

Bioethics Position Statement: Human Biological Samples

Human biological samples have long been utilized in preclinical and clinical pharmaceutical research, but now play an increasingly important role in the post-human genome initiative era. Specifically, genomic samples are essential to understanding how genome variations affect or are affected by pharmaceutical interventions.

Lilly has an ethical obligation to pursue scientific and healthcare innovation that promotes a broad social good while simultaneously respecting and protecting the interests and rights of individuals who participate in biomedical research and donate biological samples. Because of the individualized information that can be extracted from genomic samples, this obligation is becoming increasingly important. The degree to which donors feel respected and that their interests and rights are protected will determine the degree to which they are willing to participate in clinical trials, and thus, the degree to which scientific innovation can flourish.

Therefore, Lilly conducts its research involving human biological samples with rigorous oversight of the following areas:

- Acquisition and sources of biological samples
- Use and management of biological samples
- Knowledge acquired from biological samples

For each of these areas, Lilly applies ethical guidelines that respect human life, respect an individual's autonomy and unique belief systems, and protect individual privacy and confidentiality. Lilly commits to use human biological samples in a manner that will minimize the potential for physical, dignitary, discriminatory, or stigmatizing harms. Through the informed consent process, research subjects are informed that sensitive personal information and data derived from the human biological sample will be protected and used in a responsible manner. In compliance with the informed consent process, the conduct of Lilly research on human biological samples is consistent with the stated purpose of sample collection (even after death).