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I. PURPOSE

This document establishes the mission of the Human Research Protection Program (HRPP) at AUB, describing its different units and departments, and defining the responsibilities delegated to each individual serving under HRPP.

II. MISSION

The mission of the HRPP at AUB is to safeguard and foster awareness of and respect for the rights and welfare of human subjects participating in biomedical and social and behavioral research activities under the auspices of AUB. This can be maintained through the conduct of research that follows the ethical principles of Belmont Report, and that abides by the principles of responsible research conduct and scientific integrity. While exercising its oversight of human protection, the HRPP develops new approaches for monitoring, tracking, evaluating, and continuously improving human subject protection and allocating the required resources accordingly. It also assesses the effectiveness and independence of the Institutional Review Boards of AUB in the review of research activities. Moreover, it ensures continuous education for investigators and research staff about the ethical conduct of research, and intervenes and responds directly to concerns related to human research activities.

AUB has a Federal-wide Assurance (FWA) with the Office of Human Research Protection (OHRP), in the Department of Health and Human Services (DHHS), as a domestic institution. In the FWA, the Institutional Official, that is the Provost, certifies that AUB assures that all activities related to human subjects research, regardless of the funding source, are guided by the ethical principles of the Belmont Report.

AUB has established and continues to develop and improve policies to assure full compliance with the relevant laws and assurances governing the participation of Human Subjects in Research. These are the laws of Lebanon, the policies of the American University of Beirut including the current Policy for HRPP, the terms of its FWA, and US federal laws for research funded from federal sources.

The Provost is the Institutional Official ultimately in charge of the Human Research Protection Program (HRPP) at AUB and is the signatory official for the Institutional FWA. The Director in charge of the Office of the Human Research Protection Program may be a faculty member, or any other qualified person, appointed by the Provost, with the approval of the Dean of the faculty member when applicable. The Director of the Office of the Human Research Protection Program reports to the Provost of AUB. The Office of the Provost and the Office for the Human Research Protection Program are responsible for the development, dissemination, and implementation of the University Policies related to Human Research Protection.
This policy on HRPP, in addition to other policies relevant to the conduct of human research, defines how AUB conducts the proper review, education and training, resource support, monitoring, documentation, and other standard operating procedures to ensure protection of the rights and welfare of human subject participating in all research conducted at AUB or by the faculty, staff and students of AUB.

III. GOVERNING PRINCIPLES

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. Members of the Commission were from diverse disciplines, including medicine, law, religion, and bioethics. In 1979 the Commission published its report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly called the Belmont Report. Today’s federal regulations for the protection of human subjects are based on the ethical principles of the Belmont Report. The Belmont Report identifies three basic principles as particularly relevant to the ethics of research involving human subjects.

A. Respect for Persons

The principle of respect for persons means respecting an individual’s autonomy (his/her right to make decisions for him/herself). This means that individuals should participate in research voluntarily and be given enough information to make an informed decision about whether or not to participate.

"To respect autonomy is to give weight to autonomous persons’ considered opinions and choices... To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information ... when there are no compelling reasons to do so."

The Belmont Report further specifies that persons with diminished autonomy (e.g., children, cognitively impaired persons) are entitled to additional protection.

The principle of respect for persons is embodied in the informed consent process. Three elements crucial to the informed consent process are information, comprehension, and voluntariness. While there is no standard for the amount of information to be provided to potential volunteers, the Belmont Report suggests that “the extent and nature of

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information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge". The way in which information is provided to the volunteer is as important as the information itself. The investigator should adapt the presentation of information to the subject's level of understanding. When a subject's comprehension is limited due to immaturity or mental disability, respect still requires that the person be given the opportunity to choose whether or not to participate to the extent they are able. Permission from a third party who understands the subject's situation and can act in the subject's best interest further protects the subject from harm.

Finally, in order to be voluntary, consent must be given under conditions that are free of coercion and undue influence. "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence ... urge a course of action for a subject." Consent is valid only if the agreement to participate in the research is given voluntarily.

B. Beneficence

The principle of beneficence requires that the researcher not only protect individuals from harm, but make efforts to secure their well-being.

"Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms... The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks."

Risks to subjects may be balanced against the benefits to subjects directly or to society as a whole.

When the researcher and the IRB perform a systematic risk/benefit assessment, they are applying the principle of beneficence. Risk is evaluated by considering both the chance or probability of harm and the severity or magnitude of the possible harm. Risk may include consideration of psychological, physical, legal, social, and economic harm. Benefit, on the other hand, is the anticipated positive value of the research to either the subject directly or to society in terms of knowledge to be gained.

