IRB Policy 27: Complaints, Concerns, and Suggestions regarding human subjects research
Revision Date: February 16, 2008, revised April 22, 2020

I. Summary Policy

Complaints, concerns, and suggestions about the conduct of specific human research studies or about the ETSU Human Research Protection Program or IRBs are taken very seriously. All complaints, concerns, or suggestions regarding the conduct of human research at ETSU are brought to the attention of the HRPP Director, IRB Chair, and/or the Vice Provost for Research. The complaints or concerns will be investigated and handled appropriately as described in this Policy. It is the policy of both the ETSU HRPP and each IRB to investigate all complaints received regarding human subjects research conducted under its jurisdiction. Complaints, concerns, and suggestions may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study. Complaints and concerns might also include reports of any attempts to unduly influence individuals responsible for the oversight of human research (e.g., IRB chairs and members, OPHRS staff).

II. Submitting a Complaint

Complaints, concerns, or suggestions may be received by the Principal Investigator, other research study staff, IRB members, OPHRS Director or staff, the IRB website suggestion box, or other components of the HRPP. These reports may also be received by other individuals or offices within the University, including the Vice Provost for Research, the Assistant Vice President for Research, Associate Deans for Research, or others responsible for research oversight. They may also be received by study sponsors or federal agencies. The ETSU IRB website also contains an anonymous suggestion box where complaints, concerns, suggestions, or reports of violations may be made to the HRPP.

Complainants may include but are not limited to the following: participants (past, present, or potential) or their representatives, participant family members, participant advocates, investigators, or other research staff. In addition, another office within the University or an agency or individual(s) external to the University may also bring forward a complaint or concern. All complaints related to human subjects research conducted under the purview of the ETSU IRBs should be brought to the attention of the HRPP Director, IRB Chair, or VPR.

Complaints regarding the ETSU or ETSU/VA IRB or aspects of the HRPP may be reported to the Vice Provost for Research. The VPR, or designee, will attempt

to obtain adequate information to validate the circumstances of the complaint and will respond as appropriate. When a complaint, concern, recommendation, or report of violation reveals the need to consider modifying any aspect of ETSU's Human Research Protection Program, due consideration will be given and changes made as appropriate.

III. Investigator Responsibilities

The Principal Investigator is responsible for responding as quickly as possible to any questions, concerns, or complaints received from participants or any other individuals during the conduct of human subjects research. Investigators and study staff should consider and evaluate any suggestions that participants may have, and make improvements as appropriate. When the investigator receives a complaint directly or is made aware of a complaint made to another entity, they should work to resolve it whenever possible. If the investigator receives a number of complaints of the same type, the investigator is encouraged to conduct a root cause analysis in order to sufficiently resolve the issue.

Any complaint or concern that involves potential risks to participants or others, negatively impacts the rights of participants or others, or results in a change in the risk/potential benefit ratio of the study must be reported to the IRB. Any complaint or concern received by the PI that cannot be resolved in a timely manner should be reported to the IRB. Any complaint or concern received and resolved by the investigator that does not involve risk to participants or others, or does not change the risk/potential benefit ratio of the study should be submitted in a summary format to the IRB for consideration at continuing review or administrative check-in.

Investigators must maintain documentation of all research-related complaints, concerns, or suggestions and its resolution in the study record. The records must be made available to the IRB, sponsors, or regulatory agencies upon request.

IV. HRPP/IRB Responsibilities

The HRPP Director, in collaboration with the IRB Chairs, is responsible for communicating with the complainant and for conducting the initial investigations of all concerns and complaints brought to the attention of the HRPP or IRB regarding research being conducted under the purview of ETSU or ETSU/VA IRB. 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 response to the complainant in a timely manner. Each complainant will receive a response from the HRPP Director (unless the complaint was submitted anonymously).

Complaints will be handled in a confidential manner with utmost care for the complainant and the rights and welfare of research participants. Complaints or concerns are maintained electronically in the Office for the Protection of Human Research Subjects. Such complaints/concerns do not become part of the permanent study record but are made available to the IRB when necessary to perform adequate review of the associated study.

Complaints will undergo an initial administrative review by the HRPP Director, or designee, to substantiate the report, which may include detailed review or monitoring of a particular researcher or study. If needed, the HRPP Director may request additional information from the Principal Investigator or study staff regarding the complaint. When the complaint or concern has been substantiated, the HRPP Director will collaborate with the IRB Chair to identify a reasonable solution and will communicate with the complainant and study team, as applicable.

Complaints, concerns, or suggestions that are received via the IRB's general email or phone may be initially reviewed by OPHRS staff. If that individual determines the complaint to be minor and one that can be resolved easily, he/she may handle the complaint himself/herself or forward it to the HRPP Director. The HRPP Director will be apprised of the minor complaint and its resolution.

If the complaint or concern is of the nature that the safety, rights and welfare of participants are at immediate risk or hazard, the IRB Chair will contact the PI to establish an interim measure to be taken to protect participants pending formal inquiry and review by the IRB.

All substantiated complaints will be reported in summary to the VPR and convened IRB. 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 IRB Policy 25: Non-compliance. If the complaint appears to be an unanticipated problem, additional actions will be taken as described in IRB Policy 18: UPIRTSO. In addition, the IRB may take other actions as necessary. Complaints or concerns that become suggestions about the conduct of the study will be discussed with and forwarded to the Principal Investigator for consideration and evaluation and may potentially result in modifications to the study. If the complaints or concerns represent a pattern of participant complaints, the IRB may request additional information from the PI, require modifications to the protocol, or request a directed audit.

General or specific concerns, complaints, or suggestions about the HRPP or IRBs that are not about the conduct of specific human subjects research will be considered and handled on a case-by-case basis. These will be addressed by the HRPP Director, IRB Chair, and VPR, as appropriate. Any complaints,

concerns, or suggestions that can be addressed by improving systems or procedures to the overall program will be implemented.