CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

PDEV Activity-Based Budget

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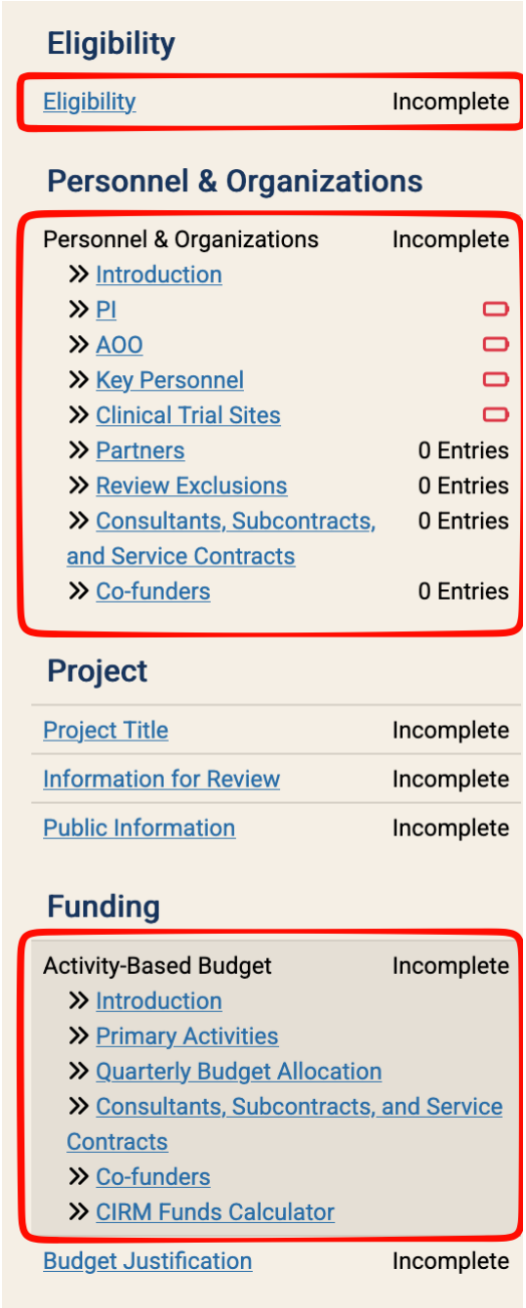

Where to start?

The purpose of the Activity-Based Budget (ABB) is to provide a breakdown of an Application's proposed budget by project activities to allow for evaluation. The ABB is both a planning tool to help Applicants reasonably allocate resources across primary activities as well as a tool for CIRM to gauge the appropriateness of proposed costs in relation to proposed activities. Enter all project costs, whether paid by CIRM or other sources. Please refer to the Program Announcement to calculate the expected start date for your project. Costs incurred prior to Award approval are unallowable (see Allowable Project Costs & Co-Funding FAQ for more information).

Eligibility

1. CIRM's Award caps are determined separately by pre-IND (Early) and IND-enabling (Late) stages. See the Program Announcement for specific caps. Award caps are on total project costs, inclusive of allowable direct costs, direct facilities costs, and Indirect Costs.
2. Co-Funding requirements are determined by your status as a For-Profit, Non-Profit with a For-Profit Partner, or Non-Profit Organization. See the Program Announcement for details.

People and Organizations

Please add the names of all entities involved in the project. If the project is co-funded by the Applicant or a third-party, please list the name of each co-funder. If the Applicant has a Partner (as defined in the CIRM Common Requirements and Definitions) enter each Partner in the Partners section. In the remainder of the Application, do not enter the names of any individuals or entities that are NOT provided in the Key Personnel, Subcontracts, Partners or Exclusions sections of the Application. Doing otherwise may void the Application. Non-Key Personnel can be budgeted and referred to in the budget justification according to their roles. Please do not enter names of vendors for licenses or contracts that are used in the normal course of business (e.g. internet/communications, productivity software, etc.).

