

# **IRB Policy 27: Complaint**

## **Revision Date: February 16, 2008**

### **I. Definitions**

- A. Whistle-blower:** An individual who reports sensitive information to the ETSU IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.
- B. Complaints:** Report of sensitive or non-sensitive information to the ETSU IRB regarding potential non-compliance issues or research activities that have or have not potentially placed participants or others at increased risk in relationship to the conduct of the research.

### **II. Summary Policy**

It is the policy of both the ETSU IRB and the ETSU/VA IRB to investigate all complaints received regarding human subjects research conducted under its jurisdiction. These may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study. The IRB houses a suggestion box on the website to voice any suggestions, concerns or complaints.

### **III. Actions Taken**

The HRPP Director must investigate all complaints received regarding human subjects in research under the ETSU IRB or ETSU/VA IRB's jurisdiction. The level of investigation will depend on the seriousness of the complaint and the potential risk to participants. The focus of the investigation will be identification of a suitable resolution and written response to the complainant in a timely manner. Complaints will be handled in a confidential manner, including complaints received from a whistle-blower.

All substantiated complaints will be forwarded for review by the convened IRB. Each complainant will receive a written response from the HRPP Director (unless the complaint was submitted anonymously). In addition, the IRB may take other actions as necessary. Those actions may include further investigation or directed audit. If the complaint includes an allegation of non-compliance, or if the investigation identifies potential non-compliance, then additional actions will be taken as delineated in the non-compliance policy.

## **IV. How to File a Complaint**

If any concerns are emergent in nature or there is potential that a participant may be placed at risk, the IRB should be notified directly at (423) 439-6053. Non-urgent concerns or complaints may be submitted on-line through the ETSU web site, mailed or faxed as indicated below.

On line: [www.etsu.edu/irb](http://www.etsu.edu/irb)

Mail:  
ETSU  
Institutional Review Board  
PO Box 70565  
Johnson City, TN 37614

Fax: (423) 439-6060

### **References:**

Complaint Procedures  
Non-Compliance Policy