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

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| **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**

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| --- | --- | --- | --- |
| **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? | |  |  | | --- | --- | | 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 |

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