Funding

Introduction questions

Applicants must complete the ABB Introduction section before entering costs. There is one question to answer:

- Does your project include any "unallowable costs?"
    - If you intend to include costs from a separate non-California organization that retains IP or independent publication rights, clicking 'Yes' will provide a checkbox for each primary activity allowing you to indicate these costs will not be charged to CIRM funds. If your answer is subsequently changed to 'No', all previously indicated unallowable costs will be relabeled as allowable costs.

Primary Activities

a. There are three main categories: CMC Primary Activities, Non-Clinical Primary Activities, and Clinical Primary Activities. Inside of each section you will be asked to add predefined activities and associated expenses as

budget line items. Access this by clicking the “Add/Remove Activities” button to the right of the category name. If your project includes a pre-IND stage (as indicated in Eligibility), each cost can be associated with the Early Stage category. Costs not specifically associated with pre-IND stage activities will automatically be assigned to the Late Stage category

b. Activities are broad identifiers that Applicants can select from a drop-down list, such as “Animal Studies” or “Manufacturing.” Add them to the Project’s ABB by clicking the “Add Primary Activity” button.
c. Expenses are the specific costs associated with a selected activity, such as “Mouse Testing” or “Quality Control.”
d. To enter costs associated with animal studies, select the “Animal Study” Primary Activity from the Non-Clinical Primary Activities category. Each animal study requires the Applicant to enter information about the purpose of the study, species utilized, number of animals, and associated costs.
e. Internal FTE should be included in the ABB as a Key Persons Primary Activity in CMC/Analytical, Clinical, or Non-Clinical sections. All Key Personnel must first be entered in People and Organizations section of the Application. It is important for conflict of interest checking that names of individuals or organizations do not appear anywhere in the Application if not listed in the People and Organizations section. Unnamed non-Key FTE can be included as part of the total cost of each primary activity.
f. Provide a narrative justification that describes the cost composition for each Primary Activity including both funding requested from CIRM as well as Co-Funding by the Applicant. This justification should be broken down by cost category: Personnel (Unnamed non-Key FTE), Supplies, Travel, Equipment, Consultants/Subcontracts/Service Contracts. Do not include the names of individuals or organizations not listed in the People and Organizations section.

Example:

Primary Activity: Manufacturing Process Development and Optimization
Total Cost: $900,000
Justification: *This is the cost for the generation of 3 GMP-grade lots required for in vivo testing and process validation in preparation for eventual clinical runs. This material will be used for the studies detailed in the proposal, as well as for validation of product release specifications in the IND filing. Costs include labor at subcontractor for the Engineering Runs ($120,000 per run, see quote), starting material and reagent costs for each lot ($40,000 per donor, 3 donors per run, 3 total runs – totaling $360,000) and associated*

project management support and required analytics and QC certificates ($180,000).

Quarterly Budget Allocation

This section is a summary of the Primary Activities entered. CIRM funding and Co-Funding are determined automatically based on information entered in previous sections of the ABB. Please project the expected timing of the project costs on a quarterly, cash basis for each Primary Activity, aligning with your proposal's Gantt Format Timeline. This information, along with the project timeline, may be used by CIRM to help determine an Award's final disbursement schedule. While critical path activities often require significant upfront costs, the initial disbursement from CIRM may not exceed 25% of the total Award.

Consultants / Subcontracts / Service Contracts

Please list all Consultants, Subcontracts, and service contracts involved in the project in the **People and Organizations** section to populate the dropdown menu. Entries that do not use the dropdown menu will not be saved. After the total cost of the third-party contract is entered, the portion of the total cost that is eligible for CIRM funding will be calculated based on the Applicant's eligibility criteria.

The CIRM eligible portion of each contract's cost above $50,000 will be automatically excluded from the base for calculating facilities and Indirect Costs.

