**THHS Site Specific Application (SSA) declaration by the Principal Investigator at the THHS site(s) for low and negligible risk (LNR) studies**

**Ethics Review Manager (ERM) Reference number:** **[Insert]**

**Project Title (in full): [Insert]**

**I declare that:**

* The information in the THHS Site Specific Application (SSA) is truthful and accurate to the best of my knowledge and belief
* I will take full responsibility for the conduct of the study at the THHS site(s)
* The research project will only commence after obtaining authorisation from THHS and approval from the responsible Human Research Ethics Committee (HREC)
* I accept responsibility for the conduct of this research project according to the principles of the NHMRC ***National Statement on the Ethical Conduct in Human Research (2018)*** and the ***Australian Code for the Responsible Conduct of Research (2018)*** and ***Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*** and all subsequent updates and all relevant legislation and regulations.
* I agree to be responsible for training of any staff undertaking protocol related activity
* I will conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
* I will adhere to the conditions of approval stipulated by the HREC and THHS RGO and will cooperate with HREC and THHS RGO monitoring requirements.
* I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC, THHS RGO and the NHMRC in accordance with ***Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)*** and all subsequent updates
* l will immediately report to the HREC and THHS RGO anything which might warrant review of the ethical approval or THHS authorisation of the research study including but not limited to:
  + Serious or unexpected adverse effects on participants;
  + Proposed changes in the protocol; and
  + Unforeseen events that might affect continued ethical acceptability of the project.
* I will discontinue the research if the HREC withdraws ethical approval.
* I will adhere to the conditions of authorisation stipulated by the authorising authority at the site(s) where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site(s) where I am Principal Investigator.
* I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the THHS RGO, the sponsor and or an independent body for audit and monitoring purposes.
* I understand that information relating to this research, and about us as researchers, will be held by Queensland Health, the reviewing HREC, the THHS RGO and on the Ethics Review Manager (ERM) platform
* This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

**Signed on behalf of:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Print name** |  | **Department and**  **Organisation** |  | **Role in project e.g Study Coordinator; Associate Investigator** |  | **Contact email address** |
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Add more lines as required by ‘hitting’ tab key in last cell

**I certify that** **as the local THHS Principal Investigator (PI):**

* I have discussed this research study with the above people and
  + They have read the study protocol and all other relevant associated research documents
  + They are aware of their role and responsibilities regarding the research study
  + They agree to be the above nominated persons on the research study
  + They have obtained the relevant Head(s) of Department support to be involved in the research

Signed by Principal Investigator responsible for THHS site(s):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Print name** |  | **Signature** |  | **Date** |

**Guidance notes**

**Local THHS Principal Investigator (PI)**

* The individual who takes overall responsibility for the research project at the THHS site(s)
* Responsible for ongoing communication with the THHS RGO
* May delegate some duties to appropriately qualified and experienced staff e.g study coordinator and or associate investigator, but remains responsible
* Must complete and maintain a Delegation Log for all research personnel involved in the research
* Must sign off on all written correspondence to the THHS RGO