



*Advancing Research. Improving Lives.™*

TO: ALL PRINCIPAL INVESTIGATORS, NURSES AND DATA MANAGERS

FROM: Protocol Development and Regulatory Compliance

DATE: August 16, 2021

RE: PROTOCOL NRG-GI007 – PROTOCOL AMENDMENTS 3

**Phase I Trial With Expansion Cohort of OBP-301 (Telomelysin™) and Definitive Chemoradiation for Patients With Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery**

NCI Version:  
Amendment 3: July 26, 2021

**Study Chair: Geoffrey Ku, MD, 646-888-4588, [kug@mskcc.org](mailto:kug@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 3 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 3 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.