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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 | | |
| *Study sponsor:* | *Please specify* | |
|  | **Category D** | Investigator initiated project that involves data capture, data mining or secondary analysis  Please specify:  Project |  Secondary Analysis | | |

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| **Proponent** |  |
| **Institution** |  |
| **Email** |  |
| **Phone/mobile number** |  |
| **TROG member status** | FULL member  AFFILIATE member  NON-member |

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| **FULL Title** |  | |
| **SHORT Title** |  | NA |
| **Acronym** |  | NA |

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| **Is this a secondary analysis / data request?** |  | Yes *(please complete sections 1, 2b, 3, 8 and 9)* |
|  | No *(please complete sections 1, 2a, 3, 4, 5, 6, 7, 8 and 9)* |

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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 |
|  | Data request approval from the chair or TMC for the original trial/s |
|  | 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)* |  | | |
| **Background, medical and scientific rationale** |  | | |
| **Hypotheses** |  | | |
| **Aim** |  | | |
| *(add additional rows if required)* | **Objective** | **Endpoint** | **Measure** |
| ***Primary:*** |  |  |  |
| ***Secondary:*** |  |  |  |
| ***Tertiary/Exploratory:*** |  |  |  |
| **Feasibility** |  | | |
| **Significance** |  | | |
| **Risks** |  | | |
| **Safety** |  | | |

1. **Trial/Project Design***(complete section ‘a’ for Cat A, B, C trials or ‘b’ Cat D secondary analysis/data requests)*
   1. *Category A, B, C trials*

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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** |  | | | | | |
| **Planned No of study sites** | **International**:  **TROG**: | | | | | |
| **Will regional centers be able to take part in this study** |  | | | | | |
| **Key eligibility** | **Inclusion:** | | | | | |
| **Exclusion:** | | | | | |
| **Intervention/s** | **Arm 1** | | **Arm 2** | | | **Arm 3** |
| ***Radiotherapy*** |  | |  | | |  |
| ***Medicinal*** *(IMP or standard)* |  | |  | | |  |
| ***Observation*** |  | |  | | |  |
| ***Other*** Please specify |  | |  | | |  |
| **RTQA program outline** | **Technique/s** |  | | | | |
| **Audit** |  | | | | |
| **Benchmarking** |  | | | | |
| **Pre Trial Review** |  | | | | |
| **Post Trial Review** |  | | | | |
| **Study duration** *(Cat A, B and C proposals)* | **Development**:  **Recruitment**:  **Follow-up**:  **Analysis**: | | | | **TOTAL**: | |

* 1. *Category D- secondary analysis/data requests*

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| **Which TROG Cancer Research clinical trial are you requesting data from?** | Protocol number:  Title:  Chair: |
| **Has this request/project been discussed with the trial chair and/or TMC?** | Yes (please attached correspondence/approval)  No |
| **Data required**  *(RTQA, RT Planning imaging, Clinical outcomes, baseline etc.)* |  |
| **Data format required**  *(DICOM, PDF, JPEG, excel etc.)* |  |
| **Anticipated timeframe** | IRB/Ethics/Approvals; dd / mm / yyyy  Data export; dd / mm / yyyy  Analysis; dd / mm / yyyy  Report/Publication; dd / mm / yyyy |
| **Will proposal require additional HREC approval or consent of the participants?** | Yes  No  Unsure |
| **Proposed project budget** |  |
| Has funding for accessing the data been included? | Yes  No |
| Funding source | Name:  Secured /  In negotiation /  Planned grant submission |

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| 1. **Statistics** | |
| **Statistical methods** |  |
| **Sample size**  *(Cat A, B and C proposals)* | **International**:  **TROG**: |
| **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  No | |
| **Proposed budget:** |  |  |
| **Funding source:** | Name:  Secured /  In negotiation /  Planned grant submission | |
| Name:  Secured /  In negotiation /  Planned grant submission | |

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| 1. **Project Logistics** *(Complete for Category A, B and C proposals)* |

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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. **Potential Substudies** *(Complete for Category A and B)* | |
| **Is there potential for a substudy?** | Yes (please completed outline below)  No |
| *Initial Outline:* | |
| 1. **Integration in to TROG Cancer Research clinical trials research program** *(Complete for Category A, B and C proposals)* | |
| **How the proposed study will support the TROG Cancer Research clinical trials research program?** |  |
| **Is the proposed new study related to a current TROG Cancer Research clinical trial or substudy?** | Yes (please completed below)  No |
| Protocol number and/or title: |  |
| Relationship: |  |
| How will it improve the current study: |  |

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