INSTITUTIONAL REVIEW BOARD

Charter and standard operating procedures

January 2017

American University of Central Asia

Institutional Review Board

Charter and Standard Operating Procedures

1. Contents

2. GOALS AND OBJECTIVES

American University of Central Asia (AUCA) strongly encourages and supports scholarly endeavors of its faculty, students and staff. Scholarly work and research often involves use of human participants for data analysis. AUCA Institutional Review Board (IRB) ensures that AUCA-affiliated research is conducted in that manner that is ethical and non-maleficent. The AUCA IRB fosters research practices that respect and protect the rights and dignity of participants, promotes the integrity of researchers, and upholds the principles of academic freedom. The goal of the reviews is to ensure that all possible risks are minimized while the potential benefits are maximized;that human participants participate on a voluntary basis after providing with informed consent with substantial information about the study and consent to be a subject in the study; Importantly, the IRB at AUCA ensures that all personal and private information is handled with confidentiality. Clearance from the AUCA IRB is absolutely required to have been obtained prior to researcher's soliciting subject participation and data collection. In carrying out its role the IRB is authorized to review, approve, require modification or disapprove proposals. Noteworthy, it is not the role of the IRB at AUCA to evaluate the soundness of the proposed research and research design. Instead, the IRB is responsible for evaluating each project's compliance with ethical standards regarding issues such as informed consent, confidentiality, and assessment of risks to the participants.

human participants

human participants

3. RESEARCH REQUIRING IRB REVIEW

All research involving living human participants requires ethics review and approval by the IRB prior to the start of research. This will include undertaking collection of information from human participants including but not limited to tests, questionnaires, interviews, written communication with living human participants. Research involving any use of secondary information with participants' identifiable information also requires approval from the IRB.

Undergraduate senior theses and graduate theses require AUCA IRB review. Undergraduate and graduate student applicants must provide a certificate of completion of the online tutorial along with their application to the IRB. Student researchers must indicate their supervisors on the application. The latter should serve as a resource for the student when completing the application, provide guidance and review the application prior to the submission.

Course project research: Course papers, assignments, research methods courses, independent study courses and projects, etc., involving human participants must be preceded with students' completion of the online tutorial. All undergraduate level assignments must be limited to minimal risk. Course instructors must make students aware of ethics requirements and review course assignments to ensure adherence to the principles of ethics in research stipulated in this charter.

4. INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes the American University of Central Asia's Human participants Institutional Review Board (IRB), a special committee designed to protect human participants in research processes. The Charter and Standard Operating Procedures have been adopted by the AUCA's Faculty Senate on January 16, 2017, by Scientific Council (Uchyonny Soviet) on May XX, 2017 and approved by AUCA President, Dr. Andrew Wachtel (May, 2017). It has also been read and approved by the AUCA Vice President and the Chief Operating Officer. This committee is hereinafter referred to as "the IRB."

5. BASIC PRINCIPLES

4.1 The basic principles that govern the IRB in assuring that the rights and welfare of human participants are protected are contained in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report"). Therefore, the following principles apply to all research regardless of funding, including student senior thesis and projects, involving human participants at AUCA to ensure that adequate safeguards are provided:

4.2 Subjects' rights to privacy, dignity, and comfort will be respected and considered in approving proposed research.

4.3 Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

4.4 Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4.5 Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless otherwise justified scientifically.

4.6 Research involving human participants must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

4.7 Participation of a human subject in research must be voluntary and the right of the subject to withdraw at any time without any penalty must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

4.8 All research programs that involve human participants must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

6. THE AUTHORITY AND RESPONSIBILITIES OF THE IRB

5 The IRB at AUCA advises and makes recommendations to the University President, to administrative bodies, and to any member of the AUCA community on all matters related to the use of human participants in research.

5.1 The IRB reviews all projects and programs involving human participants in accordance with this Charter and Standard Operating Procedures.

5.2 The IRB can approve, disapprove, or modify studies based upon consideration of any issue it

considers relevant to human subject protection.

5.3 The IRB can provide continuing advice and counsel to personnel engaged in activities involving human participants.

5.4 The IRB has authority to require progress reports from the investigators. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

5.5 The IRB has authority to observe the informed consent process as practiced by any investigator in any approved protocol especially in cases where the consentee is from a vulnerable population.

5.6 It is the responsibility of the IRB maintains policies and procedures as stipulated in the current Charter and Standard Operating Procedures. It is also the responsibility of the IRB to review this Charter and Standard Operating Procedures and recommend any necessary policy changes for approval by the Faculty Senate.

