

Johns Hopkins Bayview Medical Center

GENERAL CLINICAL RESEARCH CENTER

Policy No. 138

Core Laboratory Resource Only

Original Date: 4/16/2001

Previous Date: None

Reviewed Date: None

Purpose: To outline the process for the submission and approval of Core Laboratory only resource requests.

Procedure:

- 1) The Requesting Investigator will contact the Core Laboratory Director regarding the Investigator's needs and any budgetary implications such as cost of kits.
- 2) The investigator submits an application to the GCRC indicating the requested assays, the number of projected assays, the period for which support is requested, and confirmation of any budget arrangements. This can be in the form of a letter.
- 3) The investigator provides the Core Laboratory Director with a copy of the protocol. This can be in the format that was submitted for the appropriate approvals at the parent institution, such as GCRC / GAC application at another institutional approval boards. The protocol is then reviewed for appropriateness of the request by the Core Laboratory Director and another member of the Administrative staff, usually the Associate Program Director.
- 4) A copy of the letter from the investigator's institute approving the conduct of the protocol will be provided to the JHBMC GCRC.
- 5) The letter requesting support and a summary by the Core Laboratory Director, noting whether the Core Laboratory can provide the support, is distributed to the GCRC Advisory Committee at its monthly meeting. A decision is made at that time to approve the resource request. This will not require a scientific review by the GCRC Advisory Committee members.
- 6) The GCRC will maintain a current file on the protocol which will include copies of the current consent forms.

Originator: GCRC Program Director,
GCRC Core Laboratory Director

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