

ScienCell Research Laboratories Ethical and Legal Standards for Primary Human Cell Products & Contract Services Utilizing Primary Human Cells

ScienCell Research Laboratories is committed to operating under the highest ethical and legal standards for the acquisition of human cells used in our Primary Human Cell Products and Contract Assay Services. As such, all ScienCell Research Laboratories human cells are sourced within the USA under protocols that have obtained **Institutional Review Board (IRB) approval**.

IRBs are also known as Independent Ethics Committees (IECs) or Ethical Review Boards (ERBs) and are governed by **Title 45 of the Code of Federal Regulations (CFR) Part 46**. IRBs are federally empowered by the **US Food and Drug Administration (FDA)** and the **Department of Health and Human Services** who authorize and task them to review, modify, approve or disapprove proposed research involving human subjects under the regulations of 45 CFR Part 46. Fundamental to obtaining IRB approval is that the important ethical tenets outlined in the **Belmont Report** (*Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*) are adhered to. These basic tenets are:

1. Respect for Human Individuals

- The privacy and autonomy of all donors is protected.
- All donors are treated with courtesy and respect.
- Written informed consent is obtained from all donors prior to their donation or from donors' relatives in case of deceased donor.

2. Beneficence

- A risk/benefit assessment has been performed and the principles of "Do No Harm" and minimizing risks to the donors are upheld.

3. Justice

- Reasonable, non-exploitative, and well-considered procedures are administered fairly and equally.
- Due care is taken in the selection of donors.

The tenets of the **Belmont Report** are very similar to those of the World Medical Association's **Declaration of Helsinki**, and IRBs routinely use both sets of ethical principles to guide their decisions regarding approval or disapproval of research utilizing human subjects. We also took in consideration the UK Human Tissue Act (2004), the German Federal Data Protection Act, and the Data Protection Directive (95/46/EC).

Only utilizing cells that are obtained within the USA from IRB-approved protocols thus assures ScienCell Research Laboratories, our customers and our clients that the highest ethical and legal standards are always adhered to.

Sincerely,

Claudia Haskin

Marketing & Sales Manager