5.7 It is in the authority of the IRB to issue appropriate penalty in situations of non-compliance.

7. NON-COMPLIANCE

American University of Central Asia requires that all faculty members, staff and students adhere to the policies and procedures stipulated in the AUCA IRB Charter and Standard Operating Procedures. AUCA will consider non-compliance and inappropriate treatment of human participants a serious offence, subject to penalty, including suspension of ethical approval and disciplinary action. All acts of non-compliance will be reviewed on a case by case basis by the AUCA IRB and may involve representatives from top administration. Any actions taken will be based on consideration of the severity of non-compliance.

8. THE MEMBERSHIP AND COMPOSITION OF THE IRB

7.1 All AUCA IRB members are to be appointed by the AUCA Faculty Senate for a period of four (4) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. A member who is unable to attend meetings for an extended period must inform the Chair so that a replacement may be appointed. In either event, the Chair will appoint a replacement. Prolongation of the contract on the IRB is possible by mutual agreement between the member and the Chair. The IRB members will include:

- Chair, to be nominated by and from members of IRB for a two-year renewable term;
- One assistant professor, associate professor or full professor from the Division of Applied Sciences, Mathematics, and Computer Science;
- Two assistant professors, associate professors or full professors from the Division of Social Sciences;
- One assistant professor, associate professor or full professor from the Division of Politics and International/Area studies;
- One assistant professor, associate professor or full professor from the Division of Business Administration;
- One assistant professor, associate professor or full professor from the Division of Economics and Environmental Studies;
- One assistant professor, associate professor or full professor from the Division of Law;

- One assistant professor, associate professor or full professor from the Division of General Education;
- One representative from the Student Life Office;
- One representative from the Research Office;
- One community representative who has no affiliation with AUCA;
- AUCA IRB secretary.

7.4 Each IRB Committee should include members in good research ethics standing. The number of members may vary but must satisfy the following criteria:

- at least two members knowledgeable in ethics;
- at least two members who have broad expertise in research methods;
- at least one member knowledgeable in legal principles
- Both women and men, members.

7.5 All IRB members are required to undergo an online tutorial provided by the IRB at the time of their initial appointment. 7.6 External consultants or experts with competence in special areas may be used when deemed appropriate.

7.7 IRB members do not receive compensation for their service.

7.8 Conflict of interest policy and procedures:

- Principal Investigators (PI)/researchers/applicants shall not be involved in the selection of IRB members for IRBs regarding their projects.
- Principal Investigators (PI)/researchers who are also current IRB members will not partake in the decisions of the Committee regarding their project.

9. PROCEDURES OF THE IRB

8.1 Exempt status

The IRB Chair is responsible for exempt status determinations upon reviewing Exempt Status Determination Application Forms and may consult with others as appropriate. For research to qualify for exempt status determination, it must meet criteria specific for this category.

The categories of exemption are as follows:

a. Research is conducted in commonly accepted educational settings and involves standard educational practices such as research on regular educational strategies. Normal educational practices are defined as “research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods”[i]. Normal educational practices include research involving educational tests when subjects are not identified; surveys or interview in which the subject volunteer and do not indicate any personally identifiable information.
b. The research involves observation of people in public places where interaction or intervention is not staged by the researcher, individuals have no reasonable

expectations of privacy, and any dissemination of results does not identify specific individuals.

8.2 Full IRB review

For any research that does not meet the criteria for Exempt Status, the Principal Investigator must complete and submit application for Full IRB Review. The Principal Investigator may be invited to attend the meeting at which the proposal will be discussed. In this case, the Principal Investigator may not be present for the vote. The Principal Investigator will be notified of the approval status. Actions by the IRB include the following:

Approved: An IRB made the required determinations to allow research involving human participants to proceed consistent with the current documents. The approval will be based on the following:

a. The extent to which the human participants rights are protected.
b. Justification of the potential benefit as compared to any potential risks that may be present.
c. Acceptable debriefing process incorporated.
d. The adequacy of facilities and resources necessary for completion of the study and protection of subjects' rights.
e. The adequacy of procedures for securing informed consent from the subjects.
f. Adequacy of measures for minimizing risks and protection of the health, safety, comfort, and the rights of the subjects.
g. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved Subject to Modifications: The research can be approved pending specific conditions such as confirmation of specific understanding about the research process, submission of additional documentation, language changes to the protocol, and substantive changes to documents. Verifications of the required changes may be performed by the IRB Chair or other designated individuals.

