Instructions: The Principal Investigator completes Part I and then emails the form to OSROConsultation@nih.gov. The OSRO Director completes Part II and emails the form to the Principal Investigator. See 104-S05 Planned Deviations to Clinical Protocols for additional information.

Part I. Planned Deviation Description and Justification

Protocol Number: _____ Participant Number: _____

Deviation Request Description

Explain how the deviation mitigates the participant risk

Explain why the protocol requested change was unpredictable

Explain why the deviation does not cause a meaningful protocol change

Explain whether the participant is eligible to continue on the trial

Additional justification for the request

- I attest that the proposed change in protocol meets the criteria for a planned deviation.
- If approved by OSRO, I will not implement the planned deviation without submitting the change for IRB review and approval as necessary.
- I will expeditiously submit a protocol amendment for OSRO acceptance to correct the unforeseen event.

_____
Principal Investigator

Email address: _____
Phone Number: _____

Part II. OSRO Decision

The Sponsor's decision on the requested planned deviation for protocol _____, participant _____ is the following:

☐ Approved, with the following conditions:
1. This planned deviation approval applies only for the identified participant; and
2. The IRB will approve the planned deviation as applicable according to the IRB procedures; and
3. The Sponsor will not approve requests for an additional planned deviation for the same reason, and
4. The protocol should be amended expeditiously to address the unforeseen event.

☐ Denied

_____
Shy Shorer
Director OSRO
OCD, CCR, NCI

Note to PI: Please keep this document in the regulatory file. It may be used as the Sponsor approval for the IRB submission.