Institutional Committee Approval

Policy Number: 600-004
Effective Date: April 3, 2007
Last Updated: March 10, 2010
Issuing Authority: Vice President for Research and Compliance
Responsible Office: Office of Sponsored Programs /Research Administration and Research Compliance Office

Purpose:

To ensure that the appropriate institutional committee reviews and approvals have been obtained consistent with the policies of Howard University and all related entities, business units, subsidiaries and affiliated organizations including, but not limited to, Howard University Hospital (hereinafter referred to collectively as "Howard University") and applicable external regulations.

Policy:

It is the policy of Howard University that the Principal Investigator/Project Director (PI/PD) is responsible for ensuring that the all required institutional committee approvals/reviews (i.e., Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), BioSafety Committee, Radiation Safety Committee) have been obtained consistent with Howard University policy and applicable external regulations. The Office of Sponsored Programs/Research Administration (OSP/RA) accepts proposals in "just in time" status until the approvals have been obtained, if allowed by the sponsor, but will only accept the award after evidence of the necessary approval has been provided. Continuing awards will not be set up in the Howard University accounting system for spending unless evidence of the requisite institutional committee approval is provided.

Business Process Description:

The PI/PD is responsible for obtaining institutional committee approval for his/her sponsored project. For further information on the requirements for approval of research involving human subjects, the role of the IRB, the approval process, and the federal regulations regarding Human Subjects, please visit the Howard University IRB website at http://ovprc.howard.edu/. For further information on the review process for research involving animals, the role of the IACUC, the review process and the federal regulations regarding the use and care of animals in research, please visit the Howard University IACUC website at http://ovprc.howard.edu/. For further information on the Howard University BioSafety Committee, contact their office at Annex II, Room 215, 806-5340. For further information on the Howard University Radiation Safety Committee, contact their office at Annex II, Room 211, 806-7216.

OSP/RA reviews the *Application to Seek Off-Campus Funds* package completed by the PI/PD to determine if any institutional approvals are required at any time during the proposed project. If an institutional approval is required, the Research Administrator (RA) confirms that the appropriate approval has been obtained and verifies the expiration date with the appropriate institutional committee. If institutional approval is required, but has not been obtained, the proposal can be submitted with "just in time" status if allowed by the sponsor.*

Institutional Committee Approval

If a proposal is awarded to Howard that was submitted with an institutional approval status of "just in time", the RA contacts the appropriate institutional committee to determine the status of the approval. In the event that a protocol approval is still pending, OSP/RA may approve a portion of the budget, unrelated to the portion requiring approval, to be set-up in the system. However, **no research activity that requires institutional committee approval may be commenced until the appropriate approval has been obtained.** The RA does not finalize the processing of the award via an *Award Transmittal Notice* until evidence of all necessary approvals/reviews has been provided. (If a multi-year award supports research involving human subjects and/or animals only in the out-years of the project, OSP/RA also includes this information in the *Award Transmittal Notice* to Grants and Contracts Accounting (GCA).

For multi-year awards that involve incremental funding on an annual basis, the institutional committee notifies the PI/PD of the pending expiration of an approval at 90, 60, and 30-day intervals prior to the expiration. This is done to provide the PI/PD with adequate time to obtain the requisite approvals prior to the expiration, as well as to avoid unnecessary delays in the sponsored program. In OSP/RA, prior to notifying GCA to set up the award for a future project period, the RA ensures that the continuing approval documentation is received.

In the event a multi-year award does not require continuing involvement from OSP/RA (e.g., Department of Defense), the relevant institutional committee notifies the PI/PD, the Dean, the Director, OSP/RA, RFA-OSP/GCA, and others, of the need to obtain a continuing approval.