"...the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research,


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so long as the subjects’ rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.”

C. Justice

The principle of justice means that the benefits and burdens of the research are fairly distributed.

“For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients... In the U.S., in the 1940’s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population.”

It is a violation of the principle of justice to select a class of subjects (e.g., welfare patients, an ethnic minority, institutionalized persons) simply because of easy availability rather than for reasons directly related to the problem being studied. The principle of justice requires that there be fair procedures and outcomes in the selection of research subjects.

“Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only 'undesirable' persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.”

IV. DEFINITIONS

Human Research Protection Program (HRPP) is the program at AUB which oversees the safety and welfare of participants in human subjects’ research projects in accordance with all applicable country law, institutional policies, and federal law when applicable.

At the institutional level, the HRPP includes: The office of the Provost representing AUB as an academic institution, the Office of the Human Research Protection Program, the

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The Provost is the Institutional Official (IO) who oversees the AUB Human Research Protection Program. AUB has executed a Federal-wide Assurance (FWA) with the U.S. Department of Health and Human Services/Office for Protection from Research Risks. In its FWA, AUB assures that all research involving human subjects will comply with the principles of the Belmont Report and that all federal regulations governing research involving human subjects will be followed for research funded by US federal sponsors. The Provost is the signatory official for AUB on the FWA and assumes, on behalf of the institution, the obligations imposed by the federal regulations (45CFR46). The Office of the Provost is responsible for the overall policy, planning, coordination, and direction of research and development activities at AUB. The Provost is the Institutional Official who oversees the institutional Human Research Protection Program.

The Office for Human Research Protection Program (HRPP) is the functional division within AUB that supports and houses the Human Research Protection Program (HRPP). It ensures compliance with the relevant laws and assurances governing the participation of human subjects in research at AUB. The Office of Human Research Protection Program consists of the following bodies/units:

The Institutional Review Board(s): is the board formally designated in an institution to review the conduct of research involving human subjects.

IRB membership is established in accordance with the requirements of DHHS 45CFR 46.107 and FDA regulations at 21CFR56.107. Each AUB IRB shall meet the following requirements:

a. consist of at least five members; overlapping memberships between IRBs is permitted;
b. include at least one scientist member;
c. include at least one non-scientist member;
d. include at least one member who is not otherwise affiliated with AUB, and who is not a member of the immediate family of a person who is affiliated with AUB;
e. does not entirely consist of men or of women
f. be able to determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice;
g. when reviewing research involving a vulnerable population, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, the IRB shall include one or more members who are knowledgeable about and
experienced in working with these subjects. (This person(s) may be a Consultant to the IRB).

The Biomedical IRB and a Social and Behavioral IRB are responsible for reviewing all research protocols that involve human subjects. See Principles and Procedures of IRB at AUB.

a. The Biomedical IRB reviews research conducted at AUBMC and/or by the School of Medicine, excluding qualitative research. It also reviews research by any faculty that involves FDA oversight, specifically clinical research involving an investigational device, drug or testing, research requiring an IND (Investigational New Drug) registration or any other research where the data will be submitted for FDA regulatory review. Its members are nominated by the Dean of the School of Medicine, in consultation with Chair of the Biomedical IRB, and appointed by the Director of the HRPP in consultation with the IO.

b. The Social and Behavioral IRB reviews research conducted at the School of Arts and Sciences, the School of Agriculture and Nutrition Sciences, the Olayan School of Business, School of Engineering and Architecture, and the School of Nursing. Review of research by any of these Schools that involves FDA oversight is referred to the Biomedical IRB. At least one representative from each school at AUB is nominated to serve on the social and behavioral IRB by the Dean at that school, in consultation with the Chair/Vice Chair of the Social and Behavioral IRB, and appointed to the IRB by the Director of the HRPP in consultation with the IO. The Dean of Students or his/her representative, and the Chair of the University Research Board, are additional non-voting members of the Social and Behavioral IRB.

At the discretion of the Director, HRPP, in consultation with the IRB Chair, certain voting members of the IRB may be appointed to serve as Alternates to other voting members, in which case the number of voting members required to reach quorum does not change.

