Rules

California Organization: A California Organization is a for-profit or non-profit organization that employs and pays more than 50% of its employees in California.

For a California Organization, Allowable Project Costs include:

1. Costs for activities conducted wholly in California; and

2. Costs for activities conducted outside of California, provided that the California Organization exercises direction, supervision and control over the activities.

Non-California Organization: A Non-California Organization is a for-profit or non-profit organization that employs and pays 50% or less of its employees in California.

For a Non-California Organization, Allowable Project Costs include:

1. Preclinical Research:

   - the cost of preclinical research activities conducted wholly in California; and

   - the share of costs for preclinical research activities conducted outside of California that are directly required to support preclinical research conducted in California.

2. Clinical Research:

   - the cost of clinical research activities conducted wholly in California (e.g., manufacturing, assay development, animal studies, biomarker testing, etc.), excluding CRO services conducted in California and site specific costs for a clinical trial conducted in California; and

   - the per subject share of the costs of clinical research activities, whether conducted in California or outside of California, that are directly attributable to the treatment of California subjects, excluding the costs covered by the paragraph above.

Unallowable Costs: For both California Organizations and Non-California Organizations, Allowable Project Costs do **NOT** include the costs of activities performed by a separate out-of-state organization that retains intellectual property or publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.

CIRM Discretion: CIRM may determine, in its sole discretion, whether an applicant is a California organization and whether the project activities are allowable.

FAQ

Example 1 (Non-California Organization/California Clinical Trial Sites): If a Non-California Organization (NCO) plans to conduct a clinical trial and applies for a CLIN2 award to conduct a part of the trial at a site or sites in California, what are the allowable project costs? The allowable project costs include the per subject share of all costs for allowable project activities directly attributable to the treatment of California subjects. For example, if the NCO intends to enroll 100 subjects, 20 of whom will be treated at a California site, it must first determine the total per subject costs for the trial (including CMC/manufacturing, CRO services, etc.) and then multiply the per subject costs by the number of subjects expected to be treated in California. Thus, if the per subject costs are $100,000, $2 million of the trial expenses would be considered allowable project costs.

Example 2 (Non-California Organization/California Clinical Trial Sites and California Manufacturing): If a Non-California Organization (NCO) plans to conduct a clinical trial and applies for a CLIN2 award to conduct a part of the trial at a site or sites in California and to conduct the manufacturing in California, what are the allowable project costs? As in Example 1, the allowable project costs include the per subject share of all costs for allowable project activities, including per subject share of manufacturing costs, directly attributable to the treatment of California subjects. Alternatively, the NCO may elect to treat all of the California manufacturing costs as an allowably project cost. In this case, the NCO must first subtract the California manufacturing costs before calculating the per subject costs of costs directly attributable to the treatment of California subjects.

Example 3 (Non-California Organization/California Clinical Trial Sites and California CRO): If a Non-California Organization (NCO) plans to conduct a clinical trial and applies for a CLIN2 award to conduct a part of the trial at a site or sites in California and contracts with a California CRO to assist with the clinical trial, what costs are considered allowable costs? The NCO may use CIRM funds to pay the per subject share of all allowable clinical trial costs directly attributable to the treatment of California subjects. However, because the CRO will not conduct all of its activities wholly in California, the contract with the CRO is not considered an allowable project cost. Instead, the cost of the CRO should be included in the calculation of the total per subject cost.

Example 4 (Non-California Organization/Pre-Clinical Study in California): If a Non-California Organization plans to conduct pre-clinical research in California, what costs are considered allowable costs? The NCO may use CIRM funds to pay for the costs of the project activities wholly conducted in California. For example, if the NCO applies for CLIN1 funding to conduct a large animal study in California, it may use CIRM funds to pay for the study, including the pro rata share of the costs of manufacturing the cells out-of-state (e.g., if 30% of the cells manufactured out-of-state will be used in the California study, 30% of the manufacturing costs will be considered allowable costs).

Example 5.a (Wholly-Owned CA Subsidiary of Non-CA Organization): If a Non-California Organization has a owned subsidiary that employs and pays more than 50% of the subsidiary's employees in California, will the subsidiary qualify as California Organization? Yes, but the subsidiary must hold the IND (where applicable), manage the award activities from California, and hold exclusive rights or ownership of the parent organization's intellectual property related to the CIRM-funded project. Such IP can either be assigned to the subsidiary or exclusively licensed from the parent to the subsidiary. The transfer of any legal rights from the parent to the subsidiary must be consistent with industry standards so as to allow the subsidiary to market or commercialize the therapy. Compliance with industry standards is aimed at ensuring that any such assignment or license agreement covering the IP cannot be so easily terminated or contravened that the parent company could take the project forward instead of the CIRM-funded wholly owned subsidiary.

Example 5.b (Wholly-Owned CA Subsidiary of Non-CA Organization): If a parent company has patents and exclusively grants the rights to a CIRM-Funded indication to the wholly owned subsidiary but keeps rights to other indications in the parent company, would that be acceptable to CIRM? Depending upon the contract terms (such as termination rights), the answer will probably be yes.