

Celprogen Biomedical Ethical Standards

Ethical and legal standards governing Human; : Human Immunoglobulins (IgG, IgA, IgM and IgE) Depleted Serum solution: 100ml.

Celprogen is the original manufacturer of Human Immunoglobulins (IgG, IgA, IgM and IgE) Depleted Serum solution as indicated in our web site catalogue.

Celprogen complies with the following procedures, standards and international standards for donation and collection of human tissue used for reagents, cells, and immunoglobulins (IgG,IgA,IgM and IgE) depleted serum isolation:

The tissue and serum used by Celprogen for isolation of human cell cultures and Immunoglobulins is derived from donors:

- 1. Under guidance of investigational Review Board (IRB) protocol
- 2. Signed an informed consent form which outlines in detail the purpose of the donation and the procedure for processing the tissue.
- 3. Clinical Health Act (HITECH), which establishes new federal privacy and security laws with respect to Protected Health Information and makes changes to existing Health Insurance Portability and Accountability Act (HIPAA) requirements under HITECH became effective February 17, 2010. These requirements apply to Covered Entities and Business Associates. Individual" has the same meaning as the term "individual" in 45 CFR ~ 164. 501 and includes a person who qualifies as a personal representative in accordance with 45 CFR ~ 164. 502(g).
- 4. The Convention for Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine" published on April 4th, 1997 by the Council of Europe (European Treaty Series no 164). (for utilization of the cell lines in Europe)
- 5. The Human Tissue Act published on November 15th, 2004 by the government of the United Kingdom. This act aims to make consent a fundamental principle underpinning the use and storage of human tissue. (for utilization of the cell lines in Europe)
- 6. The Declaration of Helsinki developed by the World Medical Association as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. (for utilization of the cell lines in Europe) Should you have any questions concerning biomedical ethical practices related to the use of Primary Human Cells, Human Albumin or immunoglobulins products, do not hesitate to contact us.

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