Deferred: The convened IRB cannot fully evaluate the research under review and grant approval without modifications to the protocol or other documents, or submission of clarifications or additional materials. Convened IRB will review the investigator's response.

Disapproved: Determinations required for approval of research cannot be made, even with substantive clarifications of modifications to the protocol. The Principal Investigator may revise and resubmit his/her protocol for another review.

8.3 Annual/Continuing Review

The IRB will conduct continuing review of research not less than once per year. The Principal Investigators will be responsible for submitting an annual continuing review form on the annual basis.

8.4 Amendments

Principal investigators must submit amendments form for any changes to the research, minor and significant. Changes will be reviewed by the full IRB.

8.5 Communication of IRB Actions

After the IRB Chair approves the minutes of the convened IRB meetings, the IRB secretary prepares notification letters to inform investigators of the IRB actions. Notification letters will include at least the following information:

- Date of review
- Type of submission (full review, continued review)
- IRB action
- Approval and expiration date (when applicable)
- Modifications and clarifications required or other conditions that must be satisfied by the investigators for IRB approval
- For research that is deferred, a statement of the reasons for deferral.
- For research that is disapproved, a statement of the reasons for disapproval and a description of how the investigator can respond.

9. FINAL REPORT

Final reports must be submitted at the conclusion of any research conducted under IRB review. This is not required for research that was determined to be exempt. Final report forms much include information such as:

- Number of human participants that participated in the research
- Statement if the research was conducted as approved by the IRB
- Effects of the project on the participants
- Reporting on any unanticipated events
- Complains and concerns, if any, raised by the participants
- Information about the location and retention of informed consent forms,
- The date when informed consent forms will be destroyed and data will be de-identified.

10. OPERATIONS OF THE IRB

10.1 Voting

10.1.1 Meeting quorum shall be 50% plus one and include at least one member whose primary concerns are in nonscientific areas. Research is approved when it receives the approval of a majority of the voting members present at the meeting written submissions by those members unable to attend. IRB meetings conducted via conference call are also allowed.

10.1.2 IRB members shall come to meetings prepared with comments.

10.1.3 Members may be removed from the IRB before their term is completed for reasons of poor attendance or for other manifestations of unwillingness or incapability to serve the committee adequately.

10.1.4 Members who are unable to attend a meeting are expected to submit written comments regarding applications to be reviewed at that meeting.

10.1.5 Materials submitted for review, protocols of discussions and individual votes are considered confidential and should not be discussed outside of the meeting context.

10.1.6 Minutes of the IRB deliberations will be kept confidential but accessible to all IRB members.

10.2 Meetings

10.2.1 IRB members shall come to meetings prepared with comments.

10.2.2 Members may be removed from the IRB before their term is completed for reasons of poor attendance or for other manifestations of unwillingness or incapability to serve the committee adequately.

10.2.3 Members who are unable to attend a meeting are expected to submit written comments regarding applications to be reviewed at that meeting.

10.3 Timelines

10.3.1 Principal Investigators should allow a minimum of two weeks for the IRB to process an application, including exempt status determination. Processing applications will depend upon the IRB receipt of all of the information for review.

10.3.2 IRB meetings will be scheduled as needed but minimally quarterly. The place and time of meeting, meeting agenda and study materials to be reviewed will be distributed to IRB members at least a week prior to the meeting.

11. APPEALS

When a research application has been disapproved or determined as needing modifications by the IRB review and mutual agreement cannot be reached, Principal Investigator may write an appeal to the IRB chair who will name an ad hoc committee of three and more faculty and consultant(s) to review the protocol a second time. The ad hoc committee reviews the application and determines the decision to be further referred to the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

11.1 Waiving Informed Consent

The IRB may approve applications which do not include Informed consent, fully or partially, if it finds and documents that

a. The research involves no more than minimal risk to the human participants.
b. The research could not practically be carried out without the waiver.
c. The subjects will be provided with additional pertinent information after participation, when appropriate.

12. RECORD KEEPING

Documentation prepared and maintained by the IRB for its activities include:

a. Copies of all research applications reviewed, including informed consent document, reports, amendments and final reports by the principal investigators.
b. Minutes of the IRB meetings (including members present, results of discussions, records of voting)
c. Statements of significant new findings
d. Adverse reaction reports

e. General project information provided to the subjects.

