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Allowable Project Costs (Including Costs Covered by Co-Funding)

This document summarizes CIRM's rules regarding allowable project costs, including costs covered by an awardee's required co-funding. Please note: Only costs incurred AFTER the date of ICOC approval may be considered allowable projects costs, as described below. Costs incurred prior to ICOC approval are not allowable, regardless of the status of the organization as a California organization.

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 and that directs and controls the award activities from California.

For a California Organization, Allowable Project Costs include:

1. CLIN1 Projects:
    - costs of research activities conducted in California; and
    - costs of research activities conducted outside of California, provided that the California Organization exercises direction and control over the activities.
2. CLIN2 and 3 Projects:
    - the per subject share of the costs of clinical and non-clinical research activities that are directly attributable to the treatment of subjects enrolled in the proposed clinical trial; and
    - costs of manufacturing activities for a subsequent clinical trial when applicant adequately justifies conducting such activities during the proposed clinical trial

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]:

1. CLIN 1 Projects:
    - the cost of non-clinical research activities conducted in California, including the costs of services provided by the Stem Cell Center.
2. CLIN 2 and 3 Projects:
    - the per subject share of the costs of clinical and non-clinical research activities, whether conducted in California or outside of California that are directly attributable to the treatment of California subjects enrolled in the proposed clinical trial; and
    - the costs of manufacturing conducted in California for the proposed clinical trial for subjects enrolled, provided such costs are deducted before calculating the per subject share of costs; and
    - costs of manufacturing conducted in California for a subsequent clinical trial when the applicant adequately justifies conducting such activities during the proposed clinical trial

[1] Non-California organizations are not eligible to apply for TRAN or DISC awards.

Unallowable Costs: For both California Organizations and Non-California Organizations, unallowable costs include any costs incurred on or before the date the ICOC approves the application for funding. This date is generally set 4 months after the 1st application submission and this date must be reset for any Tier 2 or Tier 3 application resubmissions. In addition, Allowable Project Costs do **NOT** include the costs of activities performed by a separate out-of-state organization that retains intellectual property or independent 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.

Scenarios:

Question 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 incurred after the date the ICOC approves the application for funding. 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.

Question 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 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. The only exception to per subject cost rule is for manufacturing. If an NCO conducts its manufacturing for the clinical trial in California, it may treat the full costs of manufacturing in California after the date the ICOC approves the application for fundingl as an allowable cost, provided that it deducts the manufacturing costs before it calculates the per subject share of costs.

Question 3 (Non-California Organization/Non-Clinical Study in California): If a Non-California Organization plans to conduct non-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 conducted in California after the date the ICOC approves the application for funding. 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. In addition, if the NCO uses the Stem Cell Center for research services, the costs of the Center would be considered an allowable cost.

Question 4.a (Wholly-Owned CA Subsidiary of Non-CA Organization): If a Non-California Organization has a wholly-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.

Question 4.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.

Question 5 (Active Clinical Trial): If an applicant applies for funding to support an on-going clinical trial, are the costs incurred to treat subjects enrolled prior to the date of ICOC approval of the application considered allowable project costs? No, the costs of treating subjects enrolled prior to the date of ICOC approval of the application is only allowable if those costs are incurred after the ICOC application approval date. Applications that receive a Tier 2 or a Tier 3 score and apply to CIRM again must reset their planned date of ICOC approval of their application (generally 4 months after submission/resubmission).

Question 6 (Publication Rights): A California organization plans to apply for funding for research, including work performed by an out-of-state collaborator under the California PI's direction and control. The California organization will retain all IP rights. Can the out-of-state collaborator be a co-author on a paper that arises from the work? Yes, although work performed by an out-of-state collaborator may not be treated as an allowable cost if the out-of-state collaborator retains "publication rights," the term "publication rights" means the right to publish independently from the PI, as opposed to participating as a co-author on a publication along with the PI. Because the out-of-state collaborator would not retain independent publication rights or IP rights in the CIRM-funded research, and would work under the California PI's direction and control, the work would be considered an allowable cost.

Question 7 (Publication Rights): A California organization plans to apply for CLIN2 award to conduct a clinical trial. The applicant plans to contract with NIH/TrialNet to collect and publish clinical trial data, including data collected from the treatment of out-of-state subject. Is the cost of the TrialNet contract considered an allowable cost? Yes, TrialNet is a clinical trial network comprising investigators who agree to collect and publish clinical trial data through TrialNet. As discussed above, because TrialNet does not retain independent rights to publish, but rather publishes with the consent of the sponsor and the PI, the cost of the contract will be considered an allowable cost, provided that the California PI exercises direction and control over TrialNet and TrialNet does not retain IP rights in the CIRM-funded research.