Common Examples of Non-Compliance & Protocol Deviations

Non-Compliance / Minor Protocol Deviations (Requires Standard Reporting)	Serious Non-Compliance / Major Protocol Deviations (Requires Prompt Reporting)

• Deviations related to the informed consent document or process
  ○ Use of outdated/expired consent form, as long as there has been no impact on participant safety
  ○ Individual obtaining consent not listed on IRB approved application
  ○ Missing original signed and dated consent form or missing pages from executed consent form
  ○ Missing subject signature, printed name or date
  ○ Missing investigator signature, printed name or date
  ○ Copy not given to the person signing the form
  ○ Someone other than the subject dated the consent form
• Exceeding the approved sample size/enrollment for a study
• Failure to follow the approved study procedure, that in the opinion of the Principal Investigator, does not affect the participant safety or data integrity:
  ○ Study procedures conducted out of sequence
  ○ Implementation of unapproved recruitment procedures
  ○ Omission of an approved research activity on a protocol (e.g. mailing out or collecting QOL surveys, evaluating or documenting performance status), unless the omission could affect safety
  ○ Failure to perform a required lab test
  ○ Missing lab results
• Subject visit/procedure falls outside of protocol timeframe due to the following and there is no increased potential for risk to the subject or any damage to the integrity or completeness of the data there is no increased potential for risk to the subject or any damage to the integrity or completeness of the data:
  ○ Inclement weather
  ○ Time and burden
	• Intentional deviation from the protocol or regulations in a non-emergency setting
	• Deviations related to inclusion/exclusion criteria, informed consent or enrollment
	  ○ Enrollment of subjects not meeting the inclusion/exclusion criteria
	  ○ Enrollment of a participant after IRB approval of study has expired
	  ○ Failure to obtain informed consent prior to initiation of study–related procedures
	  ○ Inadequate or improper informed consent procedures (including no documentation of informed consent process)
	• Performing study procedure not approved by the IRB
	• Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity
	• Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety
	• Failure to withdraw a subject meeting withdrawal criteria
	• Any medication error involving dosing, administration and/or preparation of the study drugs
	• Any lapse in study approval where there is a continuation of research activities (i.e. recruitment, enrollment, procedures, data analysis)
	• Inappropriate destruction of study records or inadvertent loss of samples or data
	• Failure to follow federal and/or local regulations and policies
	• Failure to follow safety monitoring plan
	• Failure to report unanticipated problems to the IRB and/or the sponsor
	• Deviations by the Participant
	  ○ Participant did not disclose metal and had MRI
	  ○ Participant discontinued study meds
	  ○ Participant misses visits involving study drug
	• Engagement of new study personnel in human subjects research without prior approval
	• Frequent minor deviations

○ Rescheduling for other reasons that do not involve safety and do not compromise the integrity of the data ○ Procedures not completed at participant's request • Failure of subject to return study medication • Failure to submit continuing review application to the IRB before study expiration • Any lapse in study approval where but there is no intervention or interaction with subjects and no analysis of identifiable information during the lapsed period	• Working under an expired professional license/certification, debarred or disqualified status • Falsifying research or medical records