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

|  |  |
| --- | --- |
| **FULL Title** |  |
| **SHORT Title**  |  | [ ]  NA |
| **Acronym** |  | [ ]  NA |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Additional Study Investigators (Add rows as required)** | **Name**  | **Institution** | **Email** |
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| **Is this data for use in a research degree?** | [ ]  Yes Please specify 1. *(if different from above)* Candidate name, degree, email and institution
2. Supervisor name, email and Supervisor Institution

[ ]  No  |

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| --- | --- |
| **Has approval been obtained from the chair or TMC of the original trial/s for use of the data?** | [ ]  Approval obtained; Please outline by who and when *(and supply a copy of the evidence)*[ ]  Approval requested; Please outline to who and when [ ]  Approval has not been sort; Please outline i) to who and when it will be sort OR ii) if original study team can not be contacted or assistance is needed to obtain approval.  |

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| **Any supporting documents ATTACHED to this form***(Check all that apply)* | [ ]  | Support Letter |
| [ ]  | Ethical or Governance Review  |
| [ ]  | Other document/s; Please specify |
| [ ]  | Other document/s; Please specify |

1. **Project Synopsis**

|  |  |
| --- | --- |
| **Study summary** *(in lay terms)* |  |
| **Background, medical and scientific rationale** |  |
| **Hypotheses** |  |
| *(add additional rows if required)* | **Objective** | **Endpoint** | **Measure** |
| ***Primary:*** |  |  |  |
| ***Secondary:*** |  |  |  |
|  |  |  |  |
| ***Tertiary/Exploratory:*** |  |  |  |
|  |  |  |  |
| **Feasibility***(Explain how the requested data is suitable for addressing the hypotheses; the relevant skills the study investigators have, citing previous publications where appropriate)* |  |
| **Significance***(Specify how the proposed analysis will enable actionable outcomes from the analysed data* |  |
| **Risks** |  |
| **Safety**  |  |

1. **Project Design**

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| --- | --- | --- | --- | --- | --- |
| **Which TROG Cancer Research clinical trial/s are you requesting data from?** | **Protocol number** | **Title or Acronym** | **Trial Chair/s** | **Has the primary analysis has been published?** | **Original participant consent covers this requested data use?**  |
|  |  |  | [ ]  Yes [ ]  No\* | [ ]  Yes [ ]  No |
|  |  |  | [ ]  Yes [ ]  No\* | [ ]  Yes [ ]  No |
|  |  |  | [ ]  Yes [ ]  No\* | [ ]  Yes [ ]  No |
|  |  |  | [ ]  Yes [ ]  No\* | [ ]  Yes [ ]  No |
| \*If the primary analysis of the original study has NOT been published, has endorsement of this secondary analyses been supported by the Data Monitoring Committee?  |

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| Trial  |  |
| Support received | [ ]  Yes [ ]  No | Comment:  |
| Evidence of support attached  | [ ]  Yes [ ]  No | Comment: |

|  |  |
| --- | --- |
| Trial  |  |
| Support received | [ ]  Yes [ ]  No | Comment:  |
| Evidence of support attached  | [ ]  Yes [ ]  No | Comment:  |

 |
| **Does this proposal involve a re-analysis of the original data** | Trial: | [ ]  Yes [ ]  No | *If Yes, has the primary statistician been consulted* | [ ]  Yes [ ]  No |
| Trial: | [ ]  Yes [ ]  No | *If Yes, has the primary statistician been consulted* | [ ]  Yes [ ]  No |
| Trial: | [ ]  Yes [ ]  No | *If Yes, has the primary statistician been consulted* | [ ]  Yes [ ]  No |
| Trial: | [ ]  Yes [ ]  No | *If Yes, has the primary statistician been consulted* | [ ]  Yes [ ]  No |
| **Details of Requested data** | **Protocol number** | **Data required** *(e.g. RTQA, RT Planning imaging, Clinical outcomes, specific CRF and/or variables etc.* Please be as descriptive as possible, as this will help with collating the data extract*)* | **Data format required** *(DICOM, PDF, JPEG, excel etc.)* |
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| **How will the data be transferred, stored (include length of time) and destroyed?**  | **Transfer method**:  | **Storage**:  | **Destruction method**:  |
| **Is the proponent the receiving party for the data?**  | [ ]  Yes[ ]  No Please specify* Receiving Person:
* Institution details (name, address and *if applicable* ABN):
 |
| **Anticipated timeframe**  | IRB/Ethics/Approvals; dd / mm / yyyy Analysis; dd / mm / yyyy Report/Publication; dd / mm / yyyy  |
| **Is additional HREC approval required?**  | [ ]  Yes[ ]  This has been received (approval date dd / mm / yyyy)[ ]  Applied for, pending outcome[ ]  To be submitted (expected date of submission dd / mm / yyyy )[ ]  No  |
| **Will additional consent of the participants required for use of the data and/or request of additional data (e.g survival status, tumour recurrence, access to imaging files etc)?**  | [ ]  Yes[ ]  No |
| **Proposed project budget**  |

|  |  |
| --- | --- |
| Data extraction  | $ |
| Statistic support | $ |
| Approval fees  | $ |
| Other Please specify | $ |
| Other Please specify | $ |
| **TOTAL** | **$**  |

 |
| Funding source | Name: Status: [ ]  Secured / [ ]  In negotiation / [ ]  Planned submission |

1. **Statistics**

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| --- | --- |
| **Statistical methods /Analysis Plan** |  |
| **Have these methods been discussed with a statistician?**  | [ ]  Yes Please specify[ ]  No  |

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