

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Office of Sponsored Research
POLICY NUMBER: OSR-010
REPLACES: OSR-010 (September 29, 2008)
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POSTED FROM: _____

TITLE: Institutional Sign-Off on Sponsored Research Proposals

SUMMARY:

This revision to OSR-10 makes the following changes to the policy and procedures regarding institutional approval of applications for research funding and research contracts:

First, it has been clarified that the need for institutional sign-off applies to both internal and external sponsors, but only for projects that qualify as research. Applications for activities other than research are not the responsibility of the Research Institute, and thus are governed by alternative policies and procedures. A working definition of "research" has also been incorporated into the policy to assist in the determination of when a project application/contract must be managed through OSR.

Second, the "Just-In-Time" approach to *internal proposal approvals* has largely been repealed. Recent changes in the regulatory environment, as well analysis of current operations using the Just-In-Time approach, have identified both compliance risks and operational deficiencies created by our current procedures. Accordingly, with this new version of the policy, all competitive research applications will require, at minimum, the approval of the Principal Investigator, Center Director, Chief Academic Officer, Center Business Manager and Grant/Contract Manager of OSR, prior to submission. As documented in the policy, additional approvals may also be required, depending on the nature of the project. In the case of contracts, while the Just-In-Time approach remains on the books, the policy has been revised to give the Contracts Group in OSR the discretion to require that internal approval be secured in advance of contract negotiation, as they deem appropriate. Please note, however, that these changes are distinct from, and have no impact on, sponsor-defined Just-in-Time policies regarding IRB and IACUC approvals. The Research Institute remains committed to supporting the Just-in-Time approach to these approvals.

In conjunction with the move to upfront approvals, two new versions of the Request for Approval of Sponsored Research Application Form have been developed to document the required approvals using a single form. With the existing model, a PI may be required to submit as many as five different forms -- Request for Approval of Sponsored Project Application form, Key Factors form, NIH PI Assurances, Cost Share Authorization form, and SFI Disclosure form – in

order to get his/her proposal submitted to the sponsor. Now, with the exception of positive SFI disclosures which still require an SFI Disclosure form to be submitted to ORCE, all needed approvals are now documented on the revised Request for Approval of Sponsored Research Application forms (OSR-010-FO1 & OSR-010-F02).

The policy has been further updated to not only identify which approvals are necessary, but also the reasons why those approvals are required and what those approvals are intended to communicate. This goal of this is to reduce our risk of non-compliance with certain regulatory requirements by making both the requirements and expectations more clear.

Finally, this revision updates the policy to more accurately reflect current business practice and the Research Institute's current business model. With the move to the Center-based organizational structure, the approval requirements for applications and contracts have changed and these changes ought to be reflected in policy. Referenced names and titles have also been updated.

POLICY/PROCEDURE:

010-1 This policy addresses the requirements for institutional approval and sign-off on a) applications for research funding, and b) contracts for research, awarded with or without a formal competition. The policy applies to projects funded both by internal CHRMC research support programs (e.g., Academic Enrichment Awards) as well as external funding sources (e.g., National Institutes of Health).

Projects Requiring Approval

010-2 The institutional sign-off requirements described herein apply to **research projects** to be conducted through the auspices of the Seattle Children's Hospital Research Institute. Projects requiring approval would include:

010-2.1 Applications/contracts for research to be conducted in Children's facilities or facilities leased by Children's; and/or

010-2.2 Research funded through awards (gifts, grants or contracts) made to Seattle Children's Hospital Research Institute; and/or

010-2.1 Applications/contracts for research to that will involve the use of Children's patients as research subjects.

010-3 Although the definition of research can at times be ambiguous, for the purposes of this policy, "research" refers to clinical trials, basic research, and other activities that contribute to an identified research project. A research project is typically, though not always, funded through a competitive application and award process, results in generalizable knowledge, and possesses at least two of the following characteristics:

010-3.1 It is described by a defined work statement;

010-3.2 The funding for the project must be managed so that related expenditures can be identified by activity, function, and project period;

010-3.3 There is a specific commitment regarding deliverables and/or level of personnel effort devoted to the project;

010-3.4 At completion, a formal report summarizing the results or conclusions must be delivered to the sponsor.