Scenario #1 – Non-Profit (without a For-Profit Partner - No Co-Funding required)

VENDOR	**TOTAL COST**
Service Contract #1	$1,000,000
Consultant	$100,000
Subcontract (CA)	$375,000
Total	**$1,475,000**

Amounts automatically excluded from the base for calculating facilities and indirect costs:

VENDOR	**EXCLUDED TOTAL**
Service Contract #1	$950,000
Consultant	$50,000
Subcontract (CA)	$325,000
Total	**$1,325,000**

Scenario #2– For-Profit or Non-Profit with a For-Profit Partner (20% Co-Funding requirement)

VENDOR	TOTAL COST
Service Contract #1	$1,000,000
Consultant	$100,000
Subcontract (CA)	$375,000
Total	**$1,475,000**

CIRM-Funded Portion (total cost x 80%)

VENDOR	CIRM PORTION
Service Contract #1	$800,000
Consultant	$80,000
Subcontract (CA)	$300,000
Total	**$1,180,000**

Amounts automatically excluded from the base for calculating facilities and Indirect Costs (CIRM portion minus the first $50,000 for each contract):

VENDOR	EXCLUDED TOTAL
Service Contract #1	$750,000
Consultant	$30,000
Subcontract (CA)	$250,000
Total	**$1,030,000**

Competitive bidding or sole source justification and a quote or contract copy is REQUIRED for contracts of $500,000 and above.

What to Include

- Entity Name: Organization name
- Contract Name: Brief descriptive title
- Amount: Total cost (CIRM + co-funded)
- Contract Type: Subcontract, Consultant, or service contract
- Purpose: CRO, CDMO, or other type
- Role: Brief work description
- Additional competitive bidding information will be required for high-value contracts of $500,000 and above

Important Notes

- All costs must be included in the Primary Activities section of the ABB. This section is a ***restating*** of those ABB costs that are performed by a third-party for the purpose of calculating allowable overhead.
- Use "TBD" only for proposed activities not yet established. Critical path contracts needed at Award launch should have been identified and/or contracted at this stage.
- Upload quotes for all third-party contracts of $500,000 or above in the Document Uploads section of the Application.
- Research Subcontracts outside California must waive IP rights. Activities performed by Non-CA entities retaining IP rights must be marked as "unallowable" in the Primary Activities section.
- Excel budget template available for calculating Subawardee facilities and Indirect Costs available here.
- CIRM established the Industry Alliance Program (IAP) as a direct opportunity for the industry to partner with CIRM in accelerating the most promising stem cell, gene, and regenerative medicine therapy programs to commercialization. Under the umbrella of the IAP is the Industry Resource Partner Program (IRP) that provides valuable resources that help CIRM-funded projects advance through various stages of development—including discovery, translational, and clinical, towards commercialization. Please check if any proposed Contractors are CIRM IRP partners and; if so, inquire about the CIRM preferential pricing.

Co-funders

This section should be completed after all overhead calculations are added to the CIRM Funds Calculator. The system will display the required Co-Funding, which must be matched by entering one or more co-funders. If Warrants are requested (see our Allowable Costs and Co-Funding FAQ for more information about Warrants), the maximum amount of Warrant value will be auto calculated in the Co-funders section. Warrants can only be applied to Co-Funding up to the CIRM Award cap. Additional cash Co-Funding may also be required to cover the remainder of Project costs above and beyond this cap. Any cash Co-Funding entered into the Application that exceeds the minimum required will reduce the Warrant accordingly.

If there is any confusion about these numbers, please try removing and re-adding Warrants and Co-Funding as appropriate before reaching out to CIRM for assistance. Co-Funding amounts exceeding requirements will result in a reduction to the CIRM Award.

CIRM Funds Calculator

The CIRM Funds Calculator exists to establish the base on which allowable direct facilities and Indirect Costs are calculated.

