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**WEST VIRGINIA  
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE**

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## **(1.7) Pilot Grant EAC and NIH Approval Process**

### **Overview**

The West Virginia Clinical & Translational Science Institute (WVCTSI) Clinical and Translational Pilot Grant Core abides by NIH NOT-GM-14-111, in which, it clearly states that all pilot awards made by the WVCTSI are subject to approval by the WVCTSI's External Advisory Committee (EAC) and then the NIH Program Officers. The WVCTSI has established a process for a consistent manner to obtain both EAC and NIH approval.

#### **Purpose**

The purpose of this operating procedure is to provide guidelines to WVCTSI pilot core staff, and pilot grant recipients on the protocol necessitated to release funds to investigators.

#### **Scope**

This procedure applies to all WVCTSI Pilot Grant award recipients, pilot grant coordinators, pilot grant core chair, WVCTSI EAC, and WVU Office of Sponsored Programs (OSP).

#### **Clarification**

All grant proposals that will be funded using WV-CTR grant money or matching fund dollars are required to follow this protocol. This includes small grants, institutional collaborative funding opportunities, and open competition grant submissions.

#### **Definitions**

**External Advisory Committee (EAC)** Group of experts in clinical and translational research appointed by the WVCTSI Director to serve as council to the operations of the WVCTSI

**Institutional Review Board (IRB)** is a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.

**Institutional Animal Care Use Committee (IACUC)** The Institutional Animal Care and Use Committee (IACUC) oversees the animal programs, facilities and procedures at their respective institution, insuring the health and well-being of all animals being used for research, testing, and education.

**Principal Investigator (PI)/Investigator:** the person in charge of conducting a research study

**WVCTSI Staff:** staff members reporting to the WVCTSI cores

**Core Constituents:** a member of a WVCTSI core who participate in the activities of the institute

**Partner Sites:** WVCTSI staff members at Charleston Area Medical Center and School of Osteopathic Medicine who are named within the WVCTSI grant and contribute effort.

**NIGMS:** National Institute of General Medical Sciences

## Policy

Prior to the commencement of any pilot project, the following documentation must be submitted to NIGMS staff by the PI through the institutional signing official:

- Pilot project proposal. Using PHS398 forms and instructions, only the following sections must be submitted to the pilot program coordinator:
  - a. Face page
  - b. Project Summary (page 2)
  - c. Research Strategy section
- EAC approval – communication from the EAC chair (at a minimum) indicating that the EAC concurs with supporting the pilot project.
- IRB approval, human subjects protection section, human subjects education certification, and Targeted/Planned Enrollment Table (if applicable).
- IACUC approval, vertebrate animal 5 points (if applicable)

## **Procedures**

WVCTSI Pilot Grant program coordinator after each pilot grant competition creates a spreadsheet with final average review scores of all proposals discussed as well as a list of those proposals triaged. The spreadsheet will also include recent funding history of the PI as well as indicate whether the investigator is early stage. Full proposals will be available to the EAC upon request.

The WVCTSI director submits spreadsheet to EAC with a funding recommendation and rationale for that recommendation must be made to the EAC.

EAC members come to consensus on whether or not to accept the Director's funding recommendation. If not accepted, the EAC communicates which of the recommended pilots for funding are approved for funding and provides a rationale for those not approved. The EAC Chair communicates, in writing, the EAC decision on those project approved for funding.

The Pilot Grant coordinator works with funded PI to ensure all NIH required documentation is organized and uses established WVCTSI created checklist to ensure completeness. Pilot awards made to any of the partner site institutions will utilize their institution's IRB and IACUC. Within three weeks after the Pilot review session, the Pilot Grant coordinator then submits proposal packets to the WVU Office of Sponsored Programs (OSP) for institutional official signature. A staff member from the OSP sends proposal packets to WVCTSI's NIH Program Officers and Grants Manager for approval via email. Lastly the NIH Grants Manager via email sends approval for any and all approved proposals.

## **Roles and Responsibilities**

Principal Investigators are responsible for providing accurate documentation required by the IRB and NIH. The Program Coordinators are responsible to serve as liaisons between the PI and the other entities described above to deliver necessary documents. The EAC must without bias confirm or revise the funding decisions proposed by WVCTSI with appropriate rationale. It is the responsibility of the assigned Pre-Award Grant Specialist - WVU Office of Sponsored Programs to, review and submit the Pilot project application within five business days for approval the proposal packets to the NIH.

## References and Authority

<http://grants.nih.gov/grants/guide/notice-files/NOT-GM-14-111.html>

<http://www.apus.edu/community-scholars/institutional-review-board/>

## Approval and Authority to Proceed

I approve the project as described above, and authorize to proceed.

Name	Title	Date
Sally L. Hodder, MD	Director, West Virginia Clinical and Translational Science Institute	4/18/16



Approved By

4/18/16

Date