**GUIDANCE 30**

**GUIDANCE FOR HUMAN SUBJECT RESEARCH NON-COMPLIANCE**

**Research Noncompliance**

Research noncompliance refers to a failure (intentional or unintentional) to follow the regulations, institutional policies governing human subject research, or requirements of or determinations by the IRB by the investigators or research staff, including Rowan IRBs or IRB administrative staff. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing.

Investigators, research staff, the Institutional Review Board and the organization share responsibility for the ethical conduct of human subjects’ research and for compliance with federal regulations, applicable state and local laws, and university policy.

1. Non-serious (minor) noncompliance means any noncompliance that is not serious or continuing noncompliance. For example, non-serious noncompliance might include deviating from or violating the provisions of an IRB-approved protocol in a way that does not jeopardize subjects’ health or safety such as a delay in follow-up because the subject was on vacation.
2. Serious noncompliance means any noncompliance that increase risks of harm to subjects or adversely affects their rights, welfare or safety, or adversely affects the scientific integrity of a study. For example, serious noncompliance might include failure to obtain IRB approval prior to research conduct, enrolling subject(s) who do not meet eligibility criteria, or failure to obtain informed consent from persons before enrolling them in research.
3. Continuing noncompliance means any noncompliance that occurs repeatedly after appropriate remedial education or corrective action has occurred and, if allowed to continue, is likely to increase risk of harms to subjects or adversely affects their rights, welfare or safety, or adversely affects the scientific integrity of a study. For example, repeatedly failing to file for continuing review of a study(s) in a timely fashion constitutes continuing noncompliance.
4. Investigators, research staff and any other members of the organization charged with human subjects’ protection are required to report instances of possible noncompliance—deviations, violations or allegations of study noncompliance—by submitting a report to the electronically (https://someirb.umdnj.edu ) or by contacting the IRB directly.

Reports of noncompliance must be submitted to the IRB Office in a timely manner of discovery or allegation of noncompliant act(s). The report must contain sufficient information to enable the IRB or designee to investigate and act upon the allegation of noncompliance.