Developing an International 'Responsible Conduct of Research Program' for Clinical Researchers

By Mary Ellen Sheridan, Ghada El-Hajj Fuleihan, and Thalia Arawi

This article describes curriculum development and teaching of a Research Ethics and Responsible Conduct of Research course as a core component of a National Institutes of Health Fogarty International Center research training grant awarded to the American University of Beirut in September 2012.

AUB Background

The American University of Beirut (AUB), founded in 1866, is a private, non-sectarian, co-educational university, with 700 faculty and a student population of around 8,000. AUB is accredited by the US Middle States Accrediting Commission, and it offers 120 programs leading to the Bachelor's, Master's, M.D., and Ph.D. degrees. Since its establishment in 1867, the Faculty of Medicine at AUB has trained generations of medical students and physicians - over 4,000 to date. The Faculty of Medicine and the American University of Beirut Medical Center (AUBMC) are committed to educating and training the best physicians and biomedical researchers, to providing quality cost-effective patient care, and to performing premier clinical research.

NIH's Fogarty Center – Assisting the Development of Clinical Research in International Universities

The emphasis and outreach of the Fogarty International Center ("Fogarty"), a component of the National Institutes of Health (NIH), is improving global health. Nearly 25% of Fogarty awards are made directly to robust research institutions in the developing world. The remaining grants support academics at U.S. institutions that collaborate with colleagues abroad. The Division of International Training and Research oversees research grants, training grants and fellowship programs in more than 100 countries.

In 2010, Fogarty issued a Request for Applications (RFA) to address chronic, non-communicable diseases (NCDs) and disorders across the lifespan through collaborative research training between institutions in the U.S. and low- and middle-income countries. Unfortunately, despite the high prevalence rates of NCDs and their risk factors in the Middle East North Africa (MENA) region, the capacity to conduct the needed research to assess and influence their determinants is very limited. Consequently, the RFA was a "perfect fit" for AUB and the Faculty of Medicine's vision for enhanced clinical and translational research training and sustainably strengthening research capacity in all health science areas at AUB. Principal Investigator (PI) Dr. Ghada El-Hajj Fuleihan and her AUB colleagues seized on the opportunity and flexibility of the Fogarty RFA and proposed to establish the first training grant in the region. Faculty leadership at AUB invited colleagues at the Harvard Medical School and the Harvard School of Public Health to help shape a new Masters in Clinical Re-

search degree program emphasizing research skill development for improved patient care and research studies in NCD. The **S**cholars in **H**e**A**lth **R**esearch **P**rogram (abbreviated as 'SHARP') at AUB establishes a novel curriculum and training vehicle to generate the human capital required to conduct general NCD-related research and to investigate specifically those NCDs with the greatest burden on Lebanon and the MENA region (for example, obesity and overweight, metabolic syndrome, diabetes and cardiovascular disorders, and hypovitaminosis D [vitamin D deficiency]). In September 2012, Fogarty awarded AUB a four-year training grant of $863,000.

Commitment to Research Ethics through SHARP Bioethics/RCR Course (SHARP 315)

From the earliest stages of developing the SHARP curriculum, leaders envisioned a comprehensive bioethics and Responsible Conduct of Research (RCR) course. Dr. El-Hajj Fuleihan and consultant Dr. Mary Ellen Sheridan, who met in 2009 at a research compliance workshop sponsored by AUB's Office of Grants and Contracts, collaborated during 2010 to improve the human research infrastructure at AUB. Together, they articulated an institutional Human Research Protection Program (HRPP) and improved the University's Institutional Review Board (IRB) policies and practices. Later, Dr. El-Hajj Fuleihan, Dr. Thalia Arawi, Founding Director of the Salim El-Hoss Bioethics and Professionalism Program at the AUB's Faculty of Medicine and its medical center, and Dr. Sheridan worked together to enhance NIH's RCR training grant requirement and AUB's HRPP, in an emphatic statement of AUB's commitment to conducting research at the highest standard of ethical behavior. As a result, a large component of RCR is delivered through Research Ethics (SHARP 315), an intensive three-week summer course comprising of nine lecture sessions. It is complemented by the delivery of additional instruction in Advanced Research Ethics (SHARP 500) throughout the ensuing fall and spring terms (as part of the Longitudinal Seminar Series,) and through ongoing "Ethics Matters" lectures and conferences/workshops offered by the Salim El-Hoss Bioethics and Professionalism Program.

