



June 10, 2013

G. Ganepola MD
223 North Van Dien Avenue
Ridgewood NJ 07450

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Ridgewood, NJ 07450-2736

RE: IRB Study # 10.0036

At: The Valley Hospital

Meeting Date: 6/6/2013

Protocol Title:

Identification of Proteomic and MicroRNA Biomarkers for Early Diagnosis of Pancreatic Cancer

Dear Dr. Ganepola:

The above referenced protocol has been approved for an additional year of study at the 6/6/2013 meeting of the Institutional Review Board.

In order to ensure the protection of the rights and safety of subjects involved in this investigation, you are responsible, as Principal Investigator, for conducting your investigational research in accordance with IRB guidelines and FDA regulations. In general, you are responsible for ensuring prompt reporting to the IRB of:

- 1) Any and all changes in research activities;
- 2) Any adverse reactions or unexpected side effects; and
- 3) Any unanticipated problems involving risks to human subjects or others.

And in addition that:

- 1) Only the IRB approved informed consent document is used during the course of this investigation; and
- 2) Changes in approved research during the period for which IRB approval has been given may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

It is necessary that you utilize the assigned IRB study number in any and all communications submitted to this office, i.e. amendments, SAE's, etc. Documents or correspondence received without the IRB study number will be returned.

IRB approval for this investigation **expires on 6/5/2014**. The IRB shall require periodic progress reports as part of its continuing review process in order to monitor and oversee the conduct of the research. You will be contacted with instructions approximately one month prior to the renewal date. Please advise the IRB office at One Valley Health Plaza, Paramus, NJ 07652, when the project is complete.

Thank you for your cooperation.

Sincerely,

David Montgomery, MD
Chairperson
Institutional Review Board