- 010-4 Beyond this, for the purposes of this policy, “research” also includes projects that involve:
 - 010-4.1 The training of individuals in research techniques (i.e., “research training”) where such activities utilize the same facilities as other research and development activities; or
 - 010-4.2 The development of research protocols and other work performed in support of clinical trials and other studies typically done pursuant to a consulting agreement between the Research Institute and a sponsor.

- 010-5 Additionally, in cases where the preponderance of funding received from an external funding source is for “research” as defined above, for reasons of standardization and efficiency, as well as facilitating the maintenance of relationships with those funding sources, all funding received from such parties will defined as “research” and subject to the sign-off requirements described herein. Sponsors who are currently considered de facto “research sponsors” are the following:
 - 010-5.1 National Institutes of Health
 - 010-5.2 National Science Foundation
 - 010-5.3 Centers for Disease Control

- 010-6 Accordingly, any application submitted to a sponsor specified in Section 10.5 will be considered “research” and be subject to this policy, regardless of the specific nature of the proposed activities.

- 010-7 Any question regarding whether or not a given project qualifies as “research” should be directed to the Chief of Research Operations or the Vice-President of the Research Institute.

Required Approvals

- 010-8 The matrix (Matrix 1) below identifies the signatures/approvals required for all sponsored research applications and contracts, as well as the basis for, and meaning of, those approvals.
(Note that the term “proposal” refers to both applications and contracts.)

Matrix 1: Essential Research Project Approvals

Individual/Role	Basis / Reason for Approval
Principal Investigator	PI approval is required to confirm that a) the information in the proposal is complete and accurate; b) the proposal has been prepared in accordance with all applicable policies and regulations; c) the PI is aware that false or fraudulent statements may subject him/her to criminal, civil, or administrative penalties; d) all personnel involved in the project have read the CHRMC policy on Significant Financial Interest (RIA-03) and have made any required disclosures; and e) the PI agrees to accept responsibility for the scientific conduct of the project, if an award is made.
Center Director (CD)	Center Director approval indicates that a) the proposed research project has scientific merit, b) the project is consistent with the research mission of, and has

(Note: Not required for non-competitive* applications and/or contract modifications.)	the support of, the Center, and c) that project’s financial commitments are correct and can be fulfilled.
Chief Academic Officer (CAO) (Note: Not required for non-competitive* applications and/or contract modifications.)	CAO approval indicates that the proposed research project a) has scientific merit, b) is consistent with the research mission of, and has the support of, the Seattle Children’s Hospital Research Institute, c) and is consistent with the terms of the PI’s faculty appointment.
Center Business Manager (CBM)	CBM approval indicates that the budget for the proposed research project has been calculated in accordance with SCHRI and sponsor policies, and provides for appropriate cost recovery.
Sponsored Project Officer (SPO) - or - Contract Specialist	SPO approval indicates that the proposal has been reviewed administratively, is consistent with the sponsor’s submission requirements, and is ready to be submitted for consideration. Contract Specialist approval indicates that the contract and corresponding budget and work scope have been reviewed administratively and are consistent with Childrens policies and guidelines.
OSR Grants Manager / OSR Contracts Manager	OSR approval indicates that the proposal has all required approvals, all compliance obligations have been fulfilled, and the proposal has the institutional support of SCHRI. OSR Grants Manager (or Contracts Manager) approval is the final approval granted before the proposal is submitted to the sponsor.

* “Non-competitive” in this context refers to any application for additional funds for a project that has already been awarded to Children’s and which will not have to compete with other submitted proposals for funding. Examples include Progress Reports and NIH “Non-Competing Continuations.”

010-9 In addition to the foregoing signatures, under certain circumstances and depending on the nature of the proposed project, additional approvals may be required. The following matrix (Matrix 2) identifies the details of these additional approvals:

Matrix 2: Project-Dependent Research Project Approvals

Condition	All Proposals or Competitive Only	Required Approval	Basis / Reason for Approval
If the project provides for F&A recovery below our standard, federally negotiated rates...	Competitive	President, Research Institute (Back-up: Vice President)	Approval from the President indicates that Research Institute Executive Leadership agrees that the merits of the project in question

		or other delegated authority.	outweigh the downstream implications of the reduce F&A recovery, including possible impact on future F&A negotiations as well as Institute performance against the requirements of the Strategic Plan.
If the project includes cost sharing...	All	Budget Authority for the activity that will cover the cost share	Budget Authority approval indicates that there are funds available to cover the proposed cost share, and that the person who controls those funds agrees to direct them to the project as described.
If the proposal is being submitted to a Private Foundation for consideration...	Competitive Only	Director, CHRMC Foundation	Foundation Director approval is required to facilitate long-term relationships between CHRMC and our donor base. It is essential that the Foundation be aware of the proposals being submitted.
If the project involves human subjects... (See below for additional information related to approvals for work human subjects.)	All	1. Director, OIA/HSPP	Required to indicate that IRB approval for the proposed activity has been secured or that an IRB application has been, or will be, submitted for IRB review. Note: For sponsors with a Just-in-Time policy, OIA/HSPP approval will be secured at time of award.
		2. Clinical Research Budget Analyst (CRBA)	CRBA approval indicates either that 1) the project budget has been reviewed for clinical billing and/or CRC usage, that the projected clinical costs (if any) are accurate, and that the budget has been (or is prepared to be) entered into Study Manager, or 2) that none of the foregoing applies. CRBA approval is needed prior to submission of the proposal to the sponsor.
If the project involves vertebrate animals... (See below for additional information related to approvals for work with animals.)	All	Director, OAC (Backup: Chair, IACUC)	Required to indicate that IACUC approval for the proposed activity has been secured or that a protocol has been, or will be, submitted for IACUC review. Note: For sponsors with a Just-in-Time policy, OAC approval will be

			secured at time of award.
If the project involves radionuclides; pathogenic organisms; human or animal cells, tissue or body fluids; recombinant DNA; and/or chemical carcinogens, mutagens, or teratogens...	All	Director, Research Technical Operations	Required to indicate that appropriate Institutional Biosafety Committee approvals are in place.
If the project requires IND Pharmacy Services...	Competitive Only	Manager, Investigational Drug Services	Required to indicate that appropriate Pharmacy approvals are in place.
If the project will require the purchase of software not already in use at Childrens, new servers, or more than 25 additional computers...	Competitive Only	Director, Research IT	Required to ensure that Research IT has the infrastructure in place to support the proposed work, and that the budgeting and other resource allocations described in the proposal are accurate.
If the project requires new space or renovation...	Competitive Only	Authorized official controlling the designated space	Required to ensure that the space described in the proposal is available for use.

Timing of Approvals

010-10 **In the case of applications for research funding**, because submission of the application to the sponsor typically entails certification that the reviews have been conducted and the approvals secured, **these approvals must be in place prior to the application’s submission to the sponsor for consideration.**

010-11 **In the case of contracts**, the required timing for approvals is less precise. In all cases, **all required approvals must be in place prior to final execution of the contract. However, in certain circumstances and at the discretion of the Contracts Supervisor and Director of the Office of Sponsored Research, approval in advance of contract negotiation may be required.** As defined in the June 15, 2005 version of this policy, it is the operating principle of the Research Institute regarding industrial sponsored research (i.e., “research contracts”) that Institutional approval, IRB approval, contract negotiation and budget finalization/negotiation will occur or be secured in parallel. However, because contract negotiation represents a significant investment of Research Institute time and resources (as, to be clear, do the other steps required), in cases where OSR believes that those other requirements are not being pursued, or when they have reason to believe that the additional approvals are unlikely to be granted, OSR may require that the needed approvals be documented in advance of contract negotiation rather than contract execution.

Forms & Documentation

010-12 The preferred mechanism for documenting the necessary proposal approvals is signature on the Seattle Children's Hospital Research Institute Request for Approval of Sponsored Research Application Form. There are two versions of this form, one for competitive applications and new contracts (Form AAF-01, see Exhibit A) and one for non-competitive applications (Form AAF-02, see Exhibit B). Again, "non-competitive" in this context refers to applications for additional funds for projects *that have already been awarded to Childrens* and which will not have to compete with similar applications for funding. In the case of contracts, "non-competitive" refers to modifications to existing agreements already executed by Childrens.

010-13 For the sake of convenience and efficiency, faxed/scanned signatures on these documents are acceptable, as are signatures in counterpart (i.e., separate signatures on separate copies of the document). Approvals may also be provided via email, provided the email clearly identifies the project in question by PI name, sponsor name, project title, and total requested funding.