The Human Research Education Unit: is the unit that, in collaboration with the IRB Chairs/Vice Chairs, is responsible for the education and training of the AUB community engaged in the conduct of human research. Educational opportunities may be in the form of: (a) courses given to investigators and staff for education and development dealing with application process, informed consent, reporting of adverse events, and other processes considered crucial for maintaining the ethical conduct of research, (b) trainings sessions for IRB members, (c) periodic educational programs offered for undergraduate and graduate students, postdoctorals (d) educational sessions for medical students, fellows and residents who might be engaged in human research, and (d) training programs on special topics related to conducting research, such as research involving protected populations, development of repositories, internet research, etc. Educational training shall also be in the form of mandatory and voluntary initiatives.
This unit has two functions:
   a. Education in regulatory topics relevant to the conduct of research involving human participants/subjects; certification and continuing education.
   b. Education in academic topics relevant to the responsible conduct of research, research integrity, and research skills pertaining to the use of human subjects.

The Quality Improvement Program (QIP)/Research Compliance Unit: is the unit that, in collaboration with IRB Chairs/Vice Chairs, assesses all components of the HRPP and provides quality assurance and quality improvement activities to the AUB research community engaged in the conduct of human research. It advises the Provost, and for federally sponsored research the Department of Health and Human Services (DHHS) Under Secretary for Health, on all compliance matters affecting the integrity of human research at AUB.

Research: is the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45CFR 46.102)

Human Subject: is a living individual about whom an investigator (whether professional or student) conducting research obtains
   (1) Data through intervention or interaction with the individual, or
   (2) Identifiable private information. (45CFR 46.102)

V. RESPONSIBILITIES

1. Office of Provost: has the overall responsibility for implementation of and compliance with Lebanese law, University policy, and federal laws when applicable, concerning the conduct of human subjects research at AUB.

Provost: The Institutional Official/Provost is the person ultimately responsible for the development and implementation of the Human Research Protection Program plan and the coordination of all its components. The Provost has the authority to sign federal assurances, and place limitations on investigator’s or staff’s privilege to conduct human research, whenever such actions are necessary to maintain the integrity of the HRPP. The Provost is also authorized to suspend or terminate IRB approval of research activities, if such activities are deemed inappropriate for conduct at AUB, and is responsible for approving the Human Research Protection Program Plan. The Provost cannot overturn the decision of the IRB to suspend or disapprove a protocol (see AUB’s policy on appeals).

The Provost delegates the appointment of IRB chairs and members and the daily operation of the HRPP to the HRPP Director.
2. Office of Human Research Protection Program is the functional body within AUB that supports and is in charge of all components of the Human Research Protection Program (HRPP), excluding the Institutional Official (the Provost) who is the ultimate person in charge of the Human Research Protection Program. The Director of the HRPP is appointed by the Provost, in consultation with the Dean of the School to which the director belongs, when applicable.

The HRPP is responsible for filing and maintaining AUB IRB registration with OHRP. The IRB registration serves as the official record of voting members (and alternate voting members, in the event such alternates may be designated by AUB).

The Director of HRPP is responsible for:

- Developing, revising, and implementing institutional policies & procedures in consultation with the Provost;
- Creating and overseeing the Human Research Protection Program budget;
- Developing an annual budget to support the HRPP, in consultation with the Provost and Deans, which includes the determination of the IRB fee structure;
- Allocating resources to every unit that falls under the jurisdiction of the Human Research Protection Program;
- Reviewing periodically the plan of HRPP to assess and track the progress of the program;
- Overseeing the review and conduct of human research under the jurisdiction of Human Research Protection Program;
- Ensuring compliance with the relevant laws and assurances governing the participation of human subjects in research at AUB human subjects participation;
- Appointing the voting members of the IRB in consultation with the IO and the IRB Chair/Vice Chair.
- Overseeing and assisting the IRB in the evaluation of allegations of non-compliance with requirements for protection of human subjects;
- Assisting the IO with communication to OHRP, and sponsors, when required;
- Notifying OHRP within thirty (30) business days of changes to IRB membership.
- Acting as principal point of contact, as delegated by the IO, for communication and follow-up with OHRP and other sponsors, as designated by the IO;
- Overseeing the performance and operations of the IRBs, Human Research Education Unit, and the Quality Improvement/Research Compliance Unit;
- Ensuring that the research process is free of coercion and undue influence;
- Implementing a process for receiving and acting on complaints and allegations related to research activities;
- Implementing Quality Improvement Programs that identify, monitor, and remediate noncompliance;
• Assisting investigators and staff with advice and guidance that promotes performing human subjects research in an environment that embraces consistent ethical practices and the responsible conduct of research;
• Ensuring regular educational and training programs for all individuals involved in the human subject research conduct taking place under the auspices of the American University of Beirut.

