subject agrees to participate
- 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 the subject has questions about the study

- Written consent must include date and signed by the study subject. If oral consent is to be obtained, a written rational and text must be provided. A description of the system of documentation of oral consent is to be included.

- If an advance letter and/or solicitation by telephone are 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 subject 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. 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.

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 subject. 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)

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.