Additional Information Regarding Human Subjects and/or Animal Use

010-14 The Human Subjects Protection Program (HSPP) has final authority over the determination of whether or not a project "involves" the use of human research subjects. Similarly, the Office of Animal Care (OAC) is responsible for determining whether or not a project involves research on animals. Both offices make their determinations in accordance with Federal regulation and Children's policy. It is recommended that you consult with the appropriate office for a formal determination in cases where you are unsure of the need for IRB/IACUC approval, or where the possibility of human subject or animal use exists.

010-15 Final approval from HSPP or OAC on a Request for Approval of Sponsored Research Application form confirms three things:

010-15.1 That the IRB or IACUC has approved their respective application(s) covering the activities described in the research proposal (or have waived the approval requirement); and

010-15.2 That the IRB or IACUC has conducted a side-by-side review of the research proposal and their respective approved application(s) to confirm that the human- or animal-related activities described in the research proposal are consistent with the approved IRB/IACUC application (or waiver); and

010-15.3 That all required documentation related to the IRB/IACUC approval (or waiver), and connecting the research proposal to the IRB/IACUC application (or waiver), is in place.

010-16 In order for HSPP/OAC to provide this final approval, the office(s) must have in their possession both *an approved IRB/IACUC application and a final research proposal*. In the event that the review identifies differences between the IRB/IACUC application and the research proposal, HSPP/OAC will so notify OSR, the PI and other involved staff so that appropriate steps can be taken.

010-17 When a sponsor has a Just-in-Time policy regarding IRB/IACUC approvals, HSPP/OAC signature will not be required until such time as an award is made. For the purposes of proposal submission, the human subjects and/or animal use questions should be answered correctly and the box designating a Just-in-Time policy should be checked, but HSPP/OAC signature will not be required. If/when an award is made, OSR will request the review specified above and HSPP/OAC signature on the previously routed **Request for Approval of Sponsored Project Application** form. Please note that in order to ensure that final HSPP/OAC approval can be secured at the time the award is received, the IRB/IACUC approval process should be started upon receipt of notice from the sponsor that the proposed project has received a fundable score.

010-18 In cases where a) the sponsor does not allow for Just-in-Time IRB/IACUC approvals, and b) IRB/IACUC approval for the project *has already been secured*, the IRB/IACUC will conduct the side-by-side review specified in Sections 10-15 and 10-16 above and the HSPP/OAC office(s) will provide final sign-off on the **Request for Approval of Sponsored Project Application** form.

010-19 In cases where a) the sponsor does not allow for Just-in-Time IRB/IACUC approvals, and b) IRB/IACUC approval for the project *has not yet been secured*, the HSPP/OAC office(s) will provide a “pending” approval to the **Request for Approval of Sponsored Project Application** form. In this case, signature indicates that the research proposal and cited IRB/IACUC application have been submitted and *appear to have a general nexus* such that there is *a reasonable expectation* that a future side-by-side comparison, to be performed once the documents are final, will result in final approval.

010-20 When HSPP/OAC approval is noted as “pending,” it will be necessary for OSR to re-route the **Request for Approval of Sponsored Project Application** form to HSPP/OAC to re-sign confirming final approval before any confirmation of IRB/IACUC approval is submitted to the sponsor or an award is processed.

Requirement for Approvals

010-21 Except in exceptional circumstances, OSR will not submit an application for funding until such time as the appropriate institutional approvals as designated herein have been secured.

PROCEDURE:

010-22 The Office of Sponsored Research (OSR) co-ordinates the preparation of the necessary components for all research applications in accordance with sponsor guidelines.

010-23 When the OSR Sponsored Project Officer (SPO) deems the research proposal to be at a satisfactory level of completeness, the SPO will contact the appropriate Center Business Manager to request that a Request for Approval of Sponsored Research Application form be prepared. This form will be routed, with a copy of the research proposal (marked as a draft or final version) and any other relevant documentation, to secure the required approvals.

010-24 Children’s reserves the right to refuse any grant award based on a research proposal not reviewed and endorsed in accordance with this policy.

Submitting Office: Office of Sponsored Research

Approved by:

\s\ John Streck, Chief, Research Operations, May 15, 2009