



REGULATING MEXICAN BIOBANKS FOR HUMAN BIOMEDICAL RESEARCH: WHAT CAN BE LEARNED FROM THE EUROPEAN EXPERIENCE?

Liliana SOTO GÓMEZ*

ABSTRACT. Biobanking presents significant governance challenges. This is especially evident in Mexico, where the legal framework has not kept up with significant industry expansion. Twenty years ago, Europe was in a similar position. More recently, Europe has developed a comprehensive framework for addressing biobank expansion within ever-growing scientific and biomedical research communities. Based on this experience, we can draw many lessons, including those involving the implementation of laws, procedures and stakeholders' consensus to ethically maximize the potential of samples. Mexican biobanking raises many issues, requiring solutions that are sensitive to its own particular needs. This article analyses the flaws of current biobanking regulations in Mexico by drawing comparisons with Europe. It pays special attention to informed consent; sample/data sharing systems; ethical tissue treatment and classification; governance models; best practices and the role of ethics committees. It argues that several European provisions regarding data protection and sharing can serve as guidelines for international research collaboration currently taking place between Mexico and Europe.

KEY WORDS: *Bioethics, biobanking, biobanks, governance, regulation, data protection, informed consent, genetics, genomic regulation, data sharing.*

RESUMEN. *Los biobancos presentan grandes retos de reglamentación. Lo anterior es evidente en México, donde la legislación no se encuentra a la par de la creciente expansión de los biobancos. Hace veinte años, Europa se encontraba en la misma situación, pero actualmente ha desarrollado instrumentos capaces de atender tal expansión en el marco del aumento de investigación científica y biomédica. Parece haber numerosas lecciones por aprender de Europa: la materialización de leyes, procedimientos específicos y el consenso de actores para maximizar el potencial de muestras biológicas éticamente. Los biobancos mexicanos implican problemas particulares y cualquier propuesta debe responder a*

* Master in Biotechnological Law and Ethics from the University of Sheffield. Is currently at the final stages of PhD in Law at the University of Leeds. Sponsored by the National Council of Science and Technology (Conacyt). Works as an ethics-legal adviser on biobanking for the BTCure, European Project on rheumatoid arthritis research.

los mismos. Este artículo identifica deficiencias legislativas actuales sobre los biobancos en México y realiza comparaciones con Europa; prestando atención a temas como consentimiento informado, sistemas de intercambio de muestras e información asociada, tratamiento ético de tejido y su clasificación, modelos de reglamentación, mejores prácticas, y el rol de los comités de ética. La propuesta radica en qué instrumentos europeos son relevantes al establecer estándares de colaboración en investigación científica (la cual actualmente sucede entre México y Europa).

PALABRAS CLAVE: Bioética, biobancos, reglamentación, regulación, protección de datos genéticos, consentimiento informado, genética, derecho genómico, intercambio de datos genéticos.

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