

**NCI Informatics Technology for Cancer Research Program**  
**Policies and Procedures for the Release of Collaborative Set-Aside Funds**

**1 Set-Aside Funds**

Set-Aside Funds are funds dedicated for collaborative activities and correspond to 10 percent of the annual budget of each ITCR Cooperative Agreement, beginning in Year 2 of the award. Collaborations among ITCR Investigators and/or between ITCR members and outside non-ITCR parties are permissible. This structure is intended to provide a novel and essential approach to advancing the integration and adoption of ITCR-supported technologies.

Proposals for collaborative studies must be submitted as a team and budgeted using the Set-Aside Funds for the parent ITCR Cooperative Agreement award. Funding for multiple years will be allowed subject to annual approval and to verifiable sufficient progress. The use of Set-Aside Funds must be reviewed and recommended by the ITCR Steering Committee (see below) and approved by the NCI.

**1.1 Release and Use of Set-Aside Funds**

A Principal Investigator may only apply for the Set-Aside Funds within his/her Cooperative Agreement award. Set-Aside Funds may only be used for projects that complement the scope of the Cooperative Agreement award and abide by the terms and conditions section of the parent U01 or U24 grant award. More than one investigator may request the release of Set-Aside Funds to be used in support of one, multi-site collaborative project. A Principal Investigator may apply for more than one year's Set-Aside Funds by proposing a multi-year collaborative project; however, an annual status report must be submitted to NCI and should detail how the Set-Aside Funds were used before subsequent years' funds are considered for release. The status report must be submitted as part of the U01/U24 award annual progress report (Type 5/RPPR) submitted by the Principal Investigator. The applications for the release of Set-Aside Funds are reviewed by the SC at their quarterly meetings.

**1.2 Application Requirements for Release of Set-Aside Funds**

The proposal for use of Set-Aside Funds must follow the NIH Format, as used in PHS Form 398 [https://grants.nih.gov/grants/funding/phs398/398\\_forms.pdf](https://grants.nih.gov/grants/funding/phs398/398_forms.pdf). The proposal should be organized and submitted as follows:

- Title Page, Description (Abstract), Performance Sites, and Key Personnel, Bibliography of key researchers involved.
- Specific Aims, including a summary of the proposed collaborative activity and how it relates to the aims of the parent grant.
- Research Plan cannot exceed 6 pages and must address the review criteria defined in Section 1.3.
- Letters of Support, including letters of commitment from collaborators.

Budget Page, including adequate budget justification for direct costs. The budget cannot exceed the allocated set-aside funds for the project and must comply with NIH policies for allowable costs, [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_14/14.10\\_allowable\\_and\\_unallowable\\_costs.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_14/14.10_allowable_and_unallowable_costs.htm).

- Electronic copies of the proposal, signed by an Authorized Institutional Official, should be submitted to the NCI Program Directors assigned to the ITCR U01/U24 grants involved in the collaborative project as well as to the ITCR Program Coordinator(s).

### 1.3 Review Criteria

ITCR investigators are encouraged to propose activities that enhance the utility and/or interoperability of the informatics technology being supported through the award. These expansion activities are intended to further the impact of the technology that is the subject of the award. Review criteria for release of Set-Aside Funds are based on the following considerations:

- Significance
  - Potential impact of the proposed collaboration to cancer research
  - How the proposed work fulfills the goals of ITCR to enhance interoperability of informatics tools and resources and/or support the goals of a research project beyond the parent grant
  - Whether the proposed work will enhance the goals of the parent grant
- Innovation
  - The novelty or uniqueness of the collaboration and how the collaboration will address unmet needs
- Approach
  - Project a sound milestone plan
  - Provide a realistic scope of work, given the time and budget requested. Use of funds must be in line with NIH policy, [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_14/14.10\\_allowable\\_and\\_unallowable\\_costs.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_14/14.10_allowable_and_unallowable_costs.htm)
  - Clearly document the contributions of each of the participating collaborative units and individual researchers.
- Investigators
  - The expertise of the proposed research/scientific team to conduct and achieve the goals of the collaborative activities.
  - Investigators and entities they represent must state their willingness to collaborate and share information
- Environment
  - Are the scientific environment and physical resources appropriate for the proposed activity?

