

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE
Seattle, Washington

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Office of Sponsored Research

POLICY NUMBER: OSR-15

REPLACES: N/A

EFFECTIVE DATE: 10/15/07

REVISION DATE: N/A

POLICY TITLE: OSR Review of Unfunded Research Proposals in review by IRB

POLICY:

The Institutional Review Board (IRB) requests information regarding funding sources of support for proposed human subjects research. When the PI indicates there are no funds identified to support the research, Research Institute leadership must determine if the proposed research should be approved as unfunded, or require PI's to identify a source to support proposed research expenses. Research funding is not under the purview of the IRB, and review and decisions will then be delegated to the Institutional Official (IO) or designee.

If the proposed human subjects research is not approved as unfunded by the IO, the OSR director coordinates with the PI and Center Business Manager to conduct a review of the research, develop a detailed budget, and identify and recommend an appropriate source of support for the proposed research.

PROCEDURE:

- 1.1 OSR director is notified by HSPP of decision regarding status of request for unfunded human subject protocol proposals.
 - 1.11 If the request to conduct unfunded research is approved, OSR director will receive a copy of the approval by IO or designee.
 - 1.11.1 OSR Director will notify CBM of approved unfunded research proposal approval.
 - 1.11.2 Copies of the approval will be filed in the OSR and with the CBM.
 - 1.12 If the request to conduct unfunded research is denied, the OSR director reviews HSPP correspondence, IRB application and possibly protocol to determine source reason for denial of unfunded research.

- 1.12.1 Section I of the *Study Funding Status Form* is completed by the OSR director and forwarded to the appropriate center business manager (CBM).
- 1.2 Upon receipt of the *Study Funding Status Form*, the CBM notifies the PI and center director of IO denial.
 - 1.21 CBM develops a budget to determine the level of funding necessary to secure to support proposed research.
 - 1.21.1 If billable patient care events are involved in the proposed research, the CBM will notify the Clinical Research Billing Analyst (CRBA) for clinical pricing (see policy CTM 200 Research Patient Procedure Pricing and CTM 201 Fiscal Responsibility Analysis).
 - 1.22 CBM advises PI and CD the estimate of total costs to conduct the proposed research.
 - 1.22.1 PI, CBM and CD collaboratively seek potential appropriate sources to support unfunded research proposal. These can include center or PI discretionary, gift, and endowment funds.
 - 1.22.1.1 If a funding source is not identified, it is noted in Section II of the *Study Funding Status Form* and returned to the OSR director, who will then forward to HSPP (cc's to the IO and PI), with instructions to withdraw or close the IRB application.
 - 1.22.1.2 If a funding source is identified, Section II of the *Study Funding Status Form* is completed, and approval is obtained from the PI of the account supporting the proposed research and the CD. A copy of the detailed budget for the proposed research is attached, and the form is returned to the OSR director for review.
 - 1.22.1.2.1 If the funding source identified is a restricted gift or endowment income account, and the allocation to the proposed research is estimated at \$10,000 or more, the request must be reviewed and approved by the IO (see policy OVPR-09, Funding and Expenditure of Intramural funds Including Gift Accounts).
- 1.3 OSR director reviews Section II of the *Study Funding Status Form* and attached detailed budget. Decision is made whether the proposed budget will satisfy the original rejection criteria.
 - 1.31 If rejection criteria are met, the OSR director completes Section III of the *Study Funding Status Form*, signs and dates the form and sends form to HSPP, with a copy to IO and PI, and instruct HSPP to release IRB approval documents.

1.32 If rejection criteria are not met, the OSR director completes Section III of the *Study Funding Status Form*, signs and dates the form and sends form to IO, notifying IO or designee outcome of funding review and recommendation to withdraw or close the IRB application.

1.32.1 IO reviews OSR director's assessment for funding criteria resolution and recommendation for withdrawal or closure of IRB application. If IO concurs, IO will instruct HSPP to withdraw or close IRB application, with a cc to the PI and CBM.

1.32.2 If IO disagrees with OSR director's assessment, IO advises and reverses OSR director's assessment. OSR director then follows 1.31, rejection criteria is met.

Submitting Office: Office of Sponsored Research

Approved by:



Director, Office of Sponsored Research

11/16/02

Date