Please submit the completed form to concept@bctrials.org.au for submission to the BCT Operational Executive Committee.

The purpose of this submission is so BCT can assess if the concept proposal falls within the remit of BCT and/or if there are potentially overlapping studies already planned or in progress. If this is the case, BCT will discuss this with you to assist you with deciding whether and how to progress the concept.

Please ensure that you are familiar with the [BCT clinical trial development/discretionary funding application process](https://www.breastcancertrials.org.au/research/research-development-and-funding/) before submitting this form.

*Please ensure you have the latest version of this form by downloading from* [*https://www.breastcancertrials.org.au/research-development-and-funding*](https://www.breastcancertrials.org.au/research-development-and-funding)

|  |  |
| --- | --- |
| **Name of Investigator:**  |  |
| **Institution:**  |  |
| **Email:**  |  |
| **Phone/mobile number:**  |  |

|  |  |
| --- | --- |
| **Date submitted to BCT:** |  |

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| **Type of Project (check one only):** |
| [ ]  **Clinical Trial Development** | Supports longer-term research projects (minimum three years) of high strategic value that are unfunded. Projects will be developed and coordinated by the BCT Trials Department.*Please note: BCT typically conducts Phase II and III trials. Phase I trials may be considered by BCT where the science has originated from the laboratory of a BCT member, drug supply is available and there is a clear pathway to Phase II and III trials led by BCT.* |
| [ ]  **Discretionary Funding Application** (see below) | A one-off grant of up to $50,000 per year, over 1-2 years. Discretionary Funding grants are primarily to support small scale research studies such as Pilot studies that have the potential to lead to BCT-coordinated clinical trials. Funding may also be considered for sub-studies of existing research protocols in which BCT is participating, associated small-scale translational research studies, or projects related to research methodology. |
| **For Discretionary Funding Applications:** please provide an outline of a potential future BCT trial arising as an outcome of the Discretionary Funding concept: |
|  |
| **Title of Concept:** |  |

|  |
| --- |
| Concept ProposalPlease provide a brief description of your concept *(depending on the nature of the concept, some sections may not be relevant)*. |
| 1. **PROPOSAL OUTLINE**
 |
| **Background/Rationale (1 paragraph)** |
|  |
| **Hypothesis/Aim** |
|  |
| **Key Objectives/Endpoints** |
|  |
| **Key Inclusion/Exclusion Criteria** |
|  |
| **Sample Size** |
|  |
| **Intervention(s)** |
|  |
| 1. **PHARMACEUTICAL/DEVICE INVOLVEMENT** [ ]  Yes – please complete this section

 [ ]  No – continue to Section 3 |
| Name of drug/device involved with this concept?  |  |
| Is this drug/device currently approved by the TGA, FDA or EMA? [ ]  Yes [ ]  No\* |
| \* If not approved, what stage of clinical testing is it at? |
|  |
| What pharmaceutical company/ies make this agent/device? |
|  |
| Have you had any preliminary discussions to gauge their interest in this concept?[ ]  No [ ]  Yes – please comment below: |
|  |
| OTHER ORGANISATION INVOLVEMENT [ ]  Yes – please list other organisations and their involvement below  [ ]  No – continue to Section 4 |
|  |
| PRIOR DISCUSSION WITH RELEVANT BCT SUBGROUP [ ]  Yes – please list Subgroup and meeting date(s) below  [ ]  No – continue to Section 5 |
|  |
| 1. **DOES THIS CONCEPT RELATE TO (complete as applicable):**
 |
| [ ]  Previous BCT trial(s) (list):  |  |
| [ ]  Current BCT trial(s) (list): |  |
| [ ]  Future BCT-sponsored clinical trial proposal (please provide description): |
|  |
| **BCT’s ROLE**How do you envisage BCT assisting you in realising this concept (check all that apply): |
| [ ]  Provide feedback on a concept to allow further development |
| [ ]  BCT to consider implementing this trial proposal as Sponsor (i.e. assist with sourcing funding, protocol development and trial coordination) |
| [ ]  BCT to consider participation in an existing trial in a trial sponsored elsewhere |
| [ ]  BCT to help develop the concept and provide seed funding for a pilot project (i.e. Discretionary Funding) |
| [ ]  Other; please specify: |
|  |
| Please provide additional comment on how BCT may assist: |
|  |

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| --- |
|  Concept Development Work Group (CDWG)If the BCT Operational Executive Committee (OEC) advises you that there are no overlapping studies and you choose to progress this concept, the OEC requests that you assemble a CDWG. The purpose of the CDWG is to assist you with the next step, developing a project synopsis/discretionary funding application. The CDWG should generally include:1. A statistician; and
2. A representative from the BCT Consumer Advisory Panel;

as well as a minimum of 2 experts from the specialty area\*.Please advise below if you would like BCT to assist you in identifying appropriate people for 1) or 2). |
| 1. Name of statistician:
 |  |
| 1. Name of Consumer Advisory Panel representative:
 |  |

*\*N.B. The Operational Executive may nominate a relevant Subgroup to assist with the CDWG. The Subgroup/Subgroup Chair(s) may identify other experts (minimum of 2) from any specialty area pertaining to the subject of the proposed trial.*

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| --- |
| BCT Operational Executive Feedback |
| [ ]  **Within BCT’s remit and no overlapping studies** *(forward Project Synopsis/Discretionary Funding Application to PI)*[ ]  **Overlapping studies (requires further discussion)**[ ]  **Not within BCT’s remit** |
| **Comments:** |

*Please submit the completed form to the BCT Operational Executive (concept@bctrials.org.au).*

***PLEASE NOTE:***

*Approved Concepts undergo development in collaboration with a CDWG into either a Project Synopsis (for a proposed Clinical Trial) or a Discretionary Funding Application.*

*Discretionary Funding Applications will be considered by the BCT Operational Executive Committee.*

*A Project Synopsis will be peer reviewed; reviews will be provided to the investigator and tabled at the next scheduled SAC meeting, and the investigator will also be invited present at the SAC meeting.*

*If BCT support for a grant application is needed, then BCT support must be confirmed (usually after peer- and SAC-review of the Project Synopsis) and sufficient protocol logistics developed to allow budget formulation. Supply of study treatment or other in-kind support must be confirmed.*