International Course on Biobanks for Research Purposes: Opportunities and Challenges

The International Workshop on Biobanks for Research Purposes: Opportunities and Challenges was held in Lima, Peru from September, 5th to 6th, 2019.

This event was jointly organized by the Latin American Forum for Research Ethics Committees (FLACEIS per initials in Spanish), the Peruvian IRB Network (REDCEI), and Universidad Peruana Cayetano Heredia, with the sponsorship of The Global Health Network, EDUPYME and EMERGE, without whose support, this event could not have been held.

This collaborative educational activity among Peruvian and international organizations aimed at updating Peruvian IRB members and investigators on biobanks, ethical and legal aspects, data sharing, and broad consent, as well as in-depth discussions on review the sharing with our international attendees the Peru progress in the regulatory system, how to work in IRB networks and the role of IRBs in scientific integrity issues.

The Global Forum for Bioethics in Research (GFBR, per initials in English) gathered in November 2018 in Cape Town, South Africa, under a central theme: **The ethics of data sharing and biobanking in health research.",** among them the new ethical, legal and social concerns, as well as ownership, control, infrastructure and sustainability, issues that need to be addressed, particularly in lower and middle income countries (LMICs).

There were three keynote speakers, Guido Lombardi, MD, MA from Peru, Ana Palmero, JD from Argentina and Edward Bartlett, PhD from the United States.

Dr. Estela Quiroz, president of FLACEIS and Executive Coordinator of the Peruvian IRB Network (REDCEI) introduced the course by presenting a case which illustrated much of the debate at local IRBs, would the IRB authorize the use in secondary research of coded samples, collected from clinical practice without a consent form to store? She also reminded the audience that all of the stakeholders, investigators, IRB members, regulatory agencies and participants are moving in the same direction, that is, toward research that is scientifically sound, with adequate risk-benefit balance and with respect for subjects.

Dr. Guido Lombardi, researcher at the Paleontology Laboratory, Universidad Peruana Cayetano Heredia (UPCH) presented on Research in Old Human Remains. He highlighted the fact that use of human biosamples for research is a privilege and it is ethically justified by the benefit that knowledge will bring to society. He also reminded the audience of the importance of showing respect to the descendants and community, when we present results and when we display these remains in museums or others, considering the feelings and cultural patterns of their descendants.

The event took place in the course of two days. The first day was dedicated to the theme ***Biobanks, data sharing and broad consent.*** Ms. Palmero discussed the importance of sharing samples and data in the context of regional epidemics and reminded us that the collective good sometimes may overrule autonomy, as the sole guiding principle. Several key points were discussed, governance, custody, IRB review, broad consent and the importance of involving the community. She also provided an in-depth presentation on issues regarding data sharing, such as confidentiality, protection of personal data, and the need to formalize data sharing using Material Transfer Agreements. Ms. Palmero also described the proposed legislation in Argentinean for biobanks in order to harmonize criteria, provide security to all stakeholders, and increase donors' trust.

On the second day, Dr. Bartlett provided a detailed overview of the new Common Rule and the various exempt categories that IRBs could use for the review of research with stored samples, with or without informed consent. Group discussions, with specific case scenarios, were held, the audience participated actively and it was followed by a question and answer session that addressed several other situations. Dr. Bartlett ended his presentations by providing a series of very useful tools that could be used to learn more about biobanks.

In addition to these presentations, several Peruvian experiences with biobanks and stored samples for research purposes were shared by renown investigators, which evidenced that the topic of biobanks and sample sharing is already here and the importance of engaging IRBs into this practice, with the right tools for detailed review, and timely processes. Additionally, a presentation on scientific integrity reminded the audience of the importance of being aware of what this entails, of staying trained and ensuring their investigators are also involved in the training processes. It also highlighted the role of the world conferences on research integrity in disseminating information and promoting discussion in new regions of the world. The Peruvian regulatory agency for clinical trials, OGITT, gave a presentation on the current legislation initiatives they are working on, for emergency therapy and on medical devices. Peru has a strong clinical trials regulation, with a registry of clinical trials that has been certified by the World Health Organization, and a process that includes registration of clinical trial sites, CROs, and IRBs, as well.

The course ended with the presentation of a South African researcher, Dr. Shenuka Singh, whose dissertation topic for her PhD was on the ethical, legal and social implications of using samples from biobanks in South Africa. She reminded us of how our two countries share the same concerns, in spite of coming from two different continents, and also highlighted the importance of training investigators in this field.

A total of 102 people attended the course, among speakers, attendees and logistic support, 75 were women and 4 were foreign attendees/speakers coming from Argentina, Colombia, the United States and South Africa. A total of 32 Peruvian institutions were represented at this event, from national

hospitals to NGOs, Contract Research Organizations (CROs) and universities. 21%of the attendees were physicians, and the rest were nurses, psychologists, biologists and attorneys.

One of the follow up actions was to get a working group to develop a template for Broad Consent and Material Transfer Agreement, that they can take back to their institutions in order to implement. Very few institutions in Peru have these documents currently in use. Volunteers have already signed up for this group and we plan to meet in October.