NOVA SOUTHEASTERN UNIVERSITY

Nova Southeastern University
Standard Operating Procedure for GCP

Title: Handling Complaints and Serious/Continuing Noncompliance		**Version # 2**
SOP Number: OCR-GEN-002.1	**Effective Date: November 2015**	**Page 1 of 4**

PURPOSE: Complaints or reports of noncompliance should be evaluated and corrective actions taken when appropriate.

POLICIES:

1. Reports of non-compliance with regulations or policies, whether internally or externally generated, shall immediately be reported to the Vice President Research and Technology Transfer.
2. At any time, the Vice President Research and Technology Transfer has the discretion to turn all or part of the matter over to the research compliance program in lieu of following this process.
3. The Vice President Research and Technology Transfer or designated member will review the allegation and any other information necessary to determine whether a full investigation is warranted. Possible recommendations may include:
   3.1. Dismissal of the allegation or complaint as unjustified
   3.2. Referral of the matter to another more appropriate process or authority within the institution for resolution (*e.g.,* Medical Staff Committee)
   3.3. Resolution through corrective or educational measures where the violation of human subjects regulations is minor or inadvertent
   3.4. A formal investigation where the allegation or complaint appears founded and is of a serious nature.
4. At any time during the inquiry or investigation process, the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research may determine that it is necessary to suspend accrual of research subjects or to suspend approval of research project(s) to ensure the protection of human subjects. Unless there is the potential of imminent harm to research subjects or others, the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research will generally not suspend research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance.

5. The Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research will determine whether the identity of those persons making allegations should be provided to the investigator being reviewed, consistent with applicable policies.
6. The Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research may also initiate a complaint based on information available to him/her (*e.g.,* deficiencies noted in IRB files, media or scholarly reports of research activity).
7. The Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research shall report all serious or continuing non-compliance to the relevant agency (FDA and/or OHRP) as well as other agencies for reportable issues that do not pertain to human subject protection or scientific misconduct.

Procedures for Receipt of Compliant

1. The Center/College accepts complaints from any source, which may include:
   1.1. Subjects and/or their significant others
   1.2. Research Staff
   1.3. Non-Research Staff
   1.4. IRB or other Regulatory Authority
   1.5. General Public/Media
2. The complaints involving scientific misconduct or human subject protections violations should be forwarded, in writing, immediately to the Vice President Research and Technology Transfer.
3. An acknowledgement of receipt of the complaint should be generated.

Procedures for Routine Investigation

1. The Vice President Research and Technology Transfer and/or other individuals appointed by the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research whose areas of expertise are suited to reviewing the complaint and area of study will conduct the investigation (known as the "Investigation Committee").
2. The Investigation Committee may use any and all materials and reports gathered during the initial inquiry phase.

3. The Investigation Committee may obtain documents and other records relevant to the investigation and may interview any persons who may have information relevant to the complaint.
4. The researcher under investigation will be given an opportunity to submit written comments and to appear before the Investigation Committee on at least one occasion prior to the committee issuing its report.
5. Based on its investigation, the Investigation Committee will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions.
6. The Investigation Committee will send the report to the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research for final disposition.
7. Depending on the case, the investigation phase is generally expected to be completed within 60 working days.
8. Actions the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research may take with respect to the investigation include, but are not limited to:
   8.1. Dismissal of the complaint as unjustified
   8.2. Remediation or educational measures
   8.3. Monitoring of research activities
   8.4. Increased reporting by the researcher of his/her human subjects research activities
   8.5. Restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects
   8.6. Suspension of approval for one or more of the researcher's studies
   8.7. Termination of approval for one or more of the researcher's studies
   8.8. Referral to other institution officials or committees for possible further review and action by those bodies.
9. In cases that appear to involve misconduct outside of the realm of Human Subject Protections or Scientific Misconduct (e.g. financial improprieties) OR actions that cross other professional/legal barriers (e.g. sexual abuse of a subject), the Investigative Committee should report allegations of such misconduct to appropriate institutional officials.
10. The Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research will send a copy of its decision to the investigator and the Center/College's Chief Executive Officer.

Procedure for Reporting of Serious or Continuing Non-Compliance to Governmental Authorities

1. Based on the findings, the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research shall determine if the misconduct meets the appropriate Federal Department or Agency's definition

of "serious or continuing noncompliance" with the regulations governing the protection of human subjects or other reportable event involving a different governmental agency (i.e. fraudulent billing).

2. Reports will be prepared and submitted by the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research in accordance with similar policies on self-disclosure to regulatory agencies.