Maimonides Medical Center
IRB/Research Committee
4802 Tenth Avenue
Brooklyn, NY 11219

# MEMORANDUM

DATE: February 26, 2018

TO: Yiqing Xu, MD, PhD

CC: Yiqing Xu, MD, PhD

RE: Continuing Review Approval for **2015-07-05** - Retrospective analysis of intravenous and intraperitoneal chemotherapy in Ovarian cancer

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On **December 14, 2017**, the Maimonides Medical Center IRB/Research Committee Chair reviewed and acknowledged the receipt of the progress report for the above referenced study and approved the continuation of the study.

**Approval Period:** Approval is granted in accordance with federal regulations 45 CFR 46 and 21 CFR 50 and 56. This approval begins on **December 14, 2017**, and **expires on December 13, 2018.**

**Continuing Review:** If continuation is desired beyond the expiration date, a **Progress Report** and updated **Conflict of Interest Disclosures** for all investigators must be submitted to IRB at least 2 weeks prior to the IRB meeting scheduled in the month for which the study will expire (http://intranet.mmc/Main/IRB.aspx). Federal regulations do not permit a "grace period" for continuing review. If the deadline is not met in time for IRB approval, the study automatically expires on the date stated above and all research must stop including data analysis.

**Project Closure:** When the project expires or when it is completed or discontinued prior to the expiration date, a **Closure Report** must be submitted to the IRB.

**Amendments:** Any proposed changes (e.g., change in enrollment/recruitment number, study design, investigators) to a research project must be reviewed and approved by the IRB before they are initiated except when necessary to eliminate apparent immediate hazards to the participants. If changes are initiated to eliminate an apparent immediate hazard, the IRB must be promptly notified.

**Reporting Requirements:** Whenever an incident (e.g., Adverse Event; Serious Adverse Event; Unanticipated/Unexpected Problem Involving Risks to Participants or Others; Unanticipated Adverse Device Effect, Protocol Deviation; apparent or serious or continuing non-compliance; complaints; termination, suspension, or hold; incarceration of a research participant, changes initiated to eliminate an apparent immediate hazard, etc.) occurs with participants enrolled at or recruited from the local site, the PI must promptly report it in writing to the IRB in accordance with IRB policy. External incidents for multi-center studies must be reported at or before the time of continuing review or as required by a study group or sponsor.

**Audits:** If an external audit is conducted, the PI must promptly report the findings in writing to the IRB.

**Reminders:**

- All Applicable Clinical Trials must be registered at http://www.clinicaltrials.gov/ prior to enrolling any patients into the trial.
- For studies that are registered on clinicaltrials.gov, please update your results, data analysis, and study status (active, enrolling, closed to enrollment, closed, etc).
- Prior to initiating a research study at Maimonides Medical Center, the Office of Grants and Contracts must approve the research budget and the Legal Department must approve any contracts related to the research.

- Prior to initiating a study at Coney Island Hospital, please note that additional NYC Health and Hospitals Corporation (HHC) Approval is required for studies conducted at any of the HHC facilities. Please go to www.star.nychhc.org to begin the process.

**Questions:** If you have any questions, please feel free to contact Sara D Meeder at smeeder@maimonidesmed.org, or you may direct questions to the IRB e-mail box at IRB@maimonidesmed.org ("IRB" in global directory).

William Solomon, M.D.
Chairman, IRB

Dennis Feierman, MD, PhD
Alternate Chairman, IRB