The Director of HRPP, in consultation with the IO, has the authority to fire/hire HRPP staff, appoint and remove IRB members/chairs, and suspend or terminate IRB approval of research.

The primary mission of the IRB is to protect the rights, welfare and privacy of all individuals participating in biomedical, social, and behavioral research activities, including field or off-site research, conducted by AUB faculty, staff, and students. The IRB conducts reviews of proposed research studies employing an assessment process that determines that the methodology used is consistent with sound research design and that the risk to participants/subjects is minimized. The IRB also provides interpretive assistance and support to the research community.

As outlined in the terms of AUB’s Institutional Federal Wide Assurance, the IRB is guided by the ethical standards described in the Belmont Report, as well as institutional, local, and federal regulations governing human subject research as applicable.

The IRB must be sufficiently qualified through the training, experience and expertise of its members, and their diversity, including considerations of gender, race, and cultural backgrounds and sensitivity to issues such as community attitudes, to assure respect for its advice and determinations.

The Institutional Review Board has a wide range of authorities and functions:

IRB Authorities:
  a. Authority to review and approve the proposed research, that the required modifications have been incorporated prior to approval, or disapprove all research involving human subjects that is overseen or conducted by AUB [45 CFR 46.109(a)];
  b. Authority to exercise the option to perform expedited review, under conditions described by the federal regulations [45 CFR 46.110(b)];
  c. Authority to monitor the progress of the study on a specified continuing basis, annually or more frequently, depending on the study, and observe or have a third party observe the consent process and the human subject research conduct [45 CFR 46.109(e)];

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d. Authority to suspend or terminate any human research activity that violates regulations, policies, procedures, of an approved protocol, and report such violations, suspensions or terminations to the HRPP.[45 CFR 46.113];

IRB Functions:

a. Ensure that research is designed and conducted in an ethical manner that protects the rights, dignity, welfare, and privacy of research subjects;
b. Ensure that the participation of human subjects is voluntary and that they are adequately informed of the nature of the study;
c. Determine what types of studies to be reviewed;
d. Monitor human research activities to determine that they are conducted in accordance with ethical principles of the Belmont Report, federal regulations, where applicable, and are in compliance institutional policies and practices of AUB's Human Research Protection Program and pertinent state and local laws and regulations;
e. Evaluate conflicts of interest of investigators, research staff, consultants, and reviewers and determine if the management plan is sufficient for performing the assigned task;
f. Review reports of unanticipated problems involving risks to subjects and others, including adverse events and serious adverse events including hospitalization and mortality;
g. Ensure that the benefits of a study outweigh its risks, including review of research design and methodology to assure sufficient rigor/scientific merit to achieve research results while minimizing risks to subjects;
h. Ensure that the risks and benefits of the study are evenly distributed among the possible subject populations;
i. Ensure that all research previously approved is subject to continuing review and approval appropriate to the degree of risk, no less frequently than annually;
j. Ensure the conduct of timely review of all applications for the use of human subjects;
k. Ensure that investigators and HRPP director are being notified in writing of its decision to approve, deny or withhold approval of applications or modifications of ongoing activities, and terminate/suspend any prior approval to any research activity that falls within its jurisdiction;
l. Ensure that no IRB member participates in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB;
m. Refer matter requiring AUB Counsel review to the Director of HRPP;
n. Ensure that the allegations of noncompliance are received and are referred for the purpose of inquiring/investigating of an alleged serious or continuing noncompliance, to the subcommittee which includes at a
minimum one (1) IRB Office/Administrator, one (1) individual from Quality Improvement Program/Research Compliance Unit (QIP/RCU), and one (1) member of the IRB Committee. The IRB shall also receive the results of the investigations, and decide on corrective actions if necessary. All correspondences issued by the IRB will be shared with to the Director of the HRPP;

o. Determine which studies need verification from sources other than the investigator’s that no material changes have occurred since previous IRB review;

p. Ensure prompt reporting to the IRB of changes in research activities;

q. Ensure that changes in the approved research are not initiated prior to IRB approval except where necessary to eliminate apparent immediate hazards;

r. Ensure prompt reporting to the IRB, Director of HRPP, the Institutional Official, and FDA when applicable in cases of:
   1. Unanticipated problems involving risks to subjects or others
   2. Serious or continuing noncompliance with the principles of Belmont Report, requirements of the AUB IRB, or federal regulations when applicable
   3. Suspension or termination of IRB approved research activities.

