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| **TROG Trial Type;**  |  |
|[ ]  **Category A** | Investigator initiated trial or registry which will be carried out under the auspices of TROG |
|[ ]  **Category B** | A trial initiated by an international trials group and TROG to act in the role of the ANZ sponsor |
|  |  |  *Lead Group:* | *Please specify* |
|[ ]  **Category C** | A trial initiated and sponsored by another trials organisation, for collaboration |
|  |  |  *Sponsor:* | *Please specify* |
|  | ***Category D*** | *Investigator initiated project that involves data capture, data mining or secondary analysis.* *Please completed a TROG Data Request form*  |

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| **Proponent name**  |  |
| **Institution** |  |
| **Email** |  |
| **Phone/mobile number** |  |
| **TROG FULL member status** | [ ]  FULL member [ ]  Not a FULL member\*\*  |
| *\*\*TROG will only consider Cat A and B proposals submitted by FULL TROG members. Go to* [*https://trog.com.au/member-apply/*](https://trog.com.au/member-apply/) *to sign up as a full member or contact* *membership@trog.com.au* |

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| **FULL Title** |  |
| **SHORT Title**  |  | [ ]  NA |
| **ACRONYM** |  | [ ]  NA |
| **Proposals status**  | [ ]  New submission[ ]  Updated *(please highlight the sections in this form that have been updated)*  |

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| **Tumour Group** | Choose a subspecialty group from the drop down menu |  |
| Other;  |

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| **Has this proposal been sent to another collaborative group for review?**  | [ ]  | Yes: Please specify group and *if applicable*, trial number allocated  |
| [ ]  | Not yet, but planning to submit it to: Please specify |
| [ ]  | No other collaborative group will be involved |

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| **Additional Study Investigators**  | *
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| **Any supporting documents ATTACHED to this form***(Check all that apply)* | [ ]  | Trial synopsis/summary |
| [ ]  | Trial protocol |
| [ ]  | RTQA guidelines |
| [ ]  | Other collaborative group support letter |
| [ ]  | Other document/s; Please specify |
| [ ]  | Other document/s; Please specify |

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| 1. **Trial/Project Synopsis**

*(Please insert brief statements. Your explanations should be clear and succinct.)*  |
| **Study summary** *(in lay terms)* | *Please ensure the lay summary includes sufficient information in lay language and includes 1. Study rationale, 2. Treatment/intervention, 3. Side effects and other risks/challenges*  |
| **Background, medical and scientific rationale** |  |
| **Systematic Review status** *(As of 2020, a systematic review is required for NHMRC funding applications)* | [ ]  Completed; please provide details [ ]  Planned; please provide timeline [ ]  Not done; please state reasons  |
| **Hypotheses** |  |
| **Aim** |  |
| *(add additional rows if required)* | **Objective** | **Endpoint** | **Measure** |
| ***Primary:*** |  |  |  |
| ***Secondary:*** |  |  |  |
| ***Tertiary/Exploratory:*** |  |  |  |
| **Feasibility** |  |
| **Significance** |  |
| **Risks** |  |
| **Safety**  |  |
| **Quality of Life\*** | *Outline any potential impact of disease and intervention on patient-reported outcomes (e.g., disease symptoms, treatment toxicity, functioning).*  |
| **Health economics\*** | *Outline any potential health economic analysis that could be included.* |

*\*The Cancer Australia supported National Technical Services,* [*CQUEST*](https://www.uts.edu.au/research/centre-health-economics-research-and-evaluation/cancer-quality-life-expert-service-team-cquest) *and* [*CREST*](https://www.uts.edu.au/research-and-teaching/our-research/cancer-research-economics-support-team)*, will review all TROG Cat A & B proposals and provide feedback.*

1. **Trial/Project Design**

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| **Study phase** | Please select | Other: Please specify |
| **Outline study schema / schedule** | *(Text outline)* |
| *(Diagrammatic outline of the study)* |
| *Study procedures (type and timings) / Schedule of assessments*  |
| **Target population** |  |
| **Key eligibility** | **Inclusion:**  |
| **Exclusion:**  |
| **Planned No of study sites**  | **International**: **TROG**: |
| **Will AUST regional centers be able to take part in this study?**  | [ ]  Yes[ ]  No Please specify why  |
| **Could this be run as a tele-trial?** | [ ]  Yes[ ]  No Please specify why |
| **Intervention/s** | *Please outline treatment for each trial arm* |
| **RTQA program outline** | **Technique/s allowed**  |  |
| **Audit required**  |  |
| **Benchmarking required** |  |
| **Pre-Trial review** |  |
| **Post-Trial review** |  |
| **Study duration** | **STUDY PERIOD**  | **ESTIMATED TIME FRAME** |
| **Development** |  |
| **Recruitment** |  |
| **Follow-up** |  |
| **Analysis** |  |
| **OVERALL DURATON (Yrs)** |  |

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| 1. **Statistics**
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| **Sample size** | **International**: **TROG**:  |
| **Statistical considerations** |  |
| **Have these methods / sample sizes been discussed with a statistician?**  | [ ]  Yes Please specify[ ]  No [ ]  NA  |

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| 1. **Budget** *(Complete for Category A and B)*
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| **Has a budget been developed to conduct the study / project** | [ ]  Yes; Please specify brief details [ ]  No  |
| **Funding source:**  | Name: [ ]  Secured / [ ]  In negotiation / [ ]  Planned grant submission |
| Name: [ ]  Secured / [ ]  In negotiation / [ ]  Planned grant submission |
| **In-kind support**  |  |
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| 1. **Project Logistics**
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| **Will TROG be required to manage any of the project/trial logistics?** |
|  | **Yes** | **No;** | **specific details** *(please enter contact details of responsible party if known)* |
| **Collaborative Group Services**  |[ ] [ ]   |
| Participant indemnity |[ ] [ ]   |
| Site contracts  |[ ] [ ]   |
| Regulatory approvals (TGA, HREC etc) |[ ] [ ]   |
| **RT Quality Assurance program** |[ ] [ ]   |
| **Central Trial Services** |[ ] [ ]   |
| Site set up and management |[ ] [ ]   |
| Query management / data cleaning  |[ ] [ ]   |
| Biological specimen management  |[ ] [ ]   |
| Biological specimen shipping  |[ ] [ ]   |
| Services Australia data (request /extract)  |[ ] [ ]   |
| Study drug management  |[ ] [ ]   |
| Trial database build  |[ ] [ ]   |
| Other\*: Please specify |[ ] [ ]   |
| Other\*: Please specify |[ ] [ ]   |

\*For example; Shipping, storage and/or import licenses for Biological Specimen or Study Drug

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| 1. **References**
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| 1. **Addition information for consideration**
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| [ ]  *None to consider*  |