CIRM hiPSC Initiative - Appendix B

This Appendix applies to those human induced pluripotent stem cell (hiPSC) lines developed pursuant to RFA 12-03 ("CIRM hiPSC Lines"), and to tissues/primary source cells where specifically indicated. This Appendix is not intended to be a comprehensive summary of all terms in the applicable agreements. Further CIRM may, in its sole discretion, include terms that differ from those identified within this Appendix.

- **Key terms in Repository Agreement between CIRM and Repository:**
  - CIRM shall own all CIRM hiPSC Lines derived and delivered to the Repository.
  - The Repository must broadly distribute the CIRM hiPSC Lines, providing them to all third parties upon request, on a first come, first serve basis under the terms of the Agreement.
  - The Repository will only distribute the CIRM hiPSC Lines to end users who have executed a CIRM-approved form of MTA.
  - The only payment obligations end users owe to the Repository will be the fees set forth in a fee schedule approved by CIRM pursuant to RFA 12-04 and as set forth below;
    - The service fees associated with the CIRM hiPSC Lines shall be reasonable and subject to negotiation with CIRM; as part of the application process, the Repository shall provide its proposed fee schedule; CIRM will have the right to approve such fee schedule and any changes thereto. The fee schedule will provide preferential pricing to California researchers and be competitive with other repositories including those that are distributing hiPSC lines funded by the NIH. No royalty payments, maintenance fees or other charges will be owed by the end user unless agreed to by CIRM.
  - End users will have full rights to transfer (i) modified CIRM hiPSC Lines and (ii) unmodified CIRM hiPSC Lines to the extent they are transferred to collaborators and/or subcontractors assisting on the research project that was identified in the Material Transfer Agreement.
    - Notifications to CIRM and Repository of such transfers may be required.
  - There will be no prohibitions on patenting or publishing discoveries made with the CIRM hiPSC Lines; provided, however, that end users are required to acknowledge the Repository and CIRM in publications and to notify the Repository (or its successor) of any such publications. End users may be required to report some outcome information to CIRM.
  - The Repository shall maintain and distribute the CIRM hiPSC Lines for a minimum period of ten (10) years following completion of CIRM funding through RFA 12-04.
  - Hold harmless and indemnification benefitting CIRM

- **Key terms in Material Transfer Agreement between Tissue Collector and Deriver:**
    - Provisions implementing the terms set forth in the Repository Agreement, as applicable
    - The Tissue Collector shall own the collected tissues, to the extent permitted by law, but agrees that tissues, or derived primary source cells, remaining after Deriver's use be transferred to the Repository.
    - Hold harmless and indemnification benefitting CIRM
    - CIRM shall be a third party beneficiary

- **Key terms in Material Transfer Agreement between Deriver and Repository:**
    - Provisions implementing the terms set forth in the Repository Agreement, as applicable
    - The Deriver will submit derived CIRM hiPSC Lines to the Repository as further described in RFAs 12-03 and 12-04.
    - The Deriver will submit tissues, or derived primary source cells, remaining after Deriver's use to the Repository.
    - Hold harmless and indemnification benefitting CIRM
    - CIRM shall be a third party beneficiary

- **Key terms in Material Transfer Agreement between Repository and Third Parties (for-profit and non-profit entities):**
    - Provisions implementing the terms set forth in the Repository Agreement, as applicable
    - Restrictions on use to include prohibition against use in human subjects
    - No ownership rights in the CIRM hiPSC Lines are transferred; end user retains ownership of all inventions and modifications.
    - End users will have full rights to transfer (i) modified lines and (ii) unmodified lines to the extent they are transferred to collaborators and/or subcontractors assisting on the research project that was identified in the Material Transfer Agreement.
        - Notifications to CIRM and Repository of such transfers may be required
    - End users are required to acknowledge the Repository and CIRM in publications relating to the CIRM hiPSC Lines and to notify the Repository (or its successor) of any such publications. End users may be required to report some outcome information to CIRM.
    - End user is free to file patent applications claiming inventions made using the CIRM hiPSC Lines but agrees to provide notice to CIRM (or its successor) of such a filing.
    - No express or implied warranties as to merchantability, fitness for a particular use, or that use of the CIRM hiPSC Lines will not infringe any patent, copy right, trademark or other proprietary rights
    - End users will be required to refrain from seeking tissue donor identity and to ensure that all subsequent transferees agree to be bound by this requirement.
    - Hold harmless and indemnification benefitting CIRM
    - CIRM is a third party beneficiary of the agreement

- **Key Terms in Material Transfer Agreement between Tissue Collector and Repository**
    - The Tissue Collector shall own the collected tissues, to the extent permitted by law, but agrees that tissues or derived primary source cells that remain after Deriver's use will be maintained by the Repository, unless it becomes necessary to comply with a tissue donor's request for destruction. The Notice of Grant Award between CIRM and the Tissue Collector will define the circumstances under which the tissue/primary source cells may be accessed.
    - The Tissue Collector shall replace all patient identifiers with codes, in compliance with the Common Rule and HIPAA, and will compile the coded donor-specific demographic, medical and diagnostic information associated with each CIRM hiPSC Line and will make it available to the Repository.

- **Notice of Grant Awards ("NGA")**
    - **Tissue Collector NGA:**
        - The Tissue Collector shall own the tissues collected, to the extent permitted by law, but agrees to deliver them to the Deriver. After completing derivation of the CIRM hiPSC Lines, Deriver will deliver the remaining tissues or derived primary source cells to the Repository for distribution and storage. CIRM and the Tissue Collector will agree on the circumstances under which the tissue/primary source cells may be accessed. The Tissue Collector shall be prohibited from exclusively licensing the use of such tissues and/or expanded source cells to a third party.
        - The Tissue Collector shall replace all patient identifiers with codes, in compliance with the Common Rule and HIPAA, and will compile the coded donor-specific demographic, medical and diagnostic information associated with each CIRM hiPSC Line and will make it available to the Repository.
        - Agreement to comply with CIRM's informed consent requirements, HIPAA and other relevant laws
        - Hold harmless and indemnification benefitting CIRM
        - Ability to re-contact tissue donors as needed and in accordance with the terms of the Informed Consent
        - All other standard provisions of CIRM's NGA
    - **Deriver NGA:**
        - Representations regarding freedom to operate including but not limited to all necessary licenses and rights required to derive and transfer the CIRM hiPSC Lines for research and commercial use;
        - Hold harmless and indemnification benefitting CIRM
        - All other standard provisions of CIRM's NGA

    - **Repository NGA:**
        - Compliance with all federal and state laws related to privacy and security of individually identifiable information
        - Standard provisions of CIRM's NGA
        - Other terms, as appropriate, not set forth in the Repository Agreement