N.B. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by institutional officials. However, these officials (including the Institutional Official) may not approve the research if it has not been approved by the IRB [45 CFR 46.112].

IRB Chairs or Vice Chairs may exercise any of the authorities of the IRB that do not require the determination of a convened IRB, e.g. approval of proposed research that meets expedited review requirements; approvals of minor changes in previously approved protocol, etc.

IRB Operations

A. Consultants/Reviewers

1. During initial assignment of a proposed study to an IRB member, or after initiation of such review, the IRB Chair, Vice Chair, IRB committee member reviewer, or an IRB staff member, may determine that the current membership of the IRB may not include the full appropriate expertise to conduct an adequate study evaluation. In such instances, the IRB Chair/Vice Chair will identify and select individuals from outside the IRB committee, with competence in special areas to assist in the review.
2. Consultants may be chosen from past IRB members or by contacting the department chair or division chief of the area from which the research is being submitted;
3. Consultants shall be provided with a copy of the IRB protocol and consent document as well as any attachments (investigator brochures, multicenter protocols, etc.) prior to the IRB meeting;
4. Consultants are held to the same standards as regular members of the IRB Committee;
5. Consultants may attend the meeting to participate in the review and discussion of the research study; however, s/he may not vote or count towards quorum;
6. If the consultant is unable to attend the meeting, his/her written comments will be taken into consideration by the Committee during its review of the respective research protocol and will be documented in the IRB meeting minutes;
7. During the review of a proposed research study, an IRB committee member may obtain informal consultations by directly contacting colleagues for information related to a research study. Before obtaining advice from a consultant in this manner, the IRB committee member should ensure that the colleague does not have a conflict of interest with the research study.

B. Appointment of IRB Members

Appointments of voting regular and alternate IRB Committee members are made by the Director of the HRPP and with the approval of the Institutional Official for a period of three years subject to renewal. The appointments are made in a staggered manner to preserve IRB continuity. Recommendations for board members can be made to the Dean and Director of HRPP/IO by either the IRB Chair, Vice Chairs, or based on the specific needs of the IRB Committee (e.g. medical/scientific specialty, diversity, non-scientific, non-affiliated, etc.).

Collectively, the IRB members have varying backgrounds to provide complete and adequate review of research activities commonly conducted under the auspices of AUB. (refer to IRB website for current membership lists). One IRB may refer a protocol for review to the other IRB when the appropriate expertise for the review of the proposed research, knowledge of the local context, or special considerations would be best met by the other IRB. For example, a research project proposed by a Faculty of Medicine PI but which entails behavioral methodology and analysis may be referred by the Biomed IRB to the SBS IRB for consideration.

1. The Director of the HRPP requests nominations for faculty volunteers from the Division Chiefs, Department Chairs, and Deans as needed based on considerations including, but not limited to, required committee composition and diversity, expertise and experience; knowledge of the individual’s interest; recommendations of institutional leadership; and/or investigators involved in research studies currently or previously approved by the IRB.
2. The IRB Chair or his/her designee nominates the potential community and/or the nonscientific representative after reviewing the membership rosters and in consultation with the Director of the HRPP and after the approval of the Institutional Official. The Director of HRPP appoints the community and non scientific voting members of the IRB.

3. The Director of the HRPP shall periodically, but no less than annually, review and adjust the membership of the AUB IRBs to ensure that the composition meets all regulatory and organizational requirements.

C. Absence of the Chair
Whenever the Chair is not available to perform his or her duties, the Chair may designate the IRB Vice Chair or another member of the IRB to assume his or her responsibilities during his or her absence.

D. Quorum requirements
Except when an expedited review procedure is permitted, review of proposed research takes place at a convened meeting of the IRB at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. [If the nonscientist member is not present at a convened meeting, no official actions/votes may be undertaken by the IRB.]

In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting.

