AUA Institutional Review Board Guidebook 2019

Procedures for IRB #1 and IRB #2

1. Abbreviations

AUA	American University of Armenia
CFR	Code of Federal Regulation
CHSR	Center for Health Services Research and Development
FDA	Food & Drug Administration
FWA	Federalwide Assurance
IRB	Institutional Review Board
OHRP	Office for Human Research Protection
SPH	School of Public Health

2. Glossary

Anonymized information – The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.[1]

Anonymous information – The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.[1]

Assent – a subject's affirmative agreement to participate in research. Assent may take place when the subject does not have the capacity to informed consent (e.g. the subject is a child or mentally disabled) but has the capacity to meaningfully assent. See Informed Consent.[2]

Autonomy – 1. the capacity for self-governance, i.e. the ability to make reasonable decisions. 2. A moral principle barring interference with autonomous decision-making.[2]

Children – Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law 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".[3]

Coercion – using force, threats, or intimidation to make a person comply with a demand.[2]

Confidentiality – the obligation to keep some types of information confidential or secret. In science, confidential information typically includes: private data pertaining to human subjects, papers or research proposals submitted for peer review, personnel records, proceedings from misconduct inquiries or investigations, and proprietary data.[2]

Conflict of interest of IRB members - is defined as being the principal investigator, co-investigator or immediate family member of those and participating in the research design and conduct.[2]

Deception – in human subject research, using methods to deceive subjects about the goals and nature of a study or the methods, tests, interventions, or procedures used in the study.[2]

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.

Guardian - means an individual under applicable State or local law to consent, on behalf of a child, to general medical care.[3]

Human subject research – research involving the collection, storage, or use of private **data** or biological samples from living individuals by means of interactions, interventions, surveys, or other research methods or procedures.[2]

Informed consent – the process of making a free and informed decision (such as to participate in research). Individuals who provide informed consent must be legally competent and have enough decision-making capacity to consent to research. Research regulations specify the types of information that must be disclosed to the subject.[2]

Institutional Review Board (IRB) – is a committee established to protect the rights and welfare of human research subjects involved in research activities.[2]

Institutional Review Board (IRB) approval – the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and US federal requirements.[3]

Human interaction – includes communication or interpersonal contact between investigator and subject.[3]

Intervention – includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.[3]

Investigator – any individual who is involved in conducting human subjects research studies. Such involvement would include: (a) obtaining information about living individuals by intervening or interacting with them for research purposes; (b) obtaining identifiable private information about living individuals for research purposes; (c) obtaining the voluntary informed consent of individuals to be subjects in research; and (d) studying, interpreting, or analyzing identifiable private information or data for research purposes.[4]

Legally authorized representative – a person, such as a guardian, parent of a minor child, health care agent, or close relative, who is legally authorized to make decisions for another person when they cannot make decisions for themselves.[2]

Minimal risk – the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[3]

Parent -means the child's biological or adoptive parent.[3]

Permission – The agreement of parent(s) or guardian to the participation of their child or ward in research.[3]

Pregnancy – Encompasses the period from the implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.[3]

Prisoner – Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.[3]

Privacy – a state of being free from unwanted intrusion into one's personal space, private information, or personal affairs.[2]

Private information – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.[3]

Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[3]

Undue influence – taking advantage of someone's vulnerability to convince them to make a decision.[2]

Sources:

1) Panel on Research Ethics http://www.pre.ethics.gc.ca; Glossary http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/glossary-glossaire/

2) National Institute of Environmental Health Sciences, Glossary of Commonly Used Terms in Research Ethics, https://www.niehs.nih.gov/research/resources/bioethics/glossary/index.cfm#legal-authorized-representative

3) Code of Federal Regulations, Title 45 Public Welfare Department Of Health And Human Services, Part 46 Protection of Human Subjects, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

4) Office for Huma Research Protection, Frequently Asked Questions, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html

3. AUA IRB structure

The Institutional Review Board (IRB) of the American University of Armenia (AUA) is registered with the National Institute of Health, the United States Department of Health and Human Services: http://www.hhs.gov/ohrp/assurances/irb/index.html. The IRB functions under the guidance of the Office for Human Research Protection (OHRP), which provides regulatory oversight and clarifications on ethical issues in biomedical and social-behavioral research.

