

Use of Human Tissue and Commercially Available Human Cell Lines

Summary/Purpose: To explain the criteria for the review of research using human tissue and commercially available cell lines.

Studies that do not require IRB Review

- **Policy:** Studies using human tissue where donors cannot be identified or commercially available human cell lines are not human subjects research and do not require IRB review.
- **Regulations:** According to the Office for Human Research Protections (OHRP), “HHS-conducted or supported research that involves neither interactions nor interventions with living individuals or obtaining identifiable private information is not considered human subjects research. Accordingly, *in vitro* research and research in animals using already derived and established human cell lines, from which the identity of the donor(s) cannot readily be ascertained by the investigator, are not considered human subject research and are not governed by the HHS or FDA human subject protection regulations appearing at 45 CFR Part 46 and 21 CFR Parts 50 and 56. IRB review is not required for such research.” [Office for Human Research Protections Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles, March 19, 2002.]

Studies that require IRB Review

- **Policy:** Investigators who wish to conduct research using human tissue OR human cell lines where the donor(s) may be identified must submit an IRB application for review and approval prior to beginning their research.
- **Regulations:** OHRP also notes, “HHS-conducted or supported research that uses human cell lines where the donor(s) may be identified, including cells that retain links (such as a code) to identifying information is generally considered human subject research that is governed by 45 CFR Part 46 because the donors are human subjects. IRB review and approval is required for such research.” [Office for Human Research Protections Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles, March 19, 2002.]