Government of South Australia
SA Health

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28 July 2016

Dr Nimit Singhal
Royal Adelaide Hospital
Cancer Centre
Level 4, East Wing
Adelaide, SA 5000

Dear Dr Singhal

**HREC reference number:** HREC/16/RAH/177

**SSA reference number:** SSA/16/RAH/293

**Governance reference number:** 8234

**Project title:** Efficacy and Safety of FOLFIRINOX as Neoadjuvant Chemotherapy for Resectable Gastric or Gastroesophageal Junction Adenocarcinoma - A Run-in Pilot followed by Phase 2 Comparison between ECF and FOLFIRINOX - FIG Study.

**RE: Site Specific Assessment Review**

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to commence at Royal Adelaide Hospital, SA.

In addition to the documents approved by the Royal Adelaide Hospital HREC as listed in their letter dated 28 June 2016, specific approval is also provided for the following documents:

- RAH FIG Pilot Phase PISCF Version 1, dated 29 June 2016
- RAH FIG Phase 2 PISCF Version 1, dated 29 June 2016

The following conditions apply to the authorisation of this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval to this project:

1. Authorisation is limited to the site/s identified in this letter only.
2. Project authorisation is granted for the term of your project outlined in Section 9 of the SSA, or until the project is complete (whichever date is earlier).
3. The study must be conducted in accordance with the conditions of ethical approval provided by the lead HREC, SA Health policies, and in conjunction with the standards outlined in the *National Statement on Ethical Conduct in Human Research* (2007) and the *Australian Code for the Responsible Conduct of Research* (*2007).*
4. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the HREC for review, are copied via email to this Research Governance Office;
5. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted via email to this Research Governance Office;
6. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
7. Proposed amendments to the research protocol or conduct of the research which may affect both the ongoing ethical acceptability of the project and the site acceptability of the

project are to be submitted to this Research Governance Office after a HREC decision is made.

8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. Notification of completion of the study at this site is to be provided to this Research Governance Office.

If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.

We wish you every success in your research project.

Yours sincerely

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