Noncompliance in Human Subjects Research

HRPP Policy 206
What is Noncompliance in Human Subjects Research?

• In accordance with USF HRPP Policy 206, Noncompliance can be defined as:
  – Failure to follow the federal regulations; state and local laws; institutional policies governing human subject research; or the requirements or determinations of the IRB
  – For VA regulated research, noncompliance also includes failure to follow the requirements of VHA handbooks
To Whom Does Noncompliance Apply?

– Noncompliance can occur by
  • The Principal Investigator
  • The Research Staff (members of the research team including the co-investigators, study coordinators or others)
  • Any member of the HRPP, including the IRB staff
Determinations of the IRB Relative to Noncompliance

• When reviewing issues of noncompliance, the USF IRB will determine if the noncompliance is
  – Serious versus Non-serious
  – Continuing versus Non-continuing
What is Serious Noncompliance?

- Any noncompliance that creates an increase in risks to subjects, adversely affects the rights, welfare and safety of the research subjects, or adversely affects the scientific integrity of the study.

- Willful violation of policies, state and local laws, and/or federal regulations may also constitute serious noncompliance.

- A single instance of noncompliance may be deemed as serious noncompliance upon consideration of the facts by the USF IRB.
What Constitutes Continuing Noncompliance?

• A pattern of noncompliance that if unaddressed is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study

• The pattern may occur regardless of whether the noncompliance is a consequence of a lack of knowledge on the part of the investigator or a willful lack of commitment by the investigator and study team to human subjects protection
Examples of Noncompliance

• Failure to obtain IRB approval prior to conducting human subjects research

• Continuation of research activities after a study has expired

• Failure to obtain informed consent of research subjects

• Failure to obtain the date informed consent was obtained from research subjects enrolled in a study
Examples of Noncompliance Cont.

• Failure to follow research procedures as outlined in the protocol/research plan reviewed and approved by the USF IRB

• Implementation of changes in research procedures or a revised informed consent document prior to IRB approval

• Implementation of a new survey or survey question prior to IRB approval
Examples of Continuous Noncompliance

• The occurrence of the same deviation (on multiple occasions) from the IRB approved protocol without submission of an amendment to change study procedures

• Failure to obtain informed consent on more than one subject

• Any establishment of a pattern of behavior which results in noncompliance
How Noncompliance is Reported

- Investigators and study teams are encouraged to report any observed or suspected noncompliance with human subjects research.

- Contact the USF HRPP/IRB, Research Integrity & Compliance.

- Submit an anonymous report via Ethics Point.
Contents of a Report of Noncompliance

• When reporting noncompliance, it is important to provide as much information as possible including:
  – The name of the PI
  – The title of the research study
  – IRB approval number
  – Detailed information regarding the potential noncompliance (i.e., When did the noncompliance occur? Who was involved? What happened? Who witnessed the event?)
  – Corrective Action Plan (CAPA)
Investigating Noncompliance

- Reports of noncompliance are processed by Research Integrity & Compliance

- After initial fact finding, an investigative group may be appointed to further evaluate the noncompliance

- Noncompliance is reviewed by the IRB Chairperson or the fully convened IRB

- If serious or continuing and federally funded, a letter must be sent to OHRP. If FDA regulated, a letter must be sent to FDA.
Possible Corrective Actions for Noncompliance in Human Subjects Research

- Notification of research subjects or re-consent of current research subjects
- Modifications to the protocol or informed consent document
- Modifications to the continuing review schedule
- Periodic monitoring by the RIC Quality Assurance/Quality Improvement Program
- Suspension of accrual
- Suspension or termination of research
- Suspending the privileges of a PI to conduct human subjects research