By submitting this form to the RDGU the Principal Investigator at Epworth is certifying that:

* This research project will be conducted in accordance with the *Epworth Research Policy*, the *Epworth Research Handbook* and all applicable Standard Operating Procedures (see [*Epworth Resources for Researchers webpage*](https://www.epworth.org.au/working-with-us/research/resources-for-researchers)). The researchers will abide by these as well as the guidelines and regulations described in them in the conduct of their research as appropriate.
* All relevant governance responsibilities have been fulfilled **prior to submitting this request** for governance authorisation and are available for review upon request.

**Epworth participating hospitals (tick all applicable):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  Richmond | [ ]  Freemasons | [ ]  Camberwell | [ ]  Hawthorn | [ ]  Geelong |
| [ ]  Eastern | [ ]  Other (please specify): |

**Epworth researchers and support staff:**

Complete for all AIs and research support staff. All study personnel must be suitably qualified and experienced, familiar with relevant SOPs and authorised to conduct the research at Epworth (as per *SOP-RG-04 Researcher Credentialing, SOP-TM-14 Delegation of Duties*).

|  |  |  |
| --- | --- | --- |
| **Name:** | **Role in project:** | **SOP training completed?\*** |
|  |  |  |
|  |  |  |

Duplicate as necessary

\* SOP training must be completed and documented as per *SOP-QA-01 Documentation of Qualifications and Training Records*. All researchers involved in the conduct of clinical trials under the TGA Clinical Trial Notification (CTN) scheme at Epworth are required to demonstrate SOP training compliance before governance authorisation will be granted.

**Resources required at each site involved:**

|  |
| --- |
| [ ]  Epworth Unit/Ward(s) (please specify): |
| [ ]  Slade Pharmacy[ ]  Other pharmacy (please specify): |
| [ ]  Melbourne Pathology[ ]  Other pathology provider (please specify): |
| [ ]  Epworth Medical Imaging[ ]  Other radiology provider (please specify): |
| [ ]  Health Information Services |
| [ ]  Other (please specify): |

**The below have been completed and included in the Investigator Site File /study site folder (complete all questions):**

|  |  |
| --- | --- |
| 1. **Evidence of support from all relevant parties as per the Epworth Research Governance Approval Hierarchy** *(Appendix A, Epworth Research Handbook)*
 | [ ]  Yes |
| 1. **Detailed study budget and confirmation of appropriate funding arrangements** *(as per SOP-RG-03 Developing Contracts And Budgets)*
 | [ ]  Yes [ ]  N/A |
|  |  |
| 1. **Evidence of all ethical approval letters relating to the project from the reviewing ethics committee or confirmation of exemption from ethical review** *(as per SOP-RG-01 Research Governance)***:**
	1. Epworth HealthCare is listed as a site on Ethics Approval?
	2. HREC review and approval includes assessment of the Victorian Specific Module?

*\*Low Risk projects may not need the VSM to be submitted, this is at the reviewing committees discretion* | [ ]  Yes [ ]  Yes[ ]  Yes [ ]  N/A\*  |
| 1. **Epworth site specific documents prepared using the current approved master documents** *(as per SOP-RG-01 Research Governance)*
 | [ ]  Yes [ ]  N/A |
| 1. **Where study involves ionising radiation** *(as per SOP-RG-05 Conducting Research with Ionising Radiation)**(please tick if not applicable):*
	1. Exposure is in alignment with standard of care (if no, complete 6b and 6c)
	2. Medical Physics Risk Assessment Supporting Information Form (MPRAF) completed
	3. Site specific Medical Physicist report completed
	4. MPRAF and Medical Physicist report reviewed by HREC (must be yes if single site study, or existing multi-site study where Epworth is being added as a site and the radiation risk category for Epworth is deemed higher than that previously considered by the HREC for the study)
 | [ ]  N/A[ ]  Yes [ ]  No[ ]  Yes [ ]  Yes [ ]  Yes [ ]  No |
| 1. **Evidence of adequate Insurance and Indemnity** *(as per SOP-RG-02 Clinical Research Insurance and Indemnity)*
 | [ ]  Yes |

**Please confirm the following will be filed in the Investigator Site File prior to commencement** *(as per SOP-RG-01 Research Governance)***:**

|  |  |
| --- | --- |
| 1. **Evidence of the eCTN listing Epworth HealthCare as a site**
 | [ ]  Yes [ ]  N/A |
|  |  |
| 1. **Fully executed research agreement and indemnity.**
 | [ ]  Yes [ ]  N/A |
| 1. **Evidence the clinical trial is registered on a clinical trial registry\*.**

*\*Mandatory for all clinical trials. Please see Epworth Research Handbook for further guidance.* | [ ]  Yes [ ]  N/A |

Once all the governance responsibilities have been fulfilled, as outlined above, this form in addition to the following documents are to be submitted to the Epworth RDGU:

* Evidence of ethical approval
* Copy of the MPRAF and Medical Physicist Report (where study involves ionising radiation above standard of care)
* Site specific PICFs based on HREC approved documents (tracked and clean)
* Research Agreement for final Epworth sign-off (where applicable)
* Evidence of adequate Insurance arrangements outlined in the Research Agreement (where applicable)
* Indemnity for final Epworth sign-off (where applicable)

**DECLARATION SECTION:**

By signing this form the Principal Investigator at Epworth is certifying that this research project will be conducted in accordance with the *Epworth Research Policy*, the *Epworth Research Handbook,* all applicable Standard Operating Procedures, and the relevant Epworth policies and protocols including the current COVID-19 measures and guidance.

**Principal Investigator name:**

**Signature: Date:**

**AUTHORISATION SECTION:**

*RDGU Use Only*

**Date complete submission received:**

**RDGU Reviewing Personnel:**

**The project is supported by the Research Development and Governance Unit:**

**Sign: Date:**

Once the RDGU are satisfied with the governance structure in place, sign-off from the Group Chief Executive or delegate will be sought and governance authorisation granted.