



Roche Position on Human Sample Repositories (Biobanks)

Background

Scientific progress in recent years has helped uncover a great deal of knowledge about the interplay between biomarkers, in particular genes, and between genetic, environmental and lifestyle factors. Coupled with advances in genomics and in bio-informatics, researchers can now examine a large quantity of data and human samples in their quest to understand complex diseases. This has led to the widespread establishment of sample repositories (also called biobanks) where biological human materials and the data associated with those materials are collected, stored, processed and distributed

Stakeholders' Expectations and Concerns

The generation of such sample repositories with sometimes huge numbers of human materials (tissue samples and/or bodily fluids) and their associated data leads to the expectation that researchers acquire a better understanding of common complex diseases and may be able to develop targeted therapies to treat and possibly even cure such disorders. In this evolving field, it is important that human beings asked to contribute their samples and their potentially sensitive personal information have sufficient clarity on what this means for them. As the use of human biological materials can give rise to sensitive issues, this naturally raises concerns about the protection of the rights and privacy of donors.

Roche Position

AWARENESS. Roche is aware of these concerns and takes them very seriously. We are committed to providing potential donors and other interested persons with comprehensive 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. Sample repositories are an invaluable tool in exploring aspects of diseases that might eventually lead to novel or better diagnoses or treatments and are thus employed by Roche in order to conduct research into multiple disease areas.

RESPONSIBILITY AND STANDARDS. While sample repositories are an important aid in understanding diseases, they contain sensitive information about human beings that, if disclosed, could potentially cause harm. Therefore, Roche is dedicated to applying the highest level of standards when it comes to protecting the rights and the privacy of its donors. Roche has established a harmonized policy on the management of human samples for all sample repositories in both divisions (pharma and diagnostics). All Roche employees are required to apply these internal rules, as well as to conduct their work in compliance with international, regional and national laws and regulations.



Roche's Efforts to Protect the Rights of Donors

PRIVACY PROTECTION. Roche has established processes 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 fully informs potential donors about all aspects of a participation in a human sample collection before they agree to give their samples. It is of the utmost importance to us that every donor knows precisely what will happen to his / her sample and what type of research will be conducted with it and that he / she is free to withdraw from participation at any time. We believe that the only way to deal with the legitimate concerns a donor might have is complete openness.

Outlook

Sample repositories will continue to be part of scientific biomedical research, and might even gain importance with growing knowledge about genetic and molecular correlations. 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 Engagement with advocacy group

In order to address questions and concerns of patients, Roche has, together with the European Genetic Alliances Network, EGAN, issued a booklet with some of the questions frequently asked by those thinking about donating a sample to a repository (<http://www.gig.org.uk/docs/faq-biobanklowres.pdf>). The questions were generated by patients, and the content by those experts responsible for carrying out research projects at Roche. As well as by independent experts from the patient community.

The Roche Science and Ethics Advisory Group (SEAG), a body of external experts from the fields of ethics, law, sociology, and members of the general public advises Roche on a regular basis on issues associated with innovative developments in biomedicine, with particular emphasis on their ethical impact, including biobanks. The SEAG has also reviewed this Position Paper.

For further reading, please see FAQ on [Roche Specimen Repositories](#).

This position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on May 12, 2009 and entered into force the same day.