**GUIDANCE 8**

**PROTOCOL DEVIATIONS AND VIOLATION**

1. **Deviations/Violations**

The term “protocol deviation” is not defined by either DHHS human subjects regulations (45 CFR 46) or FDA human subjects regulations (21 CFR 50). For JHM purposes, a protocol deviation is a departure from the approved protocol’s procedures made with or without prior IRB approval. However, Rowan University IRB defines deviations and violations equally when the researcher makes any change, deviation, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IRB. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, wellbeing, privacy or confidentiality. Some common examples are:

1. A research subject is scheduled by study personnel for follow-up visits and/or treatment outside of the protocol defined window only if this does not adversely affect the well-being of the subject or the scientific validity of the study.
2. Enrollment of subjects beyond the number approved by the IRB.
3. Study schedule of events is not followed, i.e. study questionnaires are administered out of order.
4. Unapproved advertisements are utilized for recruitment
5. A research subject received the wrong treatment or incorrect dose
6. A research subject met withdrawal criteria during the study but was not withdrawn
7. A research subject received an excluded concomitant medication.
8. A research subject was enrolled but does not meet the protocol's eligibility criteria.
9. Failure to treat research subjects per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
10. Changing the protocol without prior IRB approval.
11. Inadvertent loss of samples or data. Failure to obtain informed consent prior to initiation of study-related procedures
12. Falsifying research or medical records.
13. Performing tests or procedures beyond the individual's professional scope or privilege status (credentialing)
14. Breach of confidentiality
15. Improper destruction pf research records
16. Failure to follow appropriate consent procedures
17. The deviation is inconsistent with RowanSOM research, medical, and ethical principles.
18. **Continuing noncompliance**
19. Working under an expired professional license or certification
20. Failure to follow federal and/or local regulations
21. Repeated deviations.