All forms submitted must be safely secured by the investigator.

13. APPLICATION

The following information must be provided to the IRB by the principal investigator:

1. Title of the study and summary of the research
2. Purpose of the study (including risk/benefit ratio)
3. Sponsor of the study
4. Subject selection criteria (including scientific and ethical reasons for selection)
5. Justification for use of any special or vulnerable subject population.
6. Study design
7. Description of procedures
8. Measures taken to manage adverse reactions
9. Remuneration to subjects for their participation
10. Provisions for protection of subjects' privacy
11. Informed consent
12. Copies of surveys, questionnaires, advertisement, etc.

14. Appendix 1. Belmont Report

15. Appendix 2. Exempt Status Application

EXEMPT STATUS APPLICATION[ii]

Full Name:
The Research Title:
Date:
Department:
Contacts:
Tel.:
Email:

Signature_____

According to the charter of the AUCA IRB the categories of exemption are as follows:

i. Research is conducted in commonly accepted educational settings and involves standard educational practices such as research on regular educational strategies.

ii. Research involves the use of educational tests and information in recorded forms in such a way as to not disclose any human subject's responses outside of the research.

The IRB Committee will decide whether your application qualifies for Exempt Status on the basis of your application including answers to the questions below. Please answer the following questions:

Question 1
Does your research involve the documentation or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
__Yes __No

Question 2
Is your research completely anonymous (i.e., the participant cannot be identified directly or through identifiers linked to the subject)?
__Yes __No

Question 3
Does your research involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior)?
__Yes __No

Question 4
Do the procedures of your research involve more than minimal risk* to the subject?
*"More than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
__Yes __No

Question 5
Are you able to disclose to your participants all information about the actual purpose of your research without potentially influencing their behavior during the task?
__Yes __No

Question 5a
Does your research involve deception*?
*Deception occurs when a researcher intentionally misleads participants about the nature, research question, or methodologies of a study. Withholding details about the specifics of your hypothesis until after a participant has completed the task does not constitute deception. An example of a study using deception: A researcher misleads participants into believing that they will be speaking in front of a crowd in order to raise and measure the participants' stress level. An example of a study NOT using deception: A researcher informs participants that they will be answering survey questions about a variety of subjects. The researcher lists those subjects. The researcher then uses the resulting survey data to draw specific conclusions about the relationship between two of the many variables investigated.
__Yes __No

Question 6
Are the procedures of your research generally free of increased foreseeable risk to the subject?
__Yes __No

Question 7
Does your research involve existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens) where these materials, in their entirety, have been or will be collected solely for non-research purposes?
__Yes __No

Question 8
Please consider carefully and respond again: Does your research involve the collection of data which, if disclosed, could potentially place the subject at risk of criminal or civil liability or could be damaging to the subject's financial standing, employability, or reputation?
__Yes __No

Question 9
Is your research on individual or group characteristics or behavior (including but not limited to perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) and does your research employ surveys, interviews, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies?
__Yes __No

Question 10
Does your research involve the collection of data from voice, video, digital, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation?
__Yes __No

Question 11
Does your research involve collecting data through any of the following procedures: non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves

physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subjects or an invasion of the subjects' privacy weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occuring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography moderate excercise, muscular strength testing, body composition assessment, and felxibility testing where appropriate given the age, weight, and health of the individual?
__Yes __No

Question 12
Does your research involve the prospective collection for research purposes of biological specimens? Is your research on drugs or devices for which an investigational new drug exemption is not required? Does your research involve the collection of blood samples by finger stick or venipuncture?
__Yes __No

Question 13
Will your research be conducted in established or commonly accepted educational settings and will it involve normal educational practices (e.g., research on regular and special education techniques, curricula, or classroom management methods)?
__Yes __No

Question 14
Will your research involve the use of survey procedures, interview procedures, observation of public behavior, or educational tests (cognitive, diagnostic, aptitude, achievement)?
__Yes __No

Question 15
Will your research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (for example, census tract data or data previously collected for another purpose)?
__Yes __No

Question 16
Are these existing data, documents, records, pathological specimens, or diagnostic specimens either publicly available or is it information that will be recorded anonymously?
__Yes __No

Question 17
Will your research, including demonstration projects, be conducted by or subject to the approval of federal department or agency heads?
__Yes __No

Question 17a
Is your research designed to study, evaluate or otherwise examine: Public benefit or service programs (e.g., social security, welfare, etc.) and/or Procedures for obtaining benefits or services under those programs and/or Possible changes in or alternatives to those programs or procedures and/or Possible changes in methods or levels of payment for benefits or services under those programs
__Yes __No

Question 18
Does your research involve taste or food quality evaluations or consumer acceptance studies and are the tested products wholesome foods without additives or foods containing additives at or below levels

found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture?

