HOUSTON Methodist
LEADING MEDICINE

Full AAHRPP Accreditation

APPROVAL

January 4, 2021

Dear Maen Abdelrahim:
On 1/4/2021, the IRB reviewed the following submission:

Type of Review:	Modification / Update
Title:	Molecular Profiling of Pancreatic cancer- A Retrospective Study of a Tertiary Center
Investigator:	Maen Abdelrahim
IRB ID:	MOD00002232
Funding:	Name: The Methodist Hospital
Documents Reviewed:	• Updated protocol, Category: IRB Protocol;
Modifications Reviewed	Increase number of chart review to 500 from the original 100 to ensure all patients meeting the criteria are included in the study.

This approval relates to the research to be conducted under the above referenced title and/or to any associated materials.

As the Principal Investigator, you are responsible for oversight of the conduct of this study and must assure compliance with the approved protocol and all applicable regulations and HMRI Policies and Procedures related to Human Subject Research and Research Protections Good Clinical Practice procedures which can be found by navigating to the MORTI IRB Homepage and HM Policy Tech.

Except for changes made to assure the immediate safety of a research participant, no modifications to this protocol or informed consent may be made without prior IRB review and approval.

The IRB requires prompt reporting of unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect he subject's rights, safety or well-being and / or the completeness, accuracy and reliability of the study data; suspension of enrollment or termination of the study.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the IRB is due prior to expiration or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid lapses in approval.

Sincerely,
Susan M. Miller, MD, MPH
Sr. IRB Chairperson

If you have any questions or comments, please contact the HMRI IRB Offices IRB@houstonmethodist.org or by Phone at: 346-356-1400.

The HMRI IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The HMRI IRB operates under the HM Federal Wide Assurance No. FWA00000438, as well as those of hospitals and institutions affiliated with the Institute.

Please log into MORTI directly at http://morti.tmhs.org and then navigate to the above referenced project.

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