## 2. ITCR Steering Committee Review Process

### 2.1 ITCR Steering Committee Composition

An ITCR Steering Committee (SC) will be established for the purpose of reviewing the collaborative set-aside proposals. The SC will be comprised of six ITCR PIs and the NCI Coordinator, for a total of seven members. The ITCR PI members will be selected by NCI and will serve a 1-year term. The selection of committee members will be based on a diverse representation of scientific expertise, seniority, and gender. A Chair of the SC, who will not be NCI staff, will be selected by the committee. An NCI Staff Member will serve as the Executive Secretary of the SC and will manage the operations of the committee.

## **2.2 ITCR Steering Committee Meeting Schedule and Quorum**

The ITCR Steering Committee will meet via teleconference on a quarterly basis (March, June, September, December). Meeting dates will be scheduled at the start of each year of service for a given group of SC members. Proposals will be due 1 month prior to the scheduled meeting date. Proposals not received by the deadline will be deferred to the next scheduled SC meeting.

At least five of the seven SC members must be in attendance for a regularly-scheduled meeting to proceed. If the Chair is unable to attend, they may delegate Chair responsibilities to another (non-NCI) member.

## **2.3 Review Process**

The ITCR SC Executive Secretary, with input from the NCI Coordinator and the PD of the parent grant, will select two ITCR investigators outside of the steering committee to review the set-aside proposal. The identity of these reviewers will not be made known to the SC. Proposals will be sent out to the external reviewers and to the SC members at least three weeks before the review meeting. Written reviews from the external reviewers will be made available to the ITCR SC 24 hours prior to the review meeting. If a SC member has a proposal for consideration that round, either as the PI or a collaborating partner, they will recuse themselves from review of that proposal (only); however, they will participate in the review of other proposals that round.

The Program Director (PD) assigned to the parent award of the applicant includes the review of the collaborative project application on the agenda of the Steering Committee teleconference. At the beginning of the review of the application by the SC, the PD provides a summary of the collaborative project objectives and approach to the SC followed by the comments and recommendation of the non-SC member ITCR reviewers, then the collaborative project application is open for discussion by the full SC. At the end of the discussion, the Chair seeks a motion from the SC members participating in the teleconference with one of the four recommendations:

- Approve: The committee recommends approval of the collaborative project as written
- Approve with Minor Modifications: Modifications can be reviewed and accepted by the PD of the parent grant prior to approval
- Approve with Major Modifications: Modifications are provided back to the SC for review and recommendation. A new vote is taken via email unless the Chair deems it necessary to reconvene the committee.
- Disapprove: The committee does not recommend the proposed collaboration. The SC Executive Secretary will prepare a summary of feedback to be provided to the investigator outlining the reasons for this decision.

In the event of a tie (in the case when an even number of SC members is present), the Chair will serve as the tiebreaker.

The SC Executive Secretary notifies investigators of the SC decision via email within 48 hours of the SC meeting. Any requested modifications must be returned within 2 weeks. For applications requiring re-review by the SC, a vote will be taken within 1 week of receipt of the revised proposal.

The final SC recommendation is provided to the NCI Program for a final approval decision for the release of the restricted funds. The official release of the restricted funds is by the issuance of a revised notice of award.

## **2.4 Code of Conduct**

Steering Committee members and external reviewers will be asked to adhere to a general code of conduct with the following principles:

- Confidentiality of reviews and review discussions
- While Conflict of Interest Rules associated with competitive funds do not apply here, SC members and reviewers are expected to conduct reviews in an impartial manner, maintaining focus on scientific rigor and impact

## **2.5 Appeals**

If an investigator proposing a set-aside proposal disagrees with a Disapprove decision, they may submit a rebuttal of the comments to NCI. NCI ITCR program staff will review the rebuttal and determine whether to bring to the SC for reconsideration.

## **2.6 Change Control**

Changes to the process outlined in this document may be proposed to NCI by the SC. Change requests will be reviewed by the ITCR Program Staff and if approved, the Policies and Procedures document will be updated and communicated to the ITCR investigators.