In the event that an approval expires, the institutional committee notifies the Research Compliance Officer (RCO) who sends a notice to the PI/PD (with a cc: to the Dean) and to GCA to cease immediately all activity and spending on the portion of the award requiring institutional committee approval. Further, the RCO indicates that the project may be suspended or terminated if the requisite approval is not obtained within an appropriate period of time, which the RCO will determine in conjunction with the institutional committee. **No research activity that requires institutional committee approval may continue if any of the appropriate approvals have been allowed to lapse, or have been suspended or terminated.**

*Unless protocol approval is required by the sponsor prior to application submission (e.g., NIH non-competing applications and some non-federal applications).

<u>**Roles and Responsibilities:**</u>

Academic Department
- **Principal Investigator/Project Director (PI/PD):** The PI/PD is responsible for indicating on the *Application to Seek Off-Campus Funds* whether the project involves research on human subjects or animals at any time during the proposed project. The PI/PD is responsible for completing the documentation required by the Howard University IRB, IACUC, BioSafety, and Radiation Safety; submitting the protocol application to the respective committees; responding to any concerns raised by the committee in order for an approval decision to be made; and for maintaining contact with the institutional committee until disposition. The PI/PD is responsible for providing notice and evidence of the approved protocol for a sponsored project to OSP/RA. The PI/PD is also responsible for any necessary renewals (e.g., continuing review and approval by the IRB) and providing OSP/RA with a copy of the renewal.

The Office of Sponsored Programs / Research Administration (OSP/RA)

- **Research Administrator (RA):** The RA is responsible for processing the proposals in "just in time" status, where allowed by the sponsor, until the evidence of approval is received from the institutional committee(s). Once the evidence of the approval is received, the RA is responsible for finalizing the processing of the award and notifying the Office Manager of the reference numbers. If annual approval is required due to the project spanning multiple years and OSP/RA remains involved in the continuing award, the RA confirms that the PI/PD has obtained documentation of the annual review/approval and submits copies of such to the Office Manager for inclusion in the research files maintained by OSP/RA.

  If a multi-year award not requiring ongoing involvement from OSP/RA supports research involving human subjects and/or animals only in the out-years of the project, the RA includes this information in the *Award Transmittal Notice* to GCA.

  If a sponsor requires approval of a human subject or animal protocol before issuing an award, the RA is responsible for obtaining a copy of the protocol from the PI/PD and submitting the protocol documentation to the sponsor. The RA is also responsible for keeping a copy of the approved protocol in the proposal folder.

- **Office Manager:** The office manager is responsible for maintaining updates in the database of research projects. In the case of projects that require institutional committee approval, the Office Manager updates the database with the project in "just in time" status until the approval numbers are received. Once the approval numbers are received, the Office Manager updates the database with these numbers and removes the "just in time" status.

Research Compliance Office

- **Institutional Committee Administrative Staff:** The Institutional Committee administrative staff notifies the PI/PD 90, 60, and 30 days prior to the expiration of the approval. Additionally, OSP/RA, GCA, the Manager of the Office of Sponsored Programs, the Research Compliance Officer, the Dean/Director and the PI/PD are notified if the relevant committee has not renewed any institutional committee approval, if the approval date has expired pending review and/or a decision, or if the institutional committee has decided to suspend or terminate a protocol.
- **Research Compliance Officer (RCO):** If the RCO is notified by the Institutional Committee administrative staff if an approval has expired, the RCO notifies the PI/PD (with a cc: to the Dean) and RFA-OSP/GCA that all activity and spending on the portion of the award requiring institutional committee approval must immediately cease. Further, the RCO indicates that the project may be suspended or terminated if the requisite approval is not obtained within an appropriate period of time, which the RCO will determine in conjunction with the institutional committee. The RCO also conducts periodic random checks of the award files maintained in OSP/RA to confirm that the award has an active and approved protocol or exemption notice.

Grants and Contracts Accounting

- Upon notification from an institutional committee or the RCO that continuing approval has not been obtained for an award or that approval has lapsed, GCA restricts the project's account such that no spending is permitted until the proper approvals have been obtained.

Related Policies and Procedures:
- Proposal Development, Processing and Submission Procedure
- Award Set-Up Procedure

Resources and Links:

- OVPRC Website **-** http://ovprc.howard.edu/