Manually enter the CIRM-funded portion of any capital Equipment, Research Patient Care Costs, and Tuition and Fees requested. See CIRM's Award Management Policy for definitions). The CIRM-Funded Consultants, Subcontracts, and service contracts costs of more than $50,000 each will be excluded automatically as described in the Consultants / Subcontracts / Service Contracts section of this document.

The resulting adjusted project costs are used to calculate the allowable direct facilities costs and Indirect Costs (Non-Profit Organizations only) and to determine the total allowable CIRM-funded costs. Warrants and/or cash Co-Funding must then be applied to cover the required Co-Funding percentage of your project. The sum of CIRM-funded direct costs and overhead may not exceed the Award cap. Costs requested above the cap will be automatically assigned to the Co-Funding requirement. Therefore, requesting overhead that exceeds the CIRM Award cap is not recommended. Instead, reduce the overhead requested or reduce the direct costs to stay within the CIRM Award cap.

For more information on CIRM allowable facilities costs and indirect costs, see the Award Management Policy and this overhead primer.

Budget Justification

1. Provide a high-level, narrative justification that explains the primary drivers of the costs for the project. What are the most important aspects about the product and/or the protocol that CIRM should know to understand the impact on the project budget? If cost comparison data is available, describe any unique features of this project that make the budget vary compared to other projects of similar stage, size, and disease area.
2. Describe the source(s), type(s), and nature of all Co-Funding contributed to the project. Letters of Commitment must also be provided in the Document Uploads section of the Application to substantiate the availability of all Co-Funding and Contingency Funds.

Document Uploads

Supply a quote or contract for each non-TBD contract equal to or exceeding $500,000 named in the Application.

Provide Letters of Commitment for all Co-Funding commitments made in the Co-funders (including identified source of contingency) section of the Application.

Information and Error Messaging

Message	
Quarterly Budget Allocation total allocated costs must match the total costs across all quarter allocations before the budgeting process is complete.	Required
What it means: The cost of each primary activity must be allocated across the project quarters in the Quarterly Budget Allocation section to reflect when those expenses are expected to be incurred.	
Subcontracts has no entries.	Information
What it means: There are no third-party contracts entered in the Consultants / Subcontracts / Service Contracts section. No action needed if the project does not have third-party contracts.	
Cofunders has no entries.	Information
What it means: There are no co-funders entered in the Co-Funders section. No action needed if the project does not require Co-Funding.	
Total CIRM Funds Requested Your requested CIRM funds of $XXXXX exceed the Maximum Award Cap of $XXXXX. CIRM contribution is capped at $XXXXX; the remaining $XXXXX must be covered by additional co-funding.	Information
What it means: The CIRM portion of the total direct costs requested exceeds the Award cap. Any amount above the Award cap must be co-funded. Reduce total direct costs if this is not the desired outcome.	
Co-funding of $0 does not meet the Minimum Required Co-funding of $XXXX	Required

Message	
What it means: Co-Funding (via Warrants or cash Co-Funding should be added in the co-funders section. Best practice is to enter this after all primary activities and overhead has been entered.	
Extra Co-funding Your co-funding of $XXXXX exceeds the minimum required of $XXXXX by $XXXX. The extra co-funding is reducing your Total CIRM Funds Requested to keep Total Project Funds correct.	Information
What it means: The Co-Funding entered exceeds the required amount and is therefore reducing the CIRM contribution. Reduce Co-Funding or increase the project scope to absorb the extra funding if this is not the intention.	
Justifications cannot be blank.	Required
What it means: For each Primary Activity, provide one narrative justification for all expenses. What is the cost composition for the activity and how were the costs determined?	
CIRM Funded Direct Plus Overhead is over the Award Cap by: $XXXX. At the current overhead rates in use, the Total Direct Costs must be reduced to: $XXXX	Required
What it means: The CIRM cap is exceeded after the addition of facilities or Indirect Costs to the CIRM direct costs. The two possible solutions to this are to reduce the facilities or Indirect Costs requested or to lower the direct project costs to the amount indicated.	