

**Lisa Leung**

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**Subject:** FW: 2020/ETH01283: Application HREA - Approved

**From:** [no\\_reply@regis.health.nsw.gov.au](mailto:no_reply@regis.health.nsw.gov.au) [[mailto:no\\_reply@regis.health.nsw.gov.au](mailto:no_reply@regis.health.nsw.gov.au)]

**Sent:** Wednesday, 2 December 2020 5:05 PM

**To:** Ruta Gupta (NSW Health Pathology) <[Ruta.Gupta@health.nsw.gov.au](mailto:Ruta.Gupta@health.nsw.gov.au)>

**Cc:** [svhs.research@svha.org.au](mailto:svhs.research@svha.org.au)

**Subject:** 2020/ETH01283: Application HREA - Approved

Date of Decision Notification: **02 Dec 2020**

Dear Ruta Gupta,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2020/ETH01283: A Feasibility Trial of Patient Derived Cell Culture (PDCC) Chemosensitivity in Head and Neck Carcinoma (HNC)**

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **St Vincent's Hospital Human Research Ethics Committee** at its meeting held on **9 July 2020**.

At the meeting held, 2 December 2020, the project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

**This email constitutes ethical and scientific approval only.**

**This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.**

This project has been Approved to be conducted at the following sites:

- Royal Prince Alfred Hospital
- Chris O'Brien Lifehouse
- Sydney Head and Neck Cancer Institute
- NSW Health Pathology
- Garvan Institute of Medical Research
- Macquarie University

The following documentation was reviewed and is included in this approval:

- Study Protocol, Version 2, dated 27 August 2020
- Participant Information Sheet & Consent Form, Version 2, dated 27 August 2020
- Data collection form, Version 1, dated 11 November 2019
- Master code sheet, Version 1, dated 17 December 2019
- Research Data Management Plan, Version 1, dated 10 May 2020

The following documentation was noted:

- Authorisations, approvals, letters of support or other clearances, X16-0367 HREC approval letter-0-23-Dec-2016
- Authorisations, approvals, letters of support or other clearances, X17-0423 HREC approval letter-0-30-Jan-2018
- Authorisations, approvals, letters of support or other clearances, X18-0307 HREC approval letter-0-03-Apr-2019
- Authorisations, approvals, letters of support or other clearances, X19-0282 HREC approval letter-0-03-Sep-2019
- Clinical trial letter-0-17-Jun-2020
- COBLH Radiation safety letter-0-13-Aug-2020

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 26 Nov 2020

The approval is for a period of 5 years from the date of this e-mail (**02 Dec 2020**)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- Interventional trials must be registered on one of the clinical trial registries e.g. [https://secure-web.cisco.com/1QEx9z4hmtvmYbX7WICkaslanEBK5zkfFPXxYJlCmnN\\_VY0PUM3DuxwB6YqBP4oQ\\_laiNF0XkGAF5OFcL69T9HcHHsTMktSJLlCwY2N1zhwgCLJpDbocFLpuvztMUTshxgjGciMYpEZfVvgvJJXQtC5G5rQWU\\_A9aNj0WJg\\_jm\\_z-xOniMb79stJL5rWW42XanaGfY-oWIRtlc3yU3y8iCHjkvxU0oZMzwIya3LMABf0io9jIhUpgkM1WKaWspuWDlcNlLr4aBKGeIHhQWodaLdBdJ3MDBFyVWJBI\\_Ji4avhWaaQQbcV9VJJ7fj7s7\\_W9PtJla4Q3N7KtdNK-M44N0J-wgea6F9kFiTqbfrKuaFCHfT0JHNM\\_czpodwUDjzp22qny1fahrRngZurDazO17ilyghY3ZhoS74p5JJ68ileYb7WZkAgXwYBix4An-E-CVonKJEPgEQxLYzMxjGXzGN2CztgjWaUI5XYAnIPs/https%3A%2F%2Fwww.anzctr.org.au](https://secure-web.cisco.com/1QEx9z4hmtvmYbX7WICkaslanEBK5zkfFPXxYJlCmnN_VY0PUM3DuxwB6YqBP4oQ_laiNF0XkGAF5OFcL69T9HcHHsTMktSJLlCwY2N1zhwgCLJpDbocFLpuvztMUTshxgjGciMYpEZfVvgvJJXQtC5G5rQWU_A9aNj0WJg_jm_z-xOniMb79stJL5rWW42XanaGfY-oWIRtlc3yU3y8iCHjkvxU0oZMzwIya3LMABf0io9jIhUpgkM1WKaWspuWDlcNlLr4aBKGeIHhQWodaLdBdJ3MDBFyVWJBI_Ji4avhWaaQQbcV9VJJ7fj7s7_W9PtJla4Q3N7KtdNK-M44N0J-wgea6F9kFiTqbfrKuaFCHfT0JHNM_czpodwUDjzp22qny1fahrRngZurDazO17ilyghY3ZhoS74p5JJ68ileYb7WZkAgXwYBix4An-E-CVonKJEPgEQxLYzMxjGXzGN2CztgjWaUI5XYAnIPs/https%3A%2F%2Fwww.anzctr.org.au)