AUA maintains two Institutional Review Boards: IRB #1, chaired by Vahe Khachadourian, MD, MPH, PhD, reviews and approves non-clinical studies; and IRB #2, chaired by Hripsime Martirosyan, MD, MPH, reviews and approves clinical studies. Dr. Sarah H. Kagan is the Senior Officer of the AUA IRBs.

AUA IRB membership appointments are based on the requirements of the Code of Federal Regulations (CFR) 46.107 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107).

Senior Officer of AUA IRB, in consultation with the AUA Gerald and Patricia Turpanjian School of Public Health Dean and the AUA Human Protections Administrator, is responsible for making recommendations for AUA IRB membership. All IRB members can also recommend new candidates for the IRB membership to the Senior Officer. AUA President, the AUA IRB Signatory Official, makes the final appointment of IRB members based on the recommendations from the Senior Officer of AUA IRB. Information on current IRB members can be found at: **http://policies.aua.am/policy/107**.

The IRB chair can supplement the IRB review by inviting experts for the research projects that require specific expertise or are out of the usual scope of research submitted for the review. However, invited exerts will not have a right to vote. The IRB Chair or a member of IRB designated by the Chair can review applications that qualify for expedited review and issue an approval letter.

IRB members and invited experts should declare conflict of interest with the proposed research under IRB review and recuse from the review process. Conflict of interest is defined as being the principal investigator, co-investigator or immediate family member of those and participating in the research design and conduct

AUA Policy on Research Ethics and IRB (http://policies.aua.am/policy/107)

4. Eligibility to apply to AUA IRB

Only AUA faculty, staff and students are eligible to submit applications for review. Application forms are available at: https://aua.am/aua-institutional-review-board-guidebook/

AUA IRB does not accept applications from investigators not affiliated with AUA, pharmaceutical companies or investigators conducting pharmaceutical, medical device or other clinical trials.

To learn about the AUA IRB application process or to submit an application please write to the Human Protections Administrator at: auairb@aua.am.

Required training on ethical conduct of research involving human subjects

All investigators applying for review and approval must show proof of current Protecting Human Research Participants (PHRP) training that conforms to the standards for ethical practice and research conduct.

AUA IRB requires research PIs and investigators (key personnel) who initiate research involving human participants undergo training on ethical conduct of research. The HHS regulation (45 CFR part 46) use the term "investigator" to denote an individual responsible for different tasks related to the conduct of human subjects research, including process of obtaining informed consent and interaction with research participants. OHRP interpretation of investigators also include the following activities during the conduct of human subject research:

- obtaining information about living individuals by intervening or interacting with them for research purposes
- obtaining identifiable private information about living individuals for research purposes
- obtaining the voluntary informed consent of individuals to be subjects in research
- studying, interpreting, or analyzing identifiable private information or data for research purposes

Training is also required for the IRB staff, management and members.

The AUA IRB online PHRP course is available in three languages without charge at: https://chsrmd.aua.am/

AUA IRB also accepts training from the following institutions:

- US National Institute of Health, Office of Extramural Research http://phrp.nihtraining.com/users/login.php?l=3

- University of California, Los Angeles (UCLA) http://training.arc.ucla.edu/ucla/register/index

Certificate of completion should be submitted to auairb@aua.am. AUA IRB requires re-certification every five years.

AUA IRB defines research staff as those individuals who have direct contact with human subjects, involved in data collection including recruitment to the proposed study, process of obtaining informed consent, survey or interview administration. Research staff could be trained by the PI or other senior researchers involved in the study. In this case training materials should be submitted for IRB review along with the other documents.

5. IRB process for students

If a student initiates a project, as part of the educational requirements at AUA, that involves human subjects, then an AUA Faculty member must assess whether the project qualifies as "a research" (set forth in 45 CFR 46.102(d), "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"). If the outcomes of such projects are presented only within AUA, are not shared in a broader media and are not "designed to develop or contribute to generalizable knowledge", then the AUA IRB will determine such projects as "not research" and no IRB review would be required in this case. However, the study PI should assure that ethical principles will govern in such projects. For the student projects the study PI, who can be only an AUA faculty member, must approve the submission by the student.