Drs. Arawi and Sheridan collaborated closely on curriculum development for SHARP 315. They agreed that the importance of articulating detailed course objectives from the inception of curriculum development could not be underestimated. Specific and tangible instructional objectives in an RCR course were clustered as attributes of Knowledge, Attitude and Behavior. Each attribute was more fully detailed in student learning objectives. Ultimately, students should be familiar with the concept of research compliance through a framework of ethical, legal, and policy considerations that affect the practice of scientific research. Most importantly, students should know how to conduct and assess research from an ethical standpoint. The resulting course subject matter is a broad spectrum covering traditional modules in RCR such as

- conduct of research involving human subjects
- research misconduct and fraud
- data acquisition, data management, sharing and ownership
- publication practices and responsible authorship, peer review
- mentor/mentee relationships
- animal welfare
- conflict of interest and commitment
- collaborative research

Two factors are noteworthy in the development of course content. To begin with, reflecting the goal of the SHARP training grant to produce NCD researchers, an emphasis on ethical behavior in human research and the important role of the IRB was paramount. Secondly, the identification of appropriate educational resources and leads for relevant course content was greatly facilitated by extensive Internet searches. Federal agencies such as the Office of Research Integrity and the Office of Human Research Protections provide invaluable links for developing educational programs. Web sites from leading U.S. Translational Research Centers are rich resources for institutional policies and practices, case studies, RCR guidelines, and postings of course materials. Reviews of these materials greatly informed the SHARP 315 curriculum and facilitated refinement of the RCR units into a sequence of topics and aspects of conduct most relevant for clinical research.

Ultimately, SHARP 315 was team taught under Dr. Arawi's leadership with the involvement of AUB faculty, the IRB Vice Chair, the IRB Administrator and Dr. Sheridan. Students attended lectures, participated in discussions, analyzed case studies and watched audio-visual materials. The course relied on both face-to-face and web-enhanced instruction via Moodle, an online learning management system. A wide variety of web-accessible materials enabled through Moodle significantly enhanced the students' learning opportunities and allowed course leaders to make the most efficient use of student and faculty time.

SHARP 315 enrolled its first class of 23 students in the summer of 2013. The class included several features that merit special mention. First, it convened a mock IRB session that was a great success. Trainees learned about preparing a protocol, role playing as members of the IRB and engaging in the dynamics of a review board. The impact of the session was maximized by its timing, following a four-unit sequence focused on clinical research. The sequence included bioethical history, human subject research policies and regulations, informed consent, and data acquisition and medical records management. Thus, SHARP students came to the mock IRB with the necessary rich background of human research ethical issues and practices.

Next, thirty percent (30%) of each student's grade was based on a special project assignment. Working in groups of about four, students were required to develop a user-friendly *Introduction to Clinical Research* pamphlet that could be used in subject-recruitment settings. The student groups prepared a rich and diverse array of brochures that reflected their awareness of recruitment, informed consent, and the roles and responsibilities of researchers and subjects in clinical research.

Finally, each student group was also assigned, by random syllabus subject, to give a five-minute presentation on the last instructional day. Students were given free latitude to express their knowledge of responsible conduct of research through their choice of presentation style. With only 36-hours' notice, the groups did a remarkable job of applying their creative skills to produce musical sketches, case studies, role-playing skits and targeted presentations on the major points of ethical decision-making in clinical research. As a last class day event, this was both an instructive and entertaining success. The students left SHARP 315 with a positive impression of the significance of ethical conduct and decision-making in their future research program. As one summer SHARP evaluator stated, "The SHARP program has put me on the right track to becoming a clinical researcher."

Looking to the Future

The RCR faculty and students alike have been pleased with the RCR course; SHARP 315 was one

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My first NCURA meeting scared me to death. I was intimidated by the number of research administrators and the amount of knowledge in the room. That knowledge is what drew me into volunteering with NCURA. Now, it didn't happen overnight. I started out by volunteering at the registration desk at a regional meeting. A couple of years later, someone asked me, "What have you done lately for NCURA?" That direct question definitely helped me become more involved. I started reaching out to others to see if I could be included in their presentations and workshops, a practice that has come full circle as I now reach out to new members to see if they want to be part of my presentation team. Becoming involved with NCURA has led me down a fantastic path. I've co-chaired PRA and FRA conferences, been on National and regional meeting programs, and am now on the Board of Directors. The exciting part is that I reach across the U.S, in volunteering for Region II and Region VI/VII. Not only has volunteering for NCURA given me countless opportunities to grow as a research administrator, it has given me opportunities to grow personally, which is a "good thing."

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of the highest rated SHARP summer courses. Now that the new SHARP program has been successfully launched, the PI, colleagues at AUB and the SHARP program's Technical Advisory Group are looking to the coming year to implement additional components of the master's program. AUB also anticipates that it will expand the reach of the RCR experience to other regional institutions, while the recruitment program for new SHARP trainees is expected to identify new and expand existing clinical research collaborations in NCD areas.

The RCR faculty attribute the success of the SHARP 315 course to a number of factors, which can be taken as Points for Success for other international institutions considering such a program:

- Proven collaborative working relationship among research administrators, consultant, and faculty colleagues at AUB and US cooperating institutions
- Continuous communication and open dialogue between consultant and PI and AUB colleagues
- Involvement of critical faculty at AUB in curriculum development
- On-site consultant participation in RCR course
- Continuing research capacity building initiatives between research administration, Drs. Sheridan and El-Hajj Fuleihan, and AUB faculty

All told, the SHARP 315 course has proven an excellent example of the opportunity for impact that exists through international research funding when combined with strong collaboration between faculty and research administrators.

References:

American University of Beirut, official website. http://www.aub.edu.lb

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Moodle Open Source Course Management System, official site. https://moodle.org

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