TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: PROTOCOL SECTION

DATE: MARCH 16, 2020

RE: PROTOCOL NRG-GY003-- PROTOCOL AMENDMENT 12

Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer
NCI Version: February 28, 2020

Study Chair: Dmitriy Zamarin, M.D., Ph.D., zamarind@mskcc.org

The NCI Central Institutional Review Board (CIRB) has approved this protocol amendment. Protocol documents can be obtained from the CTSU website.

IRB Review Recommendation:
(X) Expedited review per 45 CFR 46.110 and 21 CFR 56.110
( ) Full board review

CIRB sites must have Amendment 12 (PVD February 28, 2020) locally implemented within 30 days of notification (posting on the CTSU website).

Sites not using the NCI Central Institutional Review Board (CIRB) as their IRB of record should submit Amendment 8 to the local IRB/IRB of record for review and approval. Per CTMB Guidelines, amendments must be submitted and approved by local IRBs within 90 days of this broadcast. Sites must submit their IRB approvals for this amendment to the CTSU. As per usual, sites that do not submit their local IRB approvals are not able to enroll patients after 90 days.