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TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: Protocol Development and Regulatory Compliance

DATE: December 20, 2021

RE: PROTOCOL NRG-DT001 – PROTOCOL AMENDMENT 8

**A Phase Ib Trial of Neoadjuvant AMG 232 (KRT-232) Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS)**

NCI Version: December 01, 2021

**Study Chair:** Meng Xu Welliver, MD, PhD; 314-293-0216; [Meng.welliver@osumc.edu](mailto:Meng.welliver@osumc.edu)

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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 8 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.

Please note: The NRG-DT001 Pill Diaries for all Dose Levels have been revised and are available on the NRG website. Use the revised version, dated 11/15/2021 immediately.