HEALTH ECONOMIC CHECKLIST for CLINICAL TRIALS

1. Is the trial an international trial?
   - ☐ Yes
   - ☐ No *(go to question 4)*

2. Are you anticipating conducting local sub-studies (including an Australian/New Zealand analysis of a pre-established study outcome)?
   - ☐ Yes: Number of local patients _____ *(go to question 4)*
   - ☐ No

3. Is there scope for the local investigators to influence the international protocol?
   - ☐ Yes *(go to question 4)*
   - ☐ No *(do not complete this checklist)*

4. Have you incorporated a health economic analysis/study into your trial?
   - ☐ Yes, *please follow* ***pathway A***
   - ☐ No, *please follow* ***pathway B***

Please refer to https://www.uts.edu.au/sites/default/files/2019-04/crest-factsheet-why-economic-evaluation.pdf if you want to know more about conducting a health economic analysis.

Pathway A: a health economic analysis is either being considered or some rationale has been proposed that supports its consideration.

1. What type of clinical trial is this trial?
   - ☐ Interventional
   - ☐ Observational (non-interventional)

2. What is the aim of your study (*choose all that apply*)?
   - ☐ Descriptive (i.e. systematic review of the literature)
   - ☐ Change current practice *(e.g Phase III)*
   - ☐ Construct a registry
   - ☐ Instrument validation
   - ☐ Feasibility study *(e.g Phase II, randomised Phase II)*
   - ☐ Safety *(e.g Phase I, Phase Ib)*
   - ☐ Other

   Please specify: _____

3. Is the intervention expected to impact the quality of life (QoL) of patients or carers?
   - ☐ Yes *(please describe how it is expected to change QoL relative to current practice)*
   - ☐ No *(go to question 5)*

   Description: _____

4. If differences in terms of QoL are expected, do you plan to use any generic or disease specific instrument to measure quality of life?
   - ☐ Yes

   Which one/s: _____

   - ☐ No

5. Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?
   - ☐ Yes (*go to question 6)*
   - ☐ No (*go to question 9*)

6. What do you think is contributing to the difference in resource use (*choose all that apply*)?
   - ☐ The intervention itself.
   - ☐ Differences in the incidence of AEs which lead to differences in management, hence costs.
   - ☐ Differences in the management of the disease other than the intervention.
   - ☐ The intervention is expected to prolong life; hence patients are expected to incur more healthcare costs.
   - ☐ Differences in concomitant medications.
   - ☐ Differences in required procedures.
   - ☐ Differences in numbers of cases detected (for diagnostic interventions).

7. Do you think patients incur costs beyond health-related costs (i.e. time, carers, productivity, etc.)?
   - ☐ Yes
   - ☐ No

8. Are you considering asking patients for consent to access their Medicare data (MBS & PBS) and/or hospital record data to identify resource use?
   - ☐ Yes
   - ☐ No

9. In the context of this research, are you interested in knowing the preferences of patients or carers for the treatment options being compared in the trial?
   - ☐ Yes
   - ☐ No

Recommendation:

*If you answered **yes** to questions 3, 5 and/or 9, please contact your Clinical Trial Group (CTG) to request a health economics audit for this study.*

Pathway B: a health economic analysis is not currently being considered, but it would be helpful to assess whether it might be relevant.

1. What type of clinical trial is this trial?
   - ☐ Interventional
   - ☐ Observational (non-interventional), go to question 5.

2. What is the aim of your study (*choose all that apply*)?
   - ☐ Descriptive (i.e. systematic review of the literature)
   - ☐ Change current practice *(e.g Phase III)*
   - ☐ Construct a registry
   - ☐ Instrument validation
   - ☐ Feasibility study *(e.g Phase II, randomised Phase II)*
   - ☐ Safety *(e.g Phase I, Phase Ib)*
   - ☐ Other

   Please specify: _____

3. Is the intervention expected to impact the quality of life (QoL) of patients or carers?
   - ☐ Yes (*please describe how it is expected to change QoL relative to current practice*)
   - ☐ No

   Description: _____

4. Have you identified any potential differences in terms of resource use between the intervention and comparator/current practice (which may result in differences in costs)?
   - ☐ Yes *(please provide description below)*
   - ☐ No *(go to question 5)*

   Description: _____

5. Have you planned to collect data regarding resource use related to the intervention?
   - ☐ Yes
   - ☐ No

6. In the context of this research, are you interested in knowing about the preferences of patients or carers for the alternative treatment options in the trial?
   - ☐ Yes
   - ☐ No

Recommendation:

*If you answered **yes** to questions 3, 4, and/or 6, please contact your Clinical Trial Group (CTG) to request a health economics audit for this study.*