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| --- |
| **Project Details** |
| **Project title** |  |
| **Principal investigator** |  |
| **Unit name** |  |
| **Clinical research coordinator** |  |
| **HREC reference** |  |
| **Coordinator Contact Details** |
| **E-mail:** |  |
| **Work Number:** |  |
| **Feasibility** |
| **Can the project be adequately integrated with standard of care?**  | **YES [ ]  NO [ ]**  |
| **What is the recruitment target for this site?** |  |
| **Is the recruitment feasible in the timeframe required?** | **YES [ ]  NO [ ]**  |
| **Financial Support** |
| **How is the trial funded?**  | **Pharmaceutical sponsor [ ]  Collaborative group [ ]  Investigator led [ ]**  |
| **Does the trial have proposed external funding?**  | **YES [ ]  NO [ ]**  |
| **Is the funding considered adequate to cover the costs of the trial?** | **YES [ ]  NO [ ]**  |
| **If no, how the gap in funding be covered?** (insert response below) |
| **How is the PI’s time allocated?**  | **Clinical [ ]  Non-clinical [ ]**  |
| **Cost centre or SPA number**  |  |
| **Strategic Benefit** |
| **The project has strategic benefit for the unit** | **YES [ ]  NO [ ]**  |
| **Signatures from the research unit** |
| **Principal Investigator** |
| **Name:** | **Signature:**  | **Date:** |
| **Division / Departmental Clinical/Unit Director^** |
| **Name:** | **Signature:**  | **Date:** |
| **Does the clinical/unit director have any comments?** (insert response below) |
|  |
| **Clinical Trials Committee – Office Use Only** |
| **Attached Documents** |
| **Finance summary** | **YES [ ]  NO [ ]**  |
| **Research Contract** | **YES [ ]  NO [ ]**  |
| **Indemnity** | **YES [ ]  NO [ ]**  |
| **Budget Assessment** |
| **Fully funded [ ]**  | **Under funded [ ]**  | **Approved [ ]**  | **Not approved [ ]**  |
| **Director of Research/Chair of Clinical Trials Committee**  |
| **Name: Ross Hannan** | **Signature:**  | **Date:** |
| **Deputy Director-General, Canberra Hospital &Health Services Approval** |
| **Name: Chris Bone** | **Signature:**  | **Date:** |
| **Ethics and Governance – Office Use Only** |
| **Ethics approved [ ]**  | **Site governance approved [ ]**  |
| **Head of Research Ethics and Governance**  |
| **Name: August Marchesi** | **Signature:**  | **Date:** |

^Where the PI is also the clinical/unit director please refer through the organisational structure for endorsement

This signed document signifies governance approval has been granted to begin the above named research project at ACT Health sites. Must contain all signatures to be valid**Research governance definition:**

‘an institutional framework to effectively oversee and administer research so that its conduct complies with relevant legislation and meets appropriate standards of quality, safety, privacy, risk and financial management’ (NHMRC)

**Aspects of the framework:**

Resources: human (staff and participants), material (pathology, pharmacy, clinic space, medical imaging etc)

Funding/Budget: pharmaceutical (or other) sponsors, research collaboration, grant funded, unit funded

Compliance: Insurance, Indemnity, legislation, institutional policy, risk management, safety, privacy, ethical acceptability

Quality: knowledge, experience, standards

**What are you agreeing to?**

**Principal Investigator:** interest in the study, feasibility assessment completed, believe study fits with the unit’s research plan, believe resources (human and material) are available, believe funding appears adequate (draft budget provided; final\* budget will be confirmed at a later date)

**Clinical/Unit Director^:** confirm research protocol meets the required quality standard,confirm strategic fit of study for the unit, availability of resources (human and material) for proposed study and fit with unit’s research plan, funding appears adequate (indicative draft\* budget provided; final budget will be confirmed at a later date following negotiation with the sponsor)

**Director of Research:** confirms strategic fit of the study for ACT Health; confirms budget is appropriate to recover the costs of conducting the trial

**Deputy-Director General CHHS:** agrees with recommendations above; endorses CTA (including final budget), endorses indemnity

**Head of REGO:** confirms appropriate ethical and governance reviews have been completed; confirms legislative requirements have been met; confirms insurance coverage has been agreed; finance summary included

\*The budget will be considered final upon receipt of a finance summary from the Clinical Trials Unit finance officer, receipt of a Clinical Trial Agreement (CTA) signed by the PI and sponsor. Together these documents will be considered by the Clinical Trials Committee to assess and confirm the proposed budget meets the costs of running the trial.

^Where the clinical/unit director is also the proposed PI the proposal must be referred to management through the organisational structure. For example to the Clinical Director or Medicine or the Chief Medical Officer.