

## ***Determining What Qualifies as a Protocol-Specific Procedure***

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### **PURPOSE**

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The purpose of this document is to provide guidance to investigators about how to determine what qualifies as a protocol-specific procedure.

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### **GUIDANCE**

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Prior to the initiation of protocol-specific procedures, informed consent must be sought from the participant. If it is not feasible to obtain written informed consent to perform screening test as stipulated by the protocol, the investigator should request an alteration to the informed consent process from the IRB. This document is intended to assist the investigator in making the determination of what qualifies as a protocol-specific procedure.

Examples of protocol-specific procedures:

- Administration of protocol-specific treatment.
- Randomization procedures to determine the treatment plan for a participant
- Performing pre-screening tests that would otherwise not be performed unless the participant was being considered for participation in a protocol
- Weaning a participant from a drug(s) to meet the eligibility criteria for the protocol
- Administration of protocol-specific surveys
- Administration of drug(s) or therapy as a requirement for the participant to receive protocol treatment
- Conducting a pre-screening telephone interview related to the research
- Collection of leftover specimens following routine surgical procedures used either for analysis to answer a specific research question or to bank for future use
- Reviewing medical records to answer a specific research question