

Human Research Protection Program Future Directions at AUB



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American University of Beirut
September 16-17, 2011

Institutional Ethos



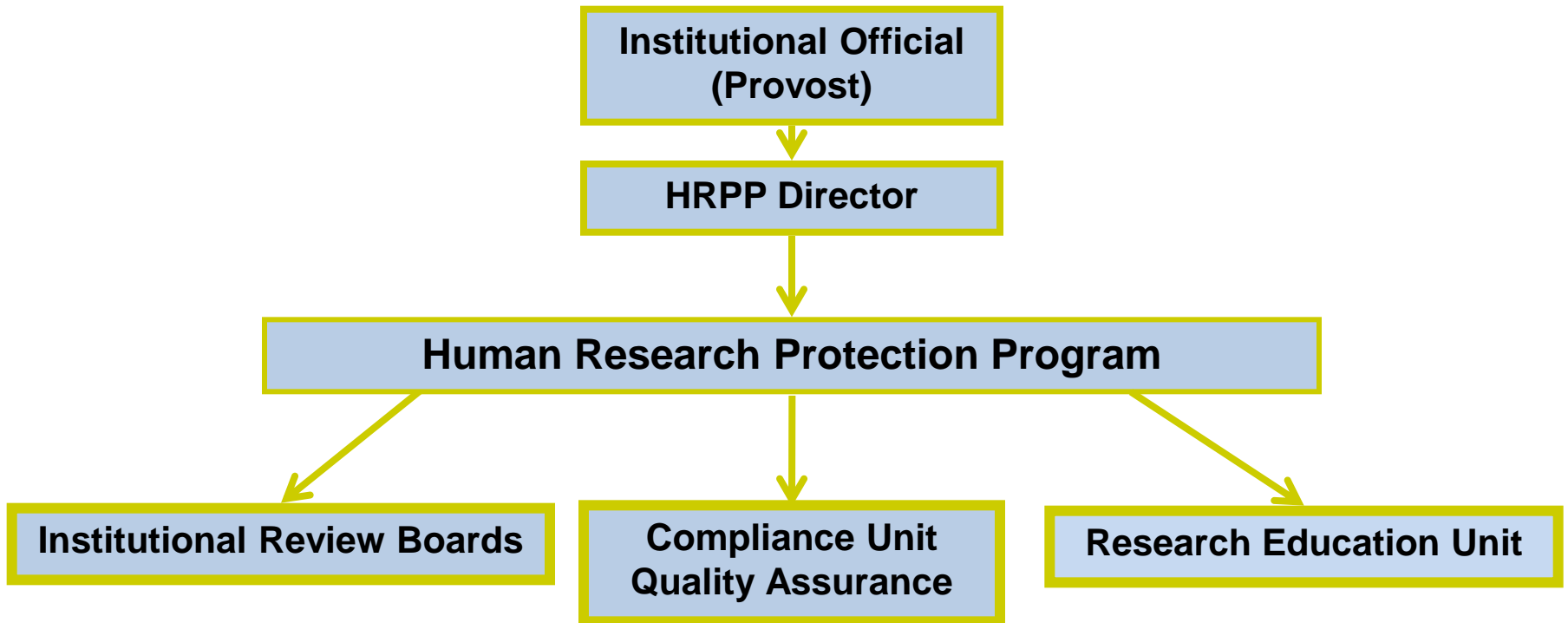
- “The American University of Beirut is committed to fostering an intellectual community on campus where faculty are empowered by their own research and are encouraged to engage in collegial discourse and interdisciplinary innovation.”
- “This commitment supports the University’s mission “to participate in the advancement of knowledge through research” and enhances the educational experience of all AUB students.”

Human Research Protection Program: The Beginning of a New Period at AUB



- IRB established in 1996, now operating under HRPP and split into Biomedical and SBS IRBs.
- HRPP was established at AUB in 2010.
- AUB signed a Federal Wide Assurance (FWA) with OHRP-DHHS as a domestic US institution.
- CITI on-line training program became an institutional requirement for ALL conducting or participating in research involving human subjects.