Students who are planning to conduct a research outside Armenia should provide additional documentation. They should try to get a local IRB approval. If that kind of a review is not available, then an authorized individual from the proposed research site must provide a written permission/support letter to the AUA IRB. The letter should be provided on the official letterhead (if applicable) and be signed and dated. The template for the letter is provided at the end of this section. In addition, to assess the cultural appropriateness of the research conducted outside Armenia, the AUA IRB will identify experts who are completely independent from proposed studies and are highly familiar with the local context and the culture of the region where the proposed study will be conducted. Experts should review the study instruments and consent forms and suggest appropriate changes to the study team and the AUA IRB if needed.

Institutional support letter template

[place on agency/institution letterhead] Date: dd/mm/yy

Institutional Support Letter

TO: American University of Armenia IRB

FROM: [*name and surname*]

I am familiar with [*name of investigator's*] research project entitled [*title of research protocol*]. We will collaborate with this project, and [*agency/institution's name*] will be involved in [*description of the specific role of the agency, such as allowing employees/students/patients to be interviewed/observed, providing archival data etc. Note: be sure to list all major data collection activities and groups.*]

This research will be carried out following sound ethical principles and that participant involvement in this research study is strictly voluntary and provides confidentiality of research data, as described in the protocol.

Therefore, as a representative of [*agency/institution name*], I agree that [*the name of the research project*] research project may be conducted with support from and in collaboration with our agency/institution.

Sincerely,

[signature]

[name and title of agency/institutional authority]

6. Types of IRB review and IRB review outcomes

AUA IRB should evaluate all human research projects prior to initiation to determine that: (1) risks to subjects are minimized; (2) risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result, (3) selection of subjects is equitable (4) informed consent will be sought from each prospective subject or the subject's legally authorized representative and (5) will be appropriately documented (in accordance with, and to the extent required by §46.117), (6) when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, (7) when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data [set forth 46.111].

AUA IRB can find the research to be exempt from the policy, can require for expedited or full board review. IRB has the authority to approve, require modifications (to secure approval), or disapprove all research activities covered by the policy [set forth 46.109(a)]. AUA IRB Chair or one or more experienced reviewers designated by the AUA IRB Chair could determine the IRB review categories. Study teams cannot make the decision if a specific project is exempt, proposed project protocols should be submitted to the AUA IRB for the final determination of the extent of the review, including granting an exemption status.

Exempt status: AUA IRB follows CFR 45 46.101(b) regulation to determine exempt status for the proposed research activity. Main exemption categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

   (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses 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.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available

or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Expedited review: AUA IRB follows CFR 45 §46.110 regulation to use the expedited review procedure to review either or both of the below listed research activities.

(1) some or all of the research appearing on the **list** and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Expedited review procedure could be carried out by the IRB Chair or experienced members of IRB designated by IRB chair (set forth in §46.110). AUA IRB board members are notified about research proposals approved using expedited procedures on an annual basis by the IRB Human Protections Administrator (in accordance with §46.110(c)). The IRB Human Protections Administrator will prepare brief annual reports and share via email with the appropriate IRB members.

List of Expedited Review Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 50kg. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or(b) from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples:
   - hair and nail clippings in a non-disfiguring manner;
   - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   - permanent teeth if routine patient care indicates a need for extraction;
   - excreta and external secretions (including sweat);
   - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   - placenta removed at delivery;
   - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   - supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   - sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples:
   - 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 subject or an invasion of the subjects privacy;
   - weighing or testing sensory acuity;
   - magnetic resonance imaging;

- electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
   - Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4).
   - This category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
   - The phrase "…**or will be collected solely for non-research purposes**" pertains to the origin of the materials. For example, blood samples that were collected for a clinical test or the results of a course driven exam given in a history class.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
   Expedited Review does not apply if identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or
c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full board review: AUA IRB will conduct Full board review when research activities will not be eligible for exempt or expedited review, specifically, when the research involves more than minimal risk. For the research to be approved, it must receive the approval of a majority of those members.