4. Quality Improvement/Research Compliance Program
   - Is a division under the Human Research Protection Program and is independent from IRB;
   - Is authorized to conduct on-site audits, announced or un-announced, of human research activities, to assure compliance with study protocol and with AUB policies and procedures, on the behalf of the IRB and recommends actions to the IRB based on observations;
   - Is involved in assessing and processing post-approval event reports, including but not limited to reports of unanticipated problems, serious adverse events, protocol violations or incidents, safety reports, and concerns and complaints;
   - Refers any reports of unanticipated problems involving risks to study participants or others as well as incidents or allegations of serious and or continuing noncompliance to the IRB for review and management;
   - Receives reports from the IRBs about areas where quality improvement may be of concern;

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• Responds to PI requests for the emergency use of an investigational drug or device;
• Identifies potential legal issues to Director of HRPP, for referral to the University Counsel;
• Develops and conducts quality improvement activities to improve human research protections.
• Makes sure that Data Safety Monitoring Plans are in place when applicable and that Data Safety Monitoring Board (DSMB) reports are submitted in a timely manner, as described in protocol and/or trial agreement when applicable.

5. Human Research Education Unit: has two functions an academic function and a regulatory, human research protection program (HRPP), function. The function of the latter is to:
• Develop, coordinate and provide presentations on issues in Human Subjects protection;
• Deliver education, training, and updates for departments, investigators and their research staff and IRB members and their support staff when applicable;
• Respond to requests for clarification and provides guidance regarding ethical issues in biomedical and behavioral research involving human subjects;
• Maintain, promulgate, and update educational and institutional review guidance materials.

6. Principal Investigator (PI): Although research studies may be conducted by more than one investigator, including sometimes other faculty, fellows, and students, one investigator is designated the “Principal Investigator” with overall responsibility for the conduct of the research study. It is the responsibility of the Principal Investigator and his/her research team to protect the rights and welfare of human subjects participating in their research study. The PI must submit an application to the IRB for review and approval before initiating, modifying, or extending any research project using human subjects.
   The Principal Investigator does not make the Exempt determination. Under the AUB HRPP, the determination that a particular research proposal involving human subjects is Exempt from IRB review, is made by the IRB Chair or Vice Chairs, or may be delegated by the Chair to an IRB member. No Principal Investigator has the authority to make an Exempt from IRB review determination.

There are six categories of research activities involving human subjects that are eligible for Exempt Status (45 CFR 46.101(b)). Research that is found to be exempt does not receive Full [IRB] Committee or Expedited Review. Exempt research studies are not subject to continuing review or further oversight by the IRB. However, when a determination of Exempt from review is made, the PI must understand that although research that qualifies for exempt status is not subject to review and oversight by the AUB policy on Human Research Protection Program

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IRB, such studies still have a responsibility to protect the rights and welfare of their subjects, and are expected to be conducted according to the ethical principles of the Belmont Report. Such studies can be randomly reviewed by the Quality Improvement Unit in accordance with its quality improvement activities. Applications for Exempt Status are reviewed by the IRB Chair or Vice Chairs or their designees.

The Principal Investigator:

