

1 Adopt 17 Cal. Code of Regs. section 100404 to read:

2 **§ 100404. Publication-Related Biomedical Materials Requirements.**

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

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

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

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

12 (2) a sharing request is in direct conflict with the business of the Grantee;

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

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

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

17 (e) With prior approval from CIRM, a Grantee's obligations under this regulation may
18 cease when the materials are made broadly commercially available.

19 (f) Prior to transferring any Publication-related Biomedical Material, a grantee may
20 require the requestor to execute an industry-standard Material Transfer Agreement restricting the
21 use and dissemination of such materials.

22 (g) A Grantee has no obligation under these regulations to share third party materials
23 described in publications of CIRM-funded Research such as raw materials purchased by the

1 Grantee to develop or synthesize the Publication-related Biomedical Material or other materials
2 covered by third party intellectual property rights, or if the Grantee is legally prohibited from
3 doing so.

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