

## AstraZeneca Global Public Policy

### Public Policy Issue: Human Biological Samples in Research

An internal global governance framework exists to guide the acquisition, storage, use and disposal of human biological samples and associated data.

Policy and processes are implemented rigorously to ensure that human biological samples are handled in a responsible and ethical manner. This places emphasis on informed consent, designed to protect the rights and expectations of donors and families, throughout the process of acquisition, use, storage and disposal, while enabling an environment in which important medical research can flourish.

AstraZeneca ensures that its informed consent documents detail what the donor will be agreeing to, and is designed to safeguard the donor's wishes and rights.

In many cases the purpose for which the samples will be used will not be known at the time of the donation and the donor will be made aware that they are being asked to give generic consent.

No human biological sample can be acquired unless it is from an approved source which has appropriate ethical approval procedures in place. Human biological samples obtained by AstraZeneca are acquired with the informed consent of the donor (or appointed representative) and must only be used in accordance with the consent, which describes the nature and purpose of the donation and any risks and benefits associated with providing the sample. AstraZeneca may seek access to rare, hard to find historical human biological samples in diagnostic archives where original consent for research is absent. In this situation AstraZeneca requests ethical approval for use via an appropriate Research Ethics Committee.

If the use of a human biological sample provides data on the donor that might be important to them, the way of handling the finding will be described in the informed consent process. Where there is the option for the donor to be notified of research results, the donor's preferred "right to know or not to know" will be respected.

Samples and data may be transferred to a third party for the purposes of scientific research (in accordance with the consent) and responsibilities will be agreed within a written agreement.

The donor can withdraw their consent for use of a human biological sample any time after its donation (provided it has not been anonymised). AstraZeneca will locate and dispose of, or return, all unused biological samples to the donor via the approved supplier/source.

AstraZeneca will not usually destroy any results from the use of the samples.

AstraZeneca does not pay donors for samples, nor offer donor's financial incentives to provide biological samples. The only payment that a donor may receive is compensation covering expenses associated with providing a donation e.g. travel expenses.

Protecting the confidentiality of a donor's identity is of the utmost importance. A key part of this process is the coding of biological samples and associated data (including genetic data) in such a way that researchers cannot trace a sample back to an individual donor without the use of extreme and inappropriate efforts.

#### Links to Additional Resources

[AstraZeneca Sustainability](#)  
[AstraZeneca Bioethics Policy](#)

#### Version

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V4.0