

**Yale University School of Medicine / Yale New Haven Hospital
General Clinical Research Center (GCRC)
Standard Operating Policies and Procedures**

TITLE: Policy for GCRC Resources Used for Investigator Initiated/Industry-Supported Research Studies		Source: Resource Utilization Group Document No: 3
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EXECUTIVE COMMITTEE: Robert S. Sherwin, M.D. GCRC Program Director	GAC COMMITTEE: David Coleman, M.D. GCRC GAC Chairman
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I. Purpose

To outline the policy for use of GCRC resources for investigator-initiated projects supported in whole or in part by industry (e.g., drug and device companies).

II. Background

Industry-initiated studies can be performed on the GCRC and are categorized as Category D. The GCRC must be fully reimbursed for all of the costs of Category D studies. In contrast, the GCRC can provide GCRC resources at no or reduced cost for investigator-initiated projects that are supported by industry through a grant of unrestricted funds or by a donation of drugs or devices. These studies are classified as Category A or B studies. Category A, B and D studies are subject to the usual HIC and General Advisory Committee (GAC) review and approval. The category of these studies will be determined by the GAC. Investigators who are receiving industry support for projects conducted on the GCRC must be free to publish or distribute data from such studies without restriction.

III. Policies Regarding Investigator-Initiated and Industry Supported Projects

- There can be no overlap between the extramural support and the support requested from the GCRC. Funds from the proprietary organization that are budgeted for research patient care must be transferred from the investigator's grant to the GCRC grant if use of GCRC resources is approved.
- Copies of the agreement with industry or other source, including the detailed project budget, must be maintained in the GCRC's administrative files. In addition, copies of appropriate regulatory documents and other relevant correspondence are to be maintained in the GCRC's research project files. This includes, but is not limited to, all FDA-required documents and relative correspondence.
- The determination of whether a research project is industry-initiated (Category D) or investigator-initiated (Category A) will be made during the pre-review process. The Pre-review Committee will define and assess GCRC resources and the level of external support provided by industry. The Resource Utilization Group (RUG) will be consulted as needed. The GAC will then review and make the final determination of the category of the project utilizing the Pre-review recommendation which is based on the general principles outlined in NCCR Guidelines. Justification for the recommendation and pertinent discussion will be documented in the GAC minutes.

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- Due to GCRC funding limitations, it is strongly recommended that investigators include the full cost of the project in their individual project/grant budgets whenever possible. It should also be noted that GAC approved resource allocations are not guaranteed beyond any given GCRC budget period which ends November 30 of each year.
- If the research protocol is approved by the General Advisory Committee, a mechanism will be established to transfer funds from the investigator's funds to the GCRC for reimbursement of all resources provided for by the industry.