**Regulatory Review Requirements for Human Stem Cells**

The maintenance and use of **human pluripotent stem cells** (embryonic, induced or lines intended to be induced) requires review by the following regulatory committees (as mandated by federal and state agencies):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Committee** | **Covered activities** | **Why?** | **Protocol** | **Application** |
| Stem Cell Research Oversight Committee | SCRO | All handling/ use of human pluripotent cells | Ensures state mandated review of ethical concerns related to human stem cells | Stem Cell Use Authorization (SCUA) | Contact patricia.steen @ucr.edu |
| Institutional Biosafety Committee | IBC | All handling/ use of human derived materials | Ensures appropriate safety procedures for handling human cells | Biological Use Authorization (BUA) | <http://or.ucr.edu/OrPortal/index.aspx> (UCR faculty only) contact patricia.steen@ucr.edu |
| Human Research Review Board | HRRB | All research involving humans or materials derived from humans | Ensures that the rights of the original donors of human materials are maintained | UCR HRRB protocol | HRRB review of human pluripotent cell line use is accomplished through the SCUA (the HRRB reviews relevant SCUA sections), contact monica.wicker@ucr.edu |
| Institutional Animal Care and Use Committee | IACUC | Only research involving the use of live non-human vertebrate animals | Ensures appropriate animal care. Needed only if mouse embryonic fibroblasts (MEF) are to be harvested or if experiments will involve vertebrate animals | Animal Use Protocol (AUP) | <http://or.ucr.edu/Home/Forms.aspx?T=2> or contact IACUC@ucr.edu |

It will take 1-2 months to complete the above reviews, it is recommended that researchers who have not obtained the above approvals complete the necessary paperwork and begin the approval process prior to the time they anticipate beginning a stem cell project. The Academic Coordinator can provide advice on meeting these regulations.

Principal Investigators with existing BUAs (Biological Use Authorization) must amend their BUA to include the Core Facility as a location.

**Material Transfer Agreement (MTA)**

Working with human pluripotent stem cells requires **M**aterial **T**ransfer **A**greement (MTA) for each line. Principal Investigators are required to obtain their own MTAs, signed by authorized representatives, prior to using materials in the Core. The Office of Technology Commercialization reviews and approves Material Transfer Agreements (MTA). Please contact UCR’s Material Transfer Officer at MTA@ucr.edu to facilitate this process. (See <http://www.ora.ucr.edu/IP/MTA.aspx> for further information and guidance.)

Receipt, use, and storage of human pluripotent stem cells must comply with the MTA of the provider. Please be aware that different providers have different MTA requirements. All Principal Investigators are able to maintain hESCs and hiPSCs at the Stem Cell Core, subject to the following MTA requirements:

* Principal Investigators are required to obtain their own MTA to grow hESCs and hiPSCs.
* The MTA should indicate that these cells will be used in their lab and in the Core. Principal Investigators will then be able to bring cells into the Core, and obtain cells from the core for a small service fee used for cell storage, maintenance and characterization.

**Please always inform the UCR Stem Cell Core Academic Coordinator when you update your SCUA, BUA, HRRB or obtain a new MTA.**