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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*](mailto: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** | |
| **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)* | |
| **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** |
|  |
| 1. **Addition information for consideration** |
| *None to consider* |