

Statement of Use

Axol Bioscience ('Axol') is a leading supplier of high quality human cells as well as auxiliary cell culture medium and reagents. We obtain human cell resources from cell repositories who guarantee all human cell collections are performed at certified facilities under the highest ethical standards. Axol meet the following requirements under a Human Material Transfer Agreement (MTA) between the cell bank repositories and Axol. A signed MTA from Axol is not required for research orientated institutions or pharmaceutical companies who are using Axol products as research grade testing material.

Ethical considerations and protocols are used in the collection of cells. Each specimen collected from any clinic was consented to by both hospital and the individual. Discrete legal consent form was obtained and the donors' or clinics' rights to hold research uses, for any purpose, or further commercialization use were waved. All human cells are collected under protocols that are in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The collection protocol of specimen must comply with all federal, state and local laws.

Donor protection. We make sure we follow standard medical care and protect the donors' privacy. The donor's identity is anonymized and all cells and data are labelled using only ID codes to protect the identity of the donors. Informed consents are kept at cell repositories and are not provided to Axol to protect the donors' privacy.

Cell reprogramming. Axol's preferred methods of reprogramming the human cell material is the use of genome 'footprint free' episomal iPSC reprogramming vectors under UK Health and Safety Executive (HSE) category I guidelines and 'non-integrating' Sendai virus under UK Health and Safety Executive (HSE) category II guidelines.

Axol has obtained commercial licences for cell reprogramming technologies from iPS Academia Japan, Inc. and ID Pharma Co., Ltd. In addition, ID Pharma Co., Ltd, has agreed to enable Axol's customers who do not have access to ID Pharma's Sendai technology licence, to purchase a project specific sub-licence, when they contract Axol for cell reprogramming services.

Cell testing. All samples have been tested negative for HIV, Hepatitis B and C or their counterparts in animals, unless otherwise marked as “infection” patient sample in the patient history file and approved for commercial product development.

The recipient agrees that the material provided:

- a) Will not be used in human subjects, or administered to human subjects in clinical trials, or for diagnostic purposes involving human subjects without the written consent of Axol and the original cell repository.
- b) Will be used only in compliance with applicable laws and regulations and in compliance with the recipients’ applicable policies on human subject research.
- c) Will, in the case of entities receiving funding from the United States to conduct human stem cell research, be used in compliance to federal, state and local laws with applicable NIH Guidelines on Human Stem Cell Research: <http://stemcells.nih.gov/policy>.
- d) Will not be used in research in which the cells are introduced into non-human primate blastocysts.
- e) Will not be used in research involving the breeding of animals where the introduction of the material may contribute to the germ line.

Chief Executive Officer

Dr. Yichen Shi