__Yes __No

Question 19

Are all of your research participants public officials or people who are legally required to provide information to the government AND does your research involve only survey, interview, or observational research?

__Yes __No

Appendix 3. Application for full review

Application for Full Review[iii]
Institutional Review Board
American University of Central Asia

1. Contact information

Full name of a Principal Investigator :	
Email:	Phone:
Division:	Program:
For students. Full name of a supervisor:	
Email:	Phone:

2. Project Information.

Title:		
Is proposed research being conducted to meet course or degree requirements at another university?	Yes	No
If yes, has the research been reviewed by that university's IRB?	Yes	No
If yes, please attach the results to this form		
Full name of co-investigators with titles (student, faculty, etc):		
1.		
2.		
3.		

3. Purpose

Please describe the purpose of the study (no more than 200 words):

Sponsor of the study:

Please provide the information about sponsors of the study

4. Participants information

Total number of participants	Females:	Males:		
Use of existing/archival data			Yes	No
Categories of participants (check an appropriate box where necessary)				
By age	Infants (0-2 years)			
	Preschool (3-5 years)			
	Mid-Childhood (6-12 years)			
	Adolescents (13-17 years)			
	Adults (18 years and over)			
Vulnerable population	Children (under 18 years old)			
	Prisoners			
	Veterans			
	Pregnant women			
	Neonates			
	Fetuses			
	Cognitively impaired persons			
	Economically/educationally disadvantaged persons			
	Students			
	Staff			
	Faculty			
	Other			

5. Subject Selection Criteria

Please explain the scientific and ethical reasons for selection the participants

6. Vulnerable population

Please provide justification for use of any special or vulnerable subject population

7. Procedures

Please explain what procedures are to be used on human participants (no more than 200 words)

8. Risks

Please describe any potential risks for human participants and the procedures that will be taken against or for minimizing them.

9. Compensation

Will the participants receive any compensation or token gifts? If yes, please describe.

10. Confidentiality

Please describe how the obtained data will be stared and what procedures will be taken to protect the confidentiality

11. Consent/Assent Process

Please describe your consent/assent processes

12. Benefits

Please describe any potential benefits the participants/community/society/research field will receive from this research project.

13. Supplementary documents (please check an appropriate box)

Informed consent form	
Informed consent waiver form	
Copies of surveys, questionnaires, advertisement, etc.	
Other	

Principal Investigator's Full Name and Signature	Date
Co-Investigator Full Name and Signature (if applicable)	Date
Co-Investigator Full Name and Signature (if applicable)	Date
Co-Investigator Full Name and Signature (if applicable)	Date

16. Appendix 4. Guidelines for informed consent

Institutional Review Board
American University of Central Asia
Guidelines for Informed Consent Form

All the applications submitted to the IRB must contain an appropriate consent forms consonant with the risks involved. The Principal Investigator is responsible for obtaining the appropriate informed consent forms from participants of the research prior to study implementation. The language used in the form should be comprehensible and the age of the if participants should be taken into consideration.
Below is the template of the informed consent form that we recommended the principal investigators to use. In case if you wish to use your own form, please make sure you include all the required elements written here.

Informed Consent Form

Study Title:
Principal investigator:

PLEASE READ THIS DOCUMENT CAREFULLY. YOUR SIGNATURE IS REQUIRED FOR PARTICIPATION. YOU MUST BE AT LEAST 18 YEARS OF AGE TO GIVE YOUR CONSENT TO PARTICIPATE IN RESEARCH. IF YOU DESIRE A COPY OF THIS CONSENT FORM, YOU MAY REQUEST ONE AND WE WILL PROVIDE.

Please be informed that the participation in the research is voluntary, and you have the right to withdraw at any time, without prejudice, should you object to the nature of the research. You are entitled to ask questions and to receive an explanation after your participation.

Description of the Study:
Give short description of the study in 3-4 sentences.

Purpose of the study:
Give an explanation of what the research is intended to achieve

Possible Risks:
Let the participants know what risks they might experience if any.

