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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: Protocol Development and Regulatory Compliance

DATE: July 19, 2021

RE: PROTOCOL NRG-HN008 – PROTOCOL AMENDMENT 1

Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)

NCI Version: June 24, 2021

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The NCI Central Institutional Review Board (CIRB) has approved this protocol amendment. The protocol, consent form, patient brochure, and patient history forms are located on the CTSU website. All other protocol related documents are available on the NRG Oncology 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 1 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 1 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.

Please note: Changes were made to the OPEN Eligibility Checklist and are in effect as of this amendment.