Human Research Protection Program: Structure and Governance



Human Research Protection Program: Mission Statement



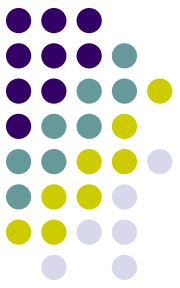
- The mission of the HRPP at AUB is to safeguard and foster awareness of and respect for the rights and welfare of human subjects participating in biomedical and social and behavioral research activities under the auspices of AUB.
- This can be maintained through the conduct of research that follows the ethical principles of Belmont Report, and that abides by the principles of responsible research conduct and scientific integrity.

Individual Responsibility



- Successful and trustworthy research requires on the researcher's part:
 - Integrity
 - Highest ethical conduct
 - Professionalism
 - Training and mentorship
 - Discipline and organization
 - Commitment and patience

Goals Moving Forward: Institutional



- To firmly establish an institutional culture guided and dominated by the principles and procedures of HRPP.
- To provide continuous education and training for conduction of research involving humans. To reduce deviations and violations.
- To integrate and apply a meaningful COI policy.
- To prepare, seek and obtain accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) in the USA.

Goals Moving Forward: National and Regional

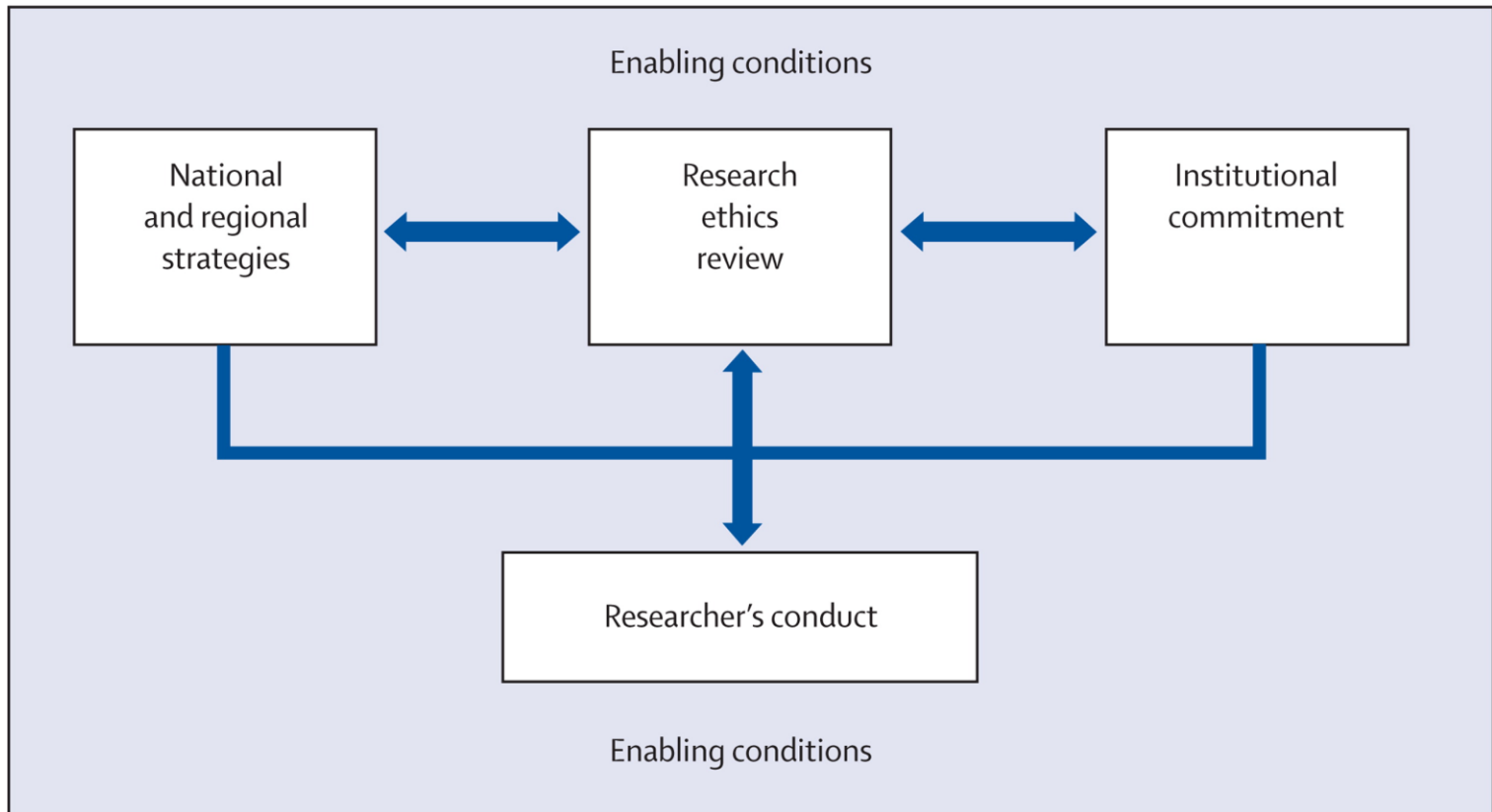


- To help establish a national standard for IRBs and Ethics Committees.
- To make available developed resources.
- To reach out and network with other regional institutions as well as national, regional and international organizations, in collaboration with the Salim El-Hoss Bioethics and Professionalism Program at AUB.

Proposed Framework for Research Ethics Systems in Developing Countries



Development



Development

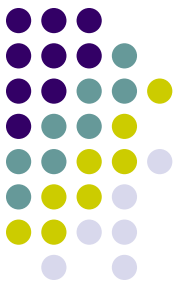
Goals Moving Forward: Establishing a New Institutional Culture



- Changing from an established, or adopting to a new, culture within an organization are challenging propositions.
- This is especially true when the change may carry a burden or is perceived as a barrier or an obstacle, irrespective of the potential common good or benefit to others.