Possible Benefits:
Inform the participants about the possible benefits from participation in your study.

Compensation for your time:
Please keep in mind that compensation for participation in research is not a benefit to the participant as it intended to cover the expenses the one can have in order to be able to participate (e.g. travel expenses). However in some cases it might be used as an incentive for participation.

Confidentiality:
Give an information on what actions will be taken to protect the confidentiality of the data. The participants should be informed on who will or may have access to the data they will provide and on the possible release of private information to the interested parties.

Opportunities to Question:
Any technical questions about this research may be directed to:

Principal investigator:
Contacts: tel.: _____; email _____

Opportunities to Withdraw at will:
If you decide now or at any point to withdraw this consent or stop participating, you are free to do so at no penalty to yourself. In this case you will not receive compensation fee for your time.

Opportunities to be Informed of Results:
Provide information on when and how can the participants get an access to the results.

Date: dd/mm/yyyy

Signature of Participant _____

Signature of Person Obtaining Consent _____

17. Appendix 5. IRB meeting minutes' form

Institutional Review Board
American University of Central Asia
Minutes #
Month day, year

Present:

Absent:

Type of review:

- Full
- Exempt

The date of application submission: dd/mm/yyyy

(Commentaries of the members)

Decision: By the decision of the board members with reference to the foregoing the research is approved/disapproved/deferred/to be returned for modification.

_____
(Signature)
(Name of the chair)

Chair of the Institutional Review Board _____

18. Appendix 6. IRB notification letter. Approval Form

Institutional Review Board
American University of Central Asia
Approval Note

Hereby, the Institutional Review Board of the American University of Central Asia states that "*title"* research project was approved (*minutes #, date*). The research should be conducted according the study application and the approved consent form should be used.

_____

(Signature)

(Name of the chair)

Chair, Institutional Review Board

Type of review: Exempt status/Full

Approval Issued: dd/mm/yyyy

Expiration Date: dd/mm/yyyy

19. Appendix 7. IRB notification letter. Approval subject to modification

Institutional Review Board
American University of Central Asia
Approval Subject to Modification Note

Hereby, the Institutional Review Board of the American University of Central Asia states that "*title"* research project has been approved and is to be modified (*minutes #, date*). In accordance with this approval the modification listed below must be made. The research must be resubmitted to *(name),(position in the board*) within - - days. The approval note will be issued upon verification of the required changes.

IRB modifications requirements:

_____

(Signature)

(Name of the chair)

Chair, Institutional Review Board

Type of review: Exempt status/Full: dd/mm/yyyy

20. Appendix 8. IRB notification letter. Deferral

Institutional Review Board
American University of Central Asia
Deferral Note

Hereby, the Institutional Review Board of the American University of Central Asia states that "*title"* research project has been deferred (*minutes #, date*). In accordance with this decision the additional information listed below must be provided to the board to proceed with an examination of the application. The application must be resubmitted within - - days.

The new decision of the IRB will be issued upon the reconsideration of the application within the time and the manner prescribed in the charter.

The requested additional information:

_____

(signature)

(Name of the chair)

Chair, Institutional Review Board

Type of review: Expedited/Exempt status/Full: dd/mm/yyyy

21. Appendix 9. IRB notification letter. Disapproval

Institutional Review Board
American University of Central Asia
Disapproval Note

Hereby, the Institutional Review Board of the American University of Central Asia states that "*title"* research project was disapproved (*minutes #, date*). The members of the IRB concluded that the research project_____

The Principal Investigator may revise and resubmit his/her protocol for another review.

_____

(Signature)

(Name of the chair)

Chair, Institutional Review Board

Type of review: Expedited/Exempt status/Full: dd/mm/yyyy

22. Appendix 10. Final report form

Institutional Review Board
American University of Central Asia
Final report form[iv]

Final reports must be submitted at the conclusion of any research conducted under IRB review. This is not required for research that was determined to be exempt.

1. Contact information

Full name of a Principal Investigator :	
Email:	Phone:
Division:	Program:
For students. Full name of a supervisor:	
Email:	Phone:

2. Project Information.

Title:		
I confirm that the research was conducted as approved by the IRB	Yes	No

3. Participants' information (enter answers / N/A where necessary):

Number of human participants that participated	
Number of participants proposed and approved by the IRB	
Number of participants screened	
Number of participants consented to participate	
Number of participants who withdrew	
Number of subjects who completed research	
Number of subjects still involved in the research	
Number of participants excluded by PI	
Reasons for exclusion	

4. Effects of the project on the participants

Describe any problems encountered or undesirable effects that involved risk or harm to participants
Describe any unexpected benefits to participants

5. Reporting on any unanticipated events

Describe any incidents/ unanticipated events that happened during the research. What appropriate actions were taken?

