

## Roche Position<sup>1</sup> on Human Specimen Resources (Biobanks)

### Background

Scientific progress in recent years has helped shed light on the interplay between biomarkers, in particular genes, and environmental and lifestyle factors. This knowledge, coupled with advances in genomics and in bio-informatics, enables researchers to better understand complex diseases. In order to gain such understanding, researchers need to examine large quantities of data and human specimens. This has led to the widespread establishment of human specimen resources (also called biobanks), where biological human materials (tissue samples and/or bodily fluids) and the data associated with those materials are collected, stored, processed and distributed.

### Stakeholders' Expectations and Concerns

Human specimen resources /biobanks represent opportunities to analyze large quantities of human materials and data. It is expected that they will help researchers acquire a better understanding of common complex diseases, and eventually to develop targeted therapies to treat and possibly even cure such diseases. In this evolving field, it is important that persons asked to contribute their specimens and their potentially sensitive personal information have sufficient clarity on what this means for them. Those who donate human biological materials for research will have questions about the protection of the rights and privacy of donors.

### Roche's Position

**Awareness.** Roche is aware of stakeholders' concerns and takes them very seriously. We are committed to providing potential donors and other interested persons with information on any relevant aspect of our work with human materials.

**Roche's Mission.** As an innovation-driven global healthcare leader, Roche aims to improve the quality of human life by providing products and services for prevention, diagnosis and treatment of diseases. Roche's goal is to help alleviate human suffering caused by diseases. Human specimen resources /biobanks are an essential tool in exploring aspects of diseases that might eventually lead to new or better diagnoses or treatments.

**Responsibility and Standards.** While human specimen resources /biobanks are an important aid in understanding diseases, they contain sensitive information about specimen donors that, if not appropriately safeguarded, could cause harm. Roche is dedicated to protecting the rights and the privacy of specimen donors. Therefore, Roche has established a policy to provide a framework

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<sup>1</sup> Pertains to SDGs 3 and 16



for the ethical and legal handling of human specimens and specimen-associated data in both divisions (pharma and diagnostics). All Roche employees are required to adhere to the policy, in addition to conducting their work in compliance with international, regional and national laws, rules and regulations.

**Privacy Protection.** Roche has processes in place to ensure the protection of its donors' privacy. For instance, all information is coded, and Roche has no access to the actual identity of the donor. In certain cases, where particular concerns regarding a donor's privacy exist, the information is encrypted a second time.

**Informed Consent.** Roche is committed to an information process that provides potential donors sufficient information about all relevant aspects of a participation in a human specimen collection before they agree to give their specimens. It is of the utmost importance to us that every donor knows the nature and purposes of the research study, how his/her specimen-associated data will be used and stored, and that he/she is free to withdraw from participation at any time. Roche believes that by being completely transparent we can address the legitimate concerns a donor might have.

## **Outlook**

Human specimen resources will continue to be part of scientific biomedical research, and have the potential to further contribute to the growing knowledge about genetic and molecular correlations, and to be a key driver in enabling personalised healthcare. Against this background, we will uphold our high standards of information and privacy protection, so as to ensure that our relationship to donors is based on trust and a mutually agreed goal – a better understanding of diseases and the discovery and application of better diagnoses and novel treatments.

## **Roche's Engagement with Stakeholders**

The Roche Science and Ethics Advisory Group (SEAG) offers advice and counsel on a broad range of ethical matters. It is a panel made up of independent external experts in bioethics and philosophy, and provides consultative feedback on ethical approaches to biomedical and clinical research, in particular on topics that are perceived as particularly sensitive or controversial by the public at large in order to take into account as many perspectives as possible. The SEAG has also provided feedback to this Position Paper.

*This updated position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on May 13, 2013 and entered into force the same day.*

*It was reviewed in April 2020.*