



Background Consent for Somatic Cells

The CIRM MES regulations contain detailed consent requirements for identifiable somatic cells “used for research intended to derive a covered stem cell line” – [Section 100090\(a\)](#). Cells and tissue are routinely collected by banks utilize IRB-approved protocols. These protocols inform the donor that the cells will be used for research but do not necessarily incorporate the detailed CIRM requirements, or contain consents that refer to creation of pluripotent cell lines.

Example (see Section 5 of interviews summary): One researcher is performing reprogramming experiments in the context of AIDS research. Ideally, the researcher would be able to access cells with varying immunological profiles for reprogramming. The bank in question holds blood samples from AIDS patients who consented to research use. These samples are not available to the researcher because of the CIRM consent requirements are more prescriptive than the bank’s research-consent.

Cell Payments and the NAS Guidelines

The NAS guidelines recognize that somatic cell procurement is covered by existing IRB regulations (section 7.1; [2008 amendments](#)). The NAS does not recommend expanded consent for basic research. The NAS does recommend expanded consent for transplantation to humans and development of commercial products.

Policy Considerations

Consider differential consent standards depending on the level of research. For example, consider whether IRB-approved research consent is appropriate for in vitro research and/or animal transplantation. Cell lines intended for human transplantation or development into commercial products could adhere to the existing consent standard that addresses each of these contingencies.