**SNAP Trial: Sub-study Expression of Interest (EOI)**

An Expression of Interest (EOI) is the first stage of the review process for all sub studies. The sub-study lead(s) will be required to complete the sub-study EOI template and return the completed form to the SNAP Management Team (snap-trial@unimelb.edu.au).

Please refer to the [**SNAP Trial Sub-Study Guidance Document**](https://www.snaptrial.com.au/for-investigators#integrity) for more information.

The EOI will be reviewed by the Design Working Group and their recommendation noted at the next GTSC meeting. All comments/questions will be returned to the sub-study lead(s) within two weeks of the Design Working Group review.

|  |
| --- |
| 1. **SUBSTUDY INVESTIGATOR DETAILS**
 |
| Name of Project Leader *(lead person)* |  |
| Email Address |  |
| Institution & Region |  |
| Other Sub-Study Collaborators |  |
| Do you or any sub-study collaborators have any conflicts of interest to declare? | [ ]  Yes [ ]  No |
| If yes, please state details of the perceived conflict(s) |  |

|  |
| --- |
| 1. **SUBSTUDY PROJECT DETAILS**
 |
| Title of project: |  |
| Proposed Short Title of Project *(if available)*:  |  |
| Proposed Sub-Study Category(*See Substudy SOP for further detail)* | [ ]  New domain[ ]  Integrated/Nested Clinical Trial[ ]  Prospective Sub-Study[ ]  Secondary Use of Data & Biospecimens Analysis |
| Proposed Regions | [ ]  Any regions interested in participating[ ]  Specific Regions *(please specify):*  |
| SNAP Enrolment*(select one)* | [ ]  Platform Patients Only[ ]  Registry Patients Only[ ]  Both Platform AND Registry Patients[ ]  Divert Patients from SNAP |
| SNAP Participants *(select all that apply)* | [ ]  Adults[ ]  Children [ ]  Pregnant Patients[ ]  Other *(please specify):*  |
| Timeline and Deadlines/Milestones for the project:*(Include recruiting start and data collection finish dates. If there is a grant associated, please provide details regarding the key milestones)* |  |

|  |
| --- |
| 1. **SUBSTUDY PROPOSAL OUTLINE – *No more than 700 words***
 |
| Background and Rationale |  |
| Hypothesis/Research Questions |  |
| Methods |  |
| Project Endpoints/Outcomes |  |
| What data points and/or specimens are required or brief schedule of events |  |

|  |
| --- |
| 1. **SUBSTUDY REVIEW CRITERIA – *Please provide a brief justification/response to each of the following points. Where a section is not relevant to the project, please indicate ‘Not applicable’ in your response.***
 |
| **Trial Integrity***Does this sub-study require access to data that could threaten trial integrity? Does this sub-study wish to report on trial outcomes prior to the SNAP Trial Results paper? Does the sub-study wish to report on sub-study outcomes by treatment allocation prior to the SNAP Trial Results paper?* |  |
| **Harmony with SNAP Protocol***Are the sample/data collection harmonised with the SNAP core protocol and other SNAP sub-studies?* |  |
| **Adoption of the Pragmatic Trial Approach***Does this sub-study place a significant additional burden on the participant or the site study team? Does the proposal include only the necessary data collection to answer the research question?* |  |
| **Feasibility***Is the sample size reasonable and achievable? Will the research question be able to be answered recruiting only SNAP Trial participants?* |  |
| **Global Application***Has the investigator considered the ability for the sub-study to be conducted in other regions/countries? Is the protocol applicable to other countries/regions?* |  |
| **Paediatric & Pregnancy Involvement***Has the investigator considered the involvement of children and pregnant patients? If not involving these participants, has this been sufficiently justified?* |  |
| **Funding***Has funding for this sub study been considered or obtained? Are there any grants the investigator is intending to apply for to cover the costs of the sub-study? Has a proposal been put forward to the central team for covering some or all of the costs?* |  |
| **Sample Collection, Analysis & Shipping***Will samples be collected for this sub study and shipped to an external location? Has the shipping and storage of theses samples been considered? Has a plan for the analysis been generated?* |  |
| **Integration with the Statistical Model***Will this sub-study require integration into the overall SNAP statistical model?*  |  |

|  |
| --- |
| 1. **Design WG REVIEW – *TMG USE ONLY***
 |
| Date of Design WG Review: |  |
| Decision: | [ ]  Revise EOI & Respond to Comments *(Section 6 below)*[ ]  Proceed to Full Protocol & Respond to Comments, if required *(Section 6 below)*[ ]  Recommend for ratification by TSC and proceed to Data / Isolate Request Process[ ]  Recommend not proceed further at this time[ ]  Recommend for co-enrolment |

|  |
| --- |
| 1. **RESPONSE TO QUERIES *– Please complete this section upon resubmission of your EOI if required***
 |
| Query 1: | Query 1 Response:  |
| Query 2 (repeat as required): | Query 2 Response (repeat as required): |

|  |
| --- |
| 1. **GTSC RATIFICATION – *TMG USE ONLY***
 |
| Date of GTSC Meeting: |  |
| Document Ratified | [ ]  EOI & Proceed to Data/Isolate Request *(Secondary Use of Data Only)*[ ]  Full Protocol *(all other sub-studies)* |