

§ 100604. Publication-Related Biomedical Materials Requirements.

(a) A Grantee shall share Publication-related Biomedical Material, for bona fide purposes of research in California. Such materials are to be shared without cost to the requestor or at the actual cost of providing the materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

(b) A Grantee must share such materials within 60 calendar days of receipt of a written request, without bias as to the affiliation of the requestor, unless otherwise prohibited by law.

(c) CIRM may approve alternatives to this sharing requirement on a showing that:

(1) the number of sharing requests has become financially onerous for the Grantee;

(2) the material or its transfer could pose a public health risk; or

(3) the request is otherwise inappropriate, as determined by CIRM.

(d) In lieu of sharing as provided herein, a Grantee may provide requestors with the information necessary to reconstruct or obtain identical material.

(e) With prior approval from CIRM, a Grantee's obligations under this regulation may cease when the materials are made broadly commercially available. CIRM's review in response to a request for such approval shall include a determination of whether Grantee's terms for access are unreasonably onerous so as to create an unreasonable barrier to access to the materials.

(f) Prior to transferring any Publication-related Biomedical Material, a Grantee may require the requestor to execute an industry-standard or university-standard Material Transfer Agreement restricting the use and dissemination of such materials and its derivatives.

(g) A Grantee has no obligation under these regulations to share third party materials described in publications, patents, patent applications or presentations of CIRM-Funded Research or CIRM-Funded Technology or CIRM-Funded Inventions such as raw materials purchased by the Grantee to develop or synthesize the Publication-related Biomedical Material or other materials covered by third party intellectual property rights, or if the Grantee is legally prohibited from doing so.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.