

Human Research Protection Program

Thursday February 25, 2010

The Human Research Protection Program (HRPP) at AUB launched on February 13 its first human research conduct seminar. The objective of the seminar is to acquaint the research community with the institutional oversight of human research conduct by highlighting its mission, its guiding ethical principles and operations, in addition to underscoring the challenges at hand.

The conference was opened by Provost Ahmad Dallal, who is also the supervisor of the program and the institutional official in charge of ensuring that the terms of the Federal Wide Assurance (FWA) are complied with.

FWA is a document that designates the Institutional Review Board that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research.

The federal Office for Human Research Protections (OHRP) requires that federally funded human subjects research only be conducted at facilities covered by a FWA.

Many institutions in the region have signed on a FWA with the Office of Human Research Protection, but compliance with such terms is not clear. This is due to cultural differences between Western and Middle Eastern Cultures, and the presence of a major gap in research education and research surveillance. By establishing the HRPP at AUB, with representation and involvement of faculty from all schools, the leadership has committed to an oversight mechanism that will ensure compliance with its FWA terms.

AUB has committed to the conduct of research according to the ethical principles of Belmont report for all human research, and to Federal regulations 45CFR 46 for federally sponsored research, in the FWA it has signed with the OHRP, Department of Health and Human Services.

The Belmont Report, which was issued by the US Department of Health, Education, and Welfare (later renamed the Department of Health and Human Services) in 1979, identified the following three ethical principles related to the protection of human subjects in biomedical and behavioral research:

- Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent;
- Beneficence: maximizing benefits for the research project while minimizing risks to the research subjects; and
- Justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly (the fair distribution of costs and benefits to potential research participants.)

Provost Dallal opened the seminar by highlighting the responsible conduct of research at AUB, and some of the challenges relevant to social and behavioral research.

Following Dallal's speech, Vice President for Medical Affairs and Dean of the Faculty of Medicine Mohamed Sayegh gave an overview on the leadership role of AUB in biomedical research regionally. The next presentation was given by Dr. Ghada El-Hajj Fuleihan, Associate Dean of Clinical Research, on the mission and components of HRPP. These include the Institutional Review Board (IRB) that was restructured into a biomedical and a social IRB in the Fall of 2009, a Research Education Unit, and a Quality Improvement Surveillance Unit.

Following a discussion and a coffee break, a presentation about IRB's past, present and future was delivered by Dr. Ibrahim Salti, the IRB Chair, describing its mission and some of the salient changes in its operations since its inception in 1996.

The IRB is the administrative body at AUB responsible for ensuring that the rights, safety, and welfare of human research subjects are fully considered and protected in accordance with international, state, and University policies and procedures. Such protections include, for example, subjects' physical or psychological well being, right to privacy, or protection of social standing or employment status. Thus, the IRB has the responsibility to review all research studies involving human subjects conducted by members of the Faculty of Medicine, the Medical Center, as well as the AUB community at large.

Another presentation was delivered by Dr. Thalia Arawi, Clinical Bioethicist and Director of the Bioethics and Professionalism Program at AUB-FM, who highlighted few of the major violations in human research that ultimately led to the current research regulations. Moreover, Arawi showed video footages revealing contemporary research violations. She also discussed the major Codes and Declaration of Research ethics and stressed the importance of the researcher's character.

From her side, Dr. Mary Ellen Sheridan, Retired Associate Vice President for Research at the University of Chicago, revolved in her presentation around the principles of research integrity and responsible conduct of research. Sheridan presented real life controversial case studies that occurred despite present regulations, thus underscoring the role and responsibility of investigators, as an integral component of the HRPP, and the need for their engagement and commitment to continuing education.

As of November 2009, the AUB research community has access to the CITI on-line program. It is an educational program that includes modules for investigators conducting biomedical research, social behavioral research in addition to modules for students and others for IRB members. CITI certification is an institutional requirement for all individuals engaged in the conduct of human research at AUB, with recertification every 2 years. In addition, the HRPP will institute a mechanism for providing continuing education (CE) credits in topics relevant to the conduct of human research, some of which can be secured by attending HRPP seminars. Four CE credits were provided to all attendees on Feb 13.

In addition to Provost Dallal and Dean Sayegh, the HRPP program was attended by members of AUB 's research community including Associate Provost Nesreene Ghaddar, and Deans Patrick McGreevy and Iman Nuwayhid with the presence of over 200 faculty members and support staff from all schools.

Future HRPP seminar series, coordinated by Dr. Mona Nabulsi, will include presentations by the IRB Vice Chairs, the President of the National Bioethics committee, legal counsel at

AUB, representatives of the office of Risk Management and Environmental Safety, Grants and Contracts, and others on topics relevant to special aspects of human research conduct, by faculty at large.

Some of the presentations will be run in collaboration with the Ethics Matters Initiative. Current and future HRPP slide presentations will be posted on the new IRB website, as of March 1, 2010.