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS](#)

[website](#).

It is noted that the **St Vincent's Hospital Human Research Ethics Committee** is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,

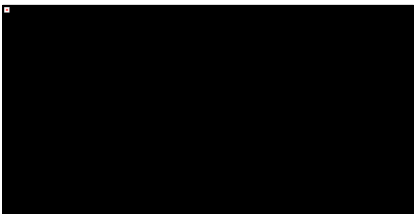
**Monica Logan**

Research Officer

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Website: [https://secure-web.cisco.com/1jNOxMXmEBkB3YD18RZP-4AKCbJeYCeEqtHZyptD26XMMA\\_e-kbfilljOkz2in-63khGVVfinZdx3fDYZ1m3ZdBATfgpEfv87fNWx0Qqgl5lxgRGkcm5vc6GbJiieJEEfwkdYi9n-7URIMltg6rgb5aFiuEoqnwHLuFRloWG0wgTUfCXR-Qi1n1HCPY\\_nnC8lVYtu2xaqV3fftjWlqVLbbLlifRM1EeVp-4SygHJPcsrjuc2px6wRpO9aRQUvZNHNLXmrMkapHnwa2Hm-vHtH9h6mcQ\\_oBzOW5Kllh7kxTlZDPcVHV6RcmdAWGzYmCx7nHYVJ8fkcau9p0bhS2kQM8GLk1cKuJpL54Xr39HLhNOMICyVpP\\_kxyJwCyqCy4MQ\\_qpMCFWGqvB25qlQBEARQUoNqChoQLOIQF1Xn3Al\\_LiuvMATkaqBU00w6pGX196y-UPQ14NCH03FOkNhhPw6-UUnVrkpVKKV8LIDvCio/https%3A%2F%2Fsvhs.org.au%2Fhome%2Fresearch-education%2Fresearch-office](https://secure-web.cisco.com/1jNOxMXmEBkB3YD18RZP-4AKCbJeYCeEqtHZyptD26XMMA_e-kbfilljOkz2in-63khGVVfinZdx3fDYZ1m3ZdBATfgpEfv87fNWx0Qqgl5lxgRGkcm5vc6GbJiieJEEfwkdYi9n-7URIMltg6rgb5aFiuEoqnwHLuFRloWG0wgTUfCXR-Qi1n1HCPY_nnC8lVYtu2xaqV3fftjWlqVLbbLlifRM1EeVp-4SygHJPcsrjuc2px6wRpO9aRQUvZNHNLXmrMkapHnwa2Hm-vHtH9h6mcQ_oBzOW5Kllh7kxTlZDPcVHV6RcmdAWGzYmCx7nHYVJ8fkcau9p0bhS2kQM8GLk1cKuJpL54Xr39HLhNOMICyVpP_kxyJwCyqCy4MQ_qpMCFWGqvB25qlQBEARQUoNqChoQLOIQF1Xn3Al_LiuvMATkaqBU00w6pGX196y-UPQ14NCH03FOkNhhPw6-UUnVrkpVKKV8LIDvCio/https%3A%2F%2Fsvhs.org.au%2Fhome%2Fresearch-education%2Fresearch-office)



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