**PTNA CLINICAL TRIAL CONCEPT DEVELOPMENT SCHEME PROCESS**

* PTNA invites its network members to submit new research concepts for review and feedback. See website for more details: [www.ptna.com.au](http://ptna.com.au/index.php/research-workshops/concept-development-scheme)
* Use the Request for Concept Development Review Template, next page.

**Step 1: Submission of concept**

Researcher

* Submit Request for review (max. 3 pages)
* Attach appropriate conflicts of interest declaration/s
* Agree to conditions of review (acknowledgement and presentation)
* Submit by deadline

PTNA

* Send a receipt for the Request to the researcher
* Review conflicts of interest declarations prior to review

**Step 2: Review, Query, Respond**

PTNA

* Panel undergoes review
* Provide feedback and queries to researcher – may include a teleconference

Researcher

* Respond to queries (+/- draft grant application for money or services)

**Step 3: Recommendation**

PTNA

* PTNA Steering Committee provides a recommendation with regard to proceeding.

**What else can PTNA do for you?**

* Offer you a grant (under $5000) or services such as biostatistics, health economics, study design to develop your concept^
* Provide you with further discounts to WebSpirit, PTNA’s clinical data management system
* Identify and approach recruitment sites and other investigators for you
* Connect you with infrastructure and services\*
* Provide a platform, the PTNA Trials Day, to present your concept to the paediatric research community.

^ PTNA recommends particular service providers. If you wish to engage an alternative service provider it would be subject to PTNA Steering Committee approval.

\*Most infrastructure and facilities that support clinical trials run on a fee-for-service basis. Remember to factor in these costs to your grant application if you wish to continue to use these services beyond the PTNA grant.

**REQUEST FOR CONCEPT DEVELOPMENT**

* Research must include at least one other state or territory
* Request should be no longer than 3 pages, font 11.

|  |
| --- |
| **TITLE OR RESEARCH QUESTION** |
|  |

|  |
| --- |
| **NAME and CONTACT DETAILS**  |
| Name |  |
| Employing Organisation/s |  |
| Telephone/Mobile |  |
| Email |  |

|  |
| --- |
| **CLINICAL DISCIPLINE/ RESEARCH THEME:**  |
|  |

|  |
| --- |
| **STUDY AIM/S** |
|  |

|  |
| --- |
| **HYPOTHESIS** |
|  |

|  |
| --- |
| **PRIMARY OUTOMES** |
|  |

|  |
| --- |
| **SECONDARY OUTCOMES** |
|  |

|  |
| --- |
| **BACKGROUND** (include why the information to be gained from this study is important) |
|  |

|  |
| --- |
| **TRIAL DESIGN and METHODS** (include the setting, procedures, general features: RCT, longitudinal, retrospective/prospective, arms, stratification, decision points, phase) |
|  |

|  |
| --- |
| **PARTICIPANTS (description of target population) (sample size and justification)** |
|  |

|  |
| --- |
| **ESTIMATED TIME FRAME (incl. planned first patient, planned closure to follow up)** |
|  |

|  |
| --- |
| **ESTIMATED BUDGET and POTENTIAL SOURCES OF FUNDING** |
|  |
| **POTENTIAL ADMINISTERING INSTITUTION FOR GRANT (if determined)** |
|  |

|  |
| --- |
| **RECRUITMENT JURISDICTIONS**  |
| [ ]  ACT  | [ ]  QLD | [ ]  NSW |
| [ ]  NT | [ ]  SA | [ ]  TAS |
| [ ]  VIC | [ ]  WA | [ ]  All/Any |

|  |
| --- |
| **INDUSTRY PARTNER/S INVOLVED?** |
|  |

|  |
| --- |
| **ANY PARTICULAR ETHICAL CONSIDERATIONS** |
|  |

|  |
| --- |
| **CHALLENGES (for which you would like particular advice)** |
|  |

|  |
| --- |
| **HAVE YOU SOUGHT REVIEW ELSEWHERE, BY WHOM AND WHEN?**  |
|  |