6. Complains and concerns of participants

List the complains and concerns, if any, raised by the participants

7. Informed consent. Provide information about:

a) the location and retention of informed consent forms
b) the date when informed consent forms will be destroyed and data will be de-identified

8. PI Assurance

Full Name:	Date:
I confirm that the information provided is complete and accurate.	Signature:

23. Appendix 11. Informed consent waiver form

Institutional Review Board
American University of Central Asia
Informed Consent Waiver Form

Informed consent is a crucial element of ethical conduct used in study of human participants. IRB obtains an exclusive right to waive the consent requirements. It is the responsibility of the board to take into consideration the potential risks and harms involved in the research before granting a waiver of informed consent.

In the boxes provided below, please answer the following how your research meets the following four statements (no more than 200 words):

1. The human participants of the research project are exposed to no more than minimal risk of harm.

2. The rights and welfare of the subjects will not be negatively affected by the waiver of consent.

3. The research cannot be conducted without the waiver.

4. The subjects reserve the right to get additional information after participation,[v] when necessary.

24. Appendix 12. Amendment form

Institutional Review Board
American University of Central Asia
Amendment Form

IRB approval expiration date	
Research title	
Principal Investigator	Full Name: Email: Tel.:

SECTION A: CHANGES IN A STUDY TEAM.

1. Change of a PI

Please explain the reason for a change

2. Change/addition of co-investigators

Full Name: Email: Tel.: Conflict of interest with the study? __Yes __No Role in the study:
Full Name: Email: Tel.: Conflict of interest with the study? __Yes __No Role in the study:
Full Name: Email: Tel.: Conflict of interest with the study? __Yes __No Role in the study:

3. Deletion of co-investigators

a. Full name :
b. Full name :
c. Full name :

SECTION B: CHANGES IN A RESEARCH.

1. Check the appropriate boxes for the proposed changes

The research title. Provide a new title:	
The research purpose	
Funding	
The population of the research	
Subject selection criteria	
The procedures of the research	
Compensation	
The consent/assent processes/forms	
The supplementary documents (research tools, advertisement, etc)	

2. Provide a detailed explanation for all the changes made by every item marked above.

3. List added/changed documents. Attach the tracked and clean versions of the documents to this form.

1.	
2.	
3.	
4.	
5.	
6.	
7.	

4. Will the changes increase the risks to the participants of the research? If, yes, provide the details about the risks and procedures for informing the participants about it.

Signature of the PI (signature of co-investigator or study staff is not acceptable)	
Date	

vi

[i] http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_nep.html

[ii] The foregoing questions were taken from the website of the Bard College IRB page. http://www.bard.edu/irb/what_to_do/

[iii] The form was prepared on the basis of the following documents:

1. Valparaiso University. *Application for Full IRB Review*. Retrieved from: http://www.valpo.edu/sponsored-and-undergraduate-research/files/2016/05/ApplicationforFullIRBReviewFillable.pdf

2. University of Central Arkansas. *UCA IRB Full Board Application.* Retrieved from: http://uca.edu/researchcompliance/files/2015/05/IRB-Full-Review-Application-v1014.pdf

[iv] The form was prepared on the basis of the following documents:

1. University of Massachusetts Lowell. (February 12, 2015). *IRB Final Report Form.* Retreived from:

https://www.uml.edu/Research/OIC/human-subjects/forms.aspx

2. Singapore University of Technology and Design. (September 6, 2012). *Final Report Of IRB-Approved Research*. Retreived from: http://www.sutd.edu.sg/Research/Institutional-Review-Board-(IRB)/Forms

[v] The given form is based on the University of Colorado Boulder. (2012, January 31). *Guidelines for Waiver of Consent.* Retrieved from: http://www.colorado.edu/innovate/sites/default/files/attached-files/Waiver%20of%20Informed%20Consent%2027Jul15-FINAL.pdf

[vi] The form was prepared on the basis of the following documents:

1. The Johns Hopkins Bloomberg School of Public Health. (2014, September 18*). JHSPH IRB Amendment Application Form.* Retrieved from: http://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/amendments/