- Has the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects involved in the research, and strict adherence to any stipulations imposed by the IRB;
- Understands that although research that qualifies for exempt status is not subject to review and oversight by the IRB, the such studies still have a responsibility to protect the rights and welfare of their subjects, and are expected to be conducted according to the ethical principles of the Belmont Report;
- Shall be familiar with institutional policies, and federal regulations for federally sponsored research, relevant to the conduct of research involving human subjects, and FDA regulations governing clinical research where applicable;
- Shall ensure that he/she as well as all research personnel performing the project are qualified, appropriately trained, have completed institutional certification and other requirements to conduct research involving human subjects, and will adhere to the provisions of the approved protocol;
- Shall have a thorough understanding of the protocol including risks and potential for unanticipated problems, including those associated with the drug or device under investigation, if applicable;
- Shall submit the research protocol and all related documents to IRB as outlined in the IRB Policies & Procedures manual, and seeks approval from the IRB after addressing all queries raised by IRB;
- Shall ensure that he/she or an appropriately trained (including CITI certification) designee explains the protocol to subject and family and seeks informed consent/assent as outlined in the IRB Policies and Procedures manual, and as approved by the IRB;
- Shall promptly report to the IRB any changes in research activity during the approval period, such as amendments in protocol or consent form, and shall implement no changes in the approved protocol or consent without prior IRB approval, except in an emergency if necessary to safeguard the well-being of human subjects, and in such event will notify IRB within two business days;
- Shall promptly report to the IRB new information that may adversely affect the safety of subjects/participants and the conduct of research;
- Shall comply with the IRB’s continuing review and approval requirements, as stipulated in the IRB-approved protocol, including reports of those unanticipated problems which did not require prompt reporting to the IRB;
• Shall immediately (within 48 hours of investigator’s knowledge of event) report to the IRB/IRB Chair any Internal (under the jurisdiction of the AUB IRB) Serious Adverse Event [where a Serious Adverse Event is defined as an adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect.);
• Shall immediately (within 48 hours of investigator’s knowledge of event) report to the IRB/IRB Chair both Internal and External events resulting in temporary or permanent interruption of study activities by PI or sponsor to avoid potential harm to participants;
• Shall report to the IRB events within 10 business days of the investigator’s or research staff member’s leaning of the event all events requiring prompt reporting to the IRB as delineated in Guidance for AUB PIs for Reporting Unanticipated Problems involving Risks to Subjects or Others, Adverse Events, and Other Problems http://www.aub.edu.lb/irb/Documents/guidance.pdf
• Shall report to the IRB any problems or incidents, not otherwise covered under Events Requiring Prompt Reporting Guidance Document, including those in the recruitment or consent process. Such report should be included in the Continuing Review application;
• Shall report to the IRB any violation of a research protocol or any use of subjects not approved by the IRB;
• Shall complete and sign the subject’s research enrollment form and ensure that it is placed in the subject/patient’s medical record, for biomedical-approved protocols or as specified by the IRB;
• Shall respond to subjects’ complaints and/or their requests for more information;
• Shall consider conflict of interests that might be related to the research participant or the outcome of the study which might affect the integrity of the human research activities. The PI shall disclose any real or perceived conflicts in accordance with AUB policy and comply with all conditions of the AUB management plan and any/all additional management practices as may be stipulated by the IRB;
• Shall advise IRB when PI intends to be absent from AUB for an extended period of time (e.g. sabbatical leave), designating an Interim PI or emergency point of contact in the absence of PI;
• Shall submit timely notification to the IRB in the event the PI intends to leave AUB. All current approved IRB protocols should either be transferred to a new PI by submission of an amendment to the existing protocol, which requires IRB review and approval before it can be considered effective; or terminated by the PI effective a designated date specified in writing to the IRB;
• Shall advise co-investigators and all members of the research team of an Administrative Hold and the consequences of such a hold on recruitment, research conduct and data analysis, in the event a research study is placed on Administrative Hold (by PI);
• Shall advise co-investigators and all members of the research team in the event a research study is suspended by the IRB, and the consequences of suspension on recruitment, research conduct and data analysis.

7. Department Chair is responsible for reviewing the activities within the department to determine that proper review and approval have been obtained and appropriate resources are available to conduct the research. The department chair is also responsible of certifying that the principal investigator is qualified by training and education to ethically conduct human research project that is scientifically valid. He/she is also responsible for overseeing the human research conduct in his/her department and forward allegations/complaints to the HRPP director and/or Institutional official.

8. HRPP Personnel/Administrative Staff are hired by the Director of the Human Research Protection Program, and are responsible for maintaining updated knowledge on policies, procedures, and regulations governing human subject research activities and IRB operations. They are also responsible for performing day to day activities that maintain the flow of work through the IRB such as: (a) preparing and distributing review materials to IRB members, consultants, and reviewers, (b) maintaining and tracking files, (c) preparing and distributing minutes, (d) sending out notifications of IRB decisions and reminders to investigators when deadlines are due, and (e) assuring that all documents and records of IRB operations are stored properly and maintained according to federal regulations regarding storage of IRB records.

The IRB Administrator is responsible for maintaining a record for each current IRB member including, but not limited to, the member’s curriculum vitae, any letters of appointment, renewal or recognition, and the member’s disclosure of conflicts of interest, if applicable.

IRB Administrative staff for each IRB is responsible for maintaining a roster of current members. HRPP shall make available to the research community rosters of all AUB IRBs. Rosters shall be posted on the AUB IRB web site.

9. Subject Injury Language included in the informed consent forms shall be determined by the IRB office, risk management unit of the Environmental Health, Safety, and Risk Management under the supervision of the Human Research Protection Program with oversight of the Institutional Official.

10. Legal Protection for individuals involved in IRB approved research: AUB is legally responsible for the acts and omissions of its employees acting in the course and scope of their University duties. In the event of a suit against an employee in connection with an IRB-approved research activity using human subjects, the University assumes the employee’s defense and indemnification, except in those circumstances where there has been willful non-compliance with the IRB-approved protocol.

