



Ethical Policy for the Supply of Human Tissue and Cells

Caltag Medsystems Ltd (Caltag) is a supplier of products to the life science research community in the UK and Ireland in their pursuit of curing disease and improving life. Caltag works in partnership with a small number of carefully selected tissue procurement organisations (TPOs) in sourcing human tissue and cells. Caltag are committed to operating under the highest ethical and legal standards in the procurement of human and animal tissues from these TPOs.

- Caltag recognises that individuals and companies are inherently responsible for their actions and the justification, purpose, and consequences of any action should be taken into account when it is determined. We rely on the protocols, policies, and procedures listed below to provide guidance for the application of ethical behaviour in our work as members of the life science society
- Caltag believes in the integrity of our activities in the field of biotechnology and that they should be conducted honestly, truthfully, lawfully, impartially, competently, and with considered regard for transparency of process.
- Caltag believes that human actions have social, economic, and environmental impact, and that they should promote good and avoid harm.

Human Tissue

As part of the wider scope of supplying products to the UK and Irish life science research community, Caltag supply human tissue and primary cells sourced from carefully selected TPOs. These TPOs are assessed before entering into partnership with Caltag as part of our Quality System.

Caltag is licensed by the Human Tissue Authority (HTA), License Number 12672, to procure, process and store human tissue in the UK. Many tissue products sold by Caltag are supplied directly from the TPO to the Customer.

Caltag warrants that:

- Affiliated TPOs must provide evidence that they are compliant with the Declaration of Helsinki and/or the principles of ICH GCP.
- All human tissue samples must be supported by informed consent either directly or through an authorised agent acting on the donor's behalf. Each informed consent form



must be written to take into account the specific type of biological material being donated and to communicate the intended research uses to the potential donor. The privacy and autonomy of donors is protected.

- Affiliated TPOs have a documented quality policy accredited to a recognised international standard (GMP, ISO 9001 etc.)
- Affiliated TPOs commit to protecting the privacy and confidentiality of individuals who act as donors.
- Caltag commits to review affiliated TPOs annually to ensure continued compliance with the policies stated above.
- TPOs who fail to meet the standards stated above will not be represented by Caltag.

Recipients

The recipient warrants that:

- They are registered with the HTA to receive and store human tissues.
- Materials will not be used in human subjects, or administered to human subjects in clinical trials, or for diagnostic purposes involving human subjects.
- Materials will only be used only in compliance with applicable laws and regulations and in compliance with the recipients' applicable policies on human subject research.