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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 analysisPlease 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 / yyyyData export; dd / mm / yyyyAnalysis; dd / mm / yyyyReport/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**
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| **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**
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| 1. **Addition information for consideration**
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| [ ]  *None to consider*  |