The following general conditions apply to the research project authorised to be conducted at the site(s) nominated in the accompanying letter. The acceptance of the site authorisation will be deemed to be an acceptance of these conditions by all investigators involved in the research project at the nominated site(s).

* The responsibility for the conduct of project at a site lies with the nominated Principal Investigator (PI) at that site, all correspondence should be signed by PI. Authorisation is limited to the site(s) identified in this letter only.
* The PI will inform the Research Governance Office (RGO) about any changes to the project. The PI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at this site until they have received HREC approval for use at site(s).
* The PI will notify the RGO of their inability to continue as PI at the site(s) and will provide the name and contact information of their replacement.
* The PI will notify the RGO of any changes to site investigators. The PI will also notify the RGO if any new site investigators join the project.
* The PI is responsible for reporting site adverse events, using the standard forms available from the website. Additional reports, other than those outlined, that are submitted will be returned without acknowledgement.
* The site has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or if the site decides to undertake an audit for quality improvement purposes.
* The site can conduct random monitoring of any project. The PI will be notified if their project has been selected. The PI will be given a copy of the monitor’s report along with the HREC and RGO.
* Complaints relating to the conduct of a project should be directed to the RGO and will be promptly investigated according to the Standard Operating Procedures of the site(s).
* The PI is reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the *Archive Act 1983*. A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation.
* The PI will provide an annual progress report to the RGO. This should include the site-specific information which should be completed by the site PI. The annual progress report is due on the anniversary of the ethics review approval from the HREC.
* The PI is required to submit to the RGO a copy of the final report that is submitted to the HREC. This should include the site-specific information which should be completed by the site PI. If the report is not received within 30 days, the project will be closed and archived. An outstanding final report could impact on the PI’s ability to apply for authorisation of future projects.
* If a project is suspended or terminated the PI must ensure that the RGO at the site(s) is informed of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information on procedures that are in place to safeguard participants.
* If a project fails to meet these conditions, the RGO will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the RGO, the issues are not addressed, the site authorisation will be withdrawn.