7. General IRB Process Overview

In order to apply to AUA IRB a study team should submit IRB application form along with all relevant to the proposed study protocols, including study proposal, consent forms, perspective participants recruitment materials, data collection instruments (survey questionnaire, in-depth or focus group discussion guides), scripts, list of investigators and research staff and other forms or documents to be used in the study.

Submission package should be send to auairb@aua.am email with request for the IRB review. AUA IRB might request additional information and clarification regarding the documents before considering the application for review. Review process will be initiated once the application will be considered eligible for the AUA IRB review. AUA IRB review process typically lasts 10 working days, the duration of the review will last longer if study teams spend more time for protocols improvements. When the AUA IRB approves the study protocol an approval letter is sent to the study PI via email. Once protocols are approved by the AUA IRB#1 or IRB#2 any changes to the protocol should be resubmitted to the AUA IRB as amendments or updates.

Typical approval period for the AUA IRBs is one year. If after one year a study continues (human subject interaction continues), then the study PI should submit continuing review form before the approval period lapses (adequate time should be given to the AUA IRB to conduct a continuing review, typically this review could take 10 working days).

Continuing review

The AUA IRBs comply with 45 CFR 46.109(e) and follows OHRP Guidance for the continuing review purpose. AUA IRBs' continuing review imply review of any new information provided by the study team or is available to IRB and could alter IRB evaluation of the potential benefits or risks to the research subjects. The AUA IRBs' continuing review also evaluates whether there is any new information that would require revision of any of the study protocols, including informed consent form.

The AUA IRBs have authority to disapprove or require modifications (to secure re-approval) research activities covered by the policy [set forth 46.109(a)]. The AUA IRBs pay particular attention to the (a) risk assessment and monitoring, (b) appropriateness of the process of obtaining informed consent, (c) investigator and institutional issues, and (d) research progress.

Minimal risk research activities require continuing review once per year. More than minimal risk research activities will undergo continuing review process "at intervals appropriate to the degree of risk, but not less than once per year" [set forth 46.109(e)].

The PI of an approved study should submit a progress report to secure continuing review process by the AUA IRB#1 and #2.

8. AUA IRB application essential parts

There is essential information that should be covered in AUA IRB application. Those parts are the following:

1. **Research question addressed by the proposed research**
2. **Rationale for research**
    a. Motivation for research (Problem)
    b. 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)
    c. Importance of proposed work (Aim)
3. **Research methods**

    a. Study design and rationale for that design (must relate to the stated aims/research questions provided earlier).

    b. Study duration

    c. 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)

    d. 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)

    e. Provide information on the frequency, duration and place of contacts between research team and the participants

    f. Briefly describe data analysis plan

    g. 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.

    h. Methods of intervention

i. Methods for dealing with adverse events and reporting those to IRB. Methods for dealing with illegal, reportable activities (i.e. child abuse)

4. Risk and benefits of research

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

b. 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.

c. A description of the level of research burden (including inconvenience to subjects)

d. 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. Description of consent process

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

- 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.
- 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.

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.

9. 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. 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 available computer programs. In the interest of simplicity, use separate consent forms for different 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: (applicable for clinical research)

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

10. Parental consent/child assent guideline

The policy guiding the AUA IRB is that with the exception of "emancipated minors" and research relating to clinical services available to children without parental consent (see definitions below), parental or guardian consent must be obtained for 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 morn (or dad) 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 to read and sign and a separate assent form for the child. 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/consent 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.

11. Additional Resources

1. AUA Training Course On Research Ethics: “Human Participant Protections”

   http://chsrd.aua.am/irb/

2. The OHRP Human Subjects Assurance Training Module (relevant for the IRB personnel)

   http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

3. The OHRP IRB Guidebook

   http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

4. The OHRP educational resources

   http://www.hhs.gov/ohrp/education/index.html

5. Belmont report

   http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

6. The HHS Regulations at 45 CFR part 46

   http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

7. The NIH Office of Extramural Research, Protecting Human Research Participants training

   https://phrp.nihtraining.com/users/login.php

12. Contacts

To learn about the AUA IRB application process or to submit an application please write to the Human Protections Administrator at: auairb@aua.am.