- Education is key.
- Responsibility is shared between Institution and Researchers/Faculty.

Organizational Culture: Unhealthy Attributes

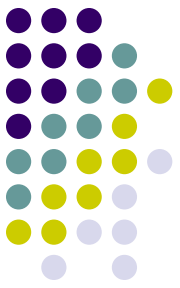
Gerald E. Caiden, The Dynamics of Public Administration 1971



- Process more importance than purpose:
 - Expecting protocol approval without proper review
- Authority more important than service:
 - Arbitrary, pedestrian or inconsistent decisions
- Form more important than reality:
 - Improper addressing of deviations by IRB
 - Overlooking, or looking at, deviations as solutions
- Precedence more important than adaptability
 - Referring to prior compromised occurrences

Organizational Culture: Healthy Attributes:

Herbert Shepard, "Changing Interpersonal and Intergroup Relationships", 1965



- Integrity
- Cooperation:
 - Acceptance and following of institutional guidelines
 - Non-coercive stand, without compromise of principles
- Collaboration:
 - Non-competing or inconsistent rules or guidelines
- Consensus-seeking behavior:
 - IRB deliberations without compromise of principles

Organizational Culture: Benedict's Concept of Synergy

A.H. Maslow, "Synergy in the Society and in the Individual", 1964



- Low synergy:

Interests of individuals & interests of the group are at odds

- Investigators and IRB / HRPP are at odds regarding importance of protecting human subjects

- High synergy:

Interests of individuals & interests of the group are in harmony

- Faculty help foster an HRPP-compliant attitude and raise awareness among students and staff

Organizational Culture: A Must Transformation under HRPP



- To a healthy organizational culture that provides:
 - A supportive environment conducive to open, honest and trusting communications.
 - Collaboration and cooperation.
 - Application of common sense, experience, knowledge, wisdom, ingenuity, and creativity.
 - Realization of individual and organizational potentials.
- To a high synergy environment to cultivate and sustain a common sense of mission and high ethics.