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VI. EVALUATION OF HRPP LEADERSHIP

- **Director of HRPP** shall be appointed by the Institutional Official and evaluated every year or two years. The basis of this evaluation shall include, but not limited to, the Director’s technical knowledge and consistent applications of the ethical principles of Belmont Report and the federal regulations and the policies governing human subject protections; the Director’s responsiveness to the concerns of the research community; the Director’s ability to interact constructively with and to manage the activities of the Human Research Protection Program; the Director’s ability to manage the efficient and effective conduct of every unit/department falling under the jurisdiction of the HRPP; and the Director’s ability to interact and achieve the respect of all individuals involved in human research conduct.

- **Chair**: The IRB Chair shall be appointed by the Director of the Human Research Protection Program with the oversight of the Institutional Official, and evaluated on an ongoing basis, but no less frequently than annually, by the Director of Human Research Protection Program. The basis for this evaluation shall include, but not be limited to, the Chair’s technical knowledge and consistent application of the ethical principles of the Belmont Report and the federal regulations and IRB policies governing human subject protections; the Chair’s responsiveness to the concerns of IRB committee members; the Chair’s ability to interact constructively with and to manage the activities of the IRB Vice Chairs; the Chair’s leadership and ability to manage the efficient and effective conduct of IRB committee meetings; engagement in the exempt and expedited review processes, effectiveness as a representative of the IRB, and the Chair’s ability to interact with and achieve the respect of human subject investigators.

- **Vice Chairs**: The IRB Vice Chairs shall be appointed by the Director of the Human Research Protection Program in consultation with the IRB Chair and with the oversight of the Institutional Official. These appointments shall be evaluated on an ongoing basis, but no less frequently than annually by the IRB Chair. The basis for this evaluation shall include, but not be limited to, the Vice Chair’s knowledge and consistent application of the ethical principles of the Belmont Report and the federal regulations and IRB policies governing human subject protections; the Vice Chair’s responsiveness to the concerns of IRB committee members; the Vice Chair’s leadership and ability to manage the efficient and effective conduct of IRB committee meetings and post meeting activities; engagement in the exempt and expedited review processes, effectiveness as a representative of the IRB and the Vice Chair’s ability to interact with and achieve the respect of human subject investigators.
Terminating/ renewing the appointment of the IRB Chairs/Vice Chair is made at the discretion of the Director of the Human Research Protection Program, in consultation with the Institutional Official.

- **IRB members** IRB members are evaluated annually by the IRB chair according to the following criteria:
  - Thoroughness of member’s pre-review and/or review for the convened meeting, his/her ability to identify ethical and scientific issues, and level of participation during and outside of meetings;
  - Thoroughness and clarity of presentations;
  - Participation in educational activities;
  - Maintenance of confidentiality;
  - Knowledge of clinical (where applicable), ethical and institutional policies and OHRP and FDA (where applicable) regulations;
  - Meeting attendance and preparedness for the meetings.

An IRB member may be removed when there is a just cause such as member’s inability to serve on the Board. Other reasons include but are not limited to lack of minimum attendance, lack of participation, incomplete reviews, and unresolved conflict of interest.

Reappointment is based on the evaluation of the IRB member made by the IRB chair, and the current and future needs of the IRB. If the IRB member wishes to remain on the IRB after completing his/her term, a letter from the Institutional Official is sent to the member thanking him/her for his/her contribution and stating the duration of the re-appointment term and the expectation regarding IRB duties and responsibilities as mentioned above attendance.

- **Administrative Staff evaluation** is done on an annual basis using the standard AUB employee appraisal form.
VII. REFERENCES


Appendix I.

Human Research Protection Program at AUB

- **Institutional Review Board**
  - Reviews Biomedical and Social/Behavioral Research
  - Involving human subjects conducted at AUB at large:
    - By members of FM
    - By members of other faculties
    - By students or staff at the University
    - On university premises
    - Using equipment and facilities at university
    - In collaboration with other institutions

- **Quality Improvement/Research Compliance Unit**
  - Ensures Quality and Integrity in Research
  - Spot reviews/audits (not for cause assessments) and for cause (directed) audits/assessment
  - Compliance with institutional and Federal P&P.
  - Data Safety Monitoring Board Oversight:
    - Internal
    - External

- **Human Research Education Unit**
  - Formulates and Implements Human Research Education Curriculum
  - Regulatory:
    - Policies and Procedures
    - Certification
  - Academic:
    - Institutional Curriculum for the Responsible Conduct of Research
    - Workshops/Courses
    - Curriculum restructuring at FM
    - Degrees: MD, MSc as scholars in clinical research

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