ACTA Statistics in Trials Interest Group (STInG) Submission on the Structural Review of NHMRC's Grant Program

Response to the Public Consultation Paper

August 2016

Submission from the
Australian Clinical Trials Alliance (ACTA)
Statistics in Trials Interest Group (STInG)

ALTERNATIVE MODEL 1

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?)

Biostatistics is the discipline that underpins the efficient design and valid analysis of medical research studies. Being a successful biostatistician requires a combination of applied collaborations to address critical questions in clinical and population health, and the scope to conduct methodological research to ensure that statistics contributes to and keeps pace with the latest methods for design and analysis. While we agree with the major aims of this review, in particular the focus on research excellence, collaboration and partnership, we feel this proposed model may not be favourable for biostatisticians because the model does not sufficiently enable the following relevant topics for the biostatistics' discipline:

1. **Recognition**: Under this proposed model team grants are the centrepiece of the funding model and applicants (CIs) are limited to apply for and hold only **a single team grant** at **any one time**. Similarly in the ideas stream, applicants are limited to **two grants** at **any one time**. Being a statistician generally involves working as part of a number of teams across various projects hence it is hard to see how this model would support the involvement of this critical discipline. There are not enough statisticians to support the grants that are currently being put into NHMRC. Restricting the available statisticians to 1-2 teams/projects on which they can be a CI would only exacerbate the problem, even if the number of NHMRC applications reduces as per the aim of this review. One alternative could be to include statisticians as AIs to ensure statistical input, but that

would not greatly value the statistician's contribution in many projects and thus we feel strongly on empowering statisticians to be CIs.

2. **Methodological research**: This proposed model would not encourage biostatisticians to conduct methodological research. Methodological research is already hard to get funded through NHMRC, and limiting the number of grants we could apply for would make this even harder to prioritise.

3. **Track record:** Although applying for people grants would be an option for a biostatistician, these are often hard to obtain due to the difficulty of demonstrating a strong track record. Statisticians are rarely CIA's on grants or the first author on published papers as the projects that they are involved with generally have a clinical lead. The only projects they would lead are methodological projects but these are extremely difficult to get funding for as they do not have easily demonstrable translational or ground-breaking outcomes. This issue would be further exacerbated by the restriction on the number of grants that a researcher is able to apply for under this proposed model.

4. **Funding:** Funding biostatistics' positions is very challenging. We would welcome the salary support for a statistician who is a CI on a team or ideas grant. The Team Grant under Model 1 mentions cross-disciplinary researchers. Statisticians are a typical example of cross-disciplinary researchers. We strongly support the recognition of cross-disciplinary streams and would encourage new funding models to explicitly incorporate ways of supporting cross-discipline researchers to ensure the sustainability and recognition of such disciplines.

Question 1.4:

Could the model be adjusted to optimise its impact? If so, how?

See suggestions outlined in our response to question 4.

ALTERNATIVE MODEL 2

Question 2.2:

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?)

Of the three models, model 2 has the potential to be the most applicable for applying for funding to conduct **methodological research**. However, this model does not recognise or acknowledge the organisational structure of statisticians within institutions. In general, statisticians in their applied work do not lead teams or sit under a clinical group leader within a specific team. Instead, statistics often forms its own team/department. For example, this is the set up at the Murdoch Childrens Research Institute where statisticians are members of the Clinical Epidemiology and Biostatistics Unit. Given this organisational structure it is unclear how the proposed model would support the inclusion of statisticians with applied research teams which is critically needed.

Similar to question 1.2, we address the relevant topics for the biostatistics' discipline:

1. **Recognition**: The limitations in terms of the number of investigator or ideas grants that can be held at any one time across both the investigator and ideas streams would be extremely restrictive for a biostatistician (see item 1 of our response to question 1.2 for our reasons).

2. **Methodological research**: This funding model, which focusses on the individual investigator and their team, could potentially support methodological research by supporting a lead biostatistician and their team to conduct methodological research.

3. **Track record**: The critical issue of how we, as biostatisticians, can demonstrate a competitive track record amongst a sea of clinical and public health researchers remains. This would severely limit our ability to obtain these grants.

4. **Funding**: As per our comments on model 1, we welcome the salary support for a statistician who is a CI on an ideas grant, and advocate the funding for cross-disciplinary researchers which is mentioned under the Investigator Scheme within Model 2.

Question 2.4:

Could the model be adjusted to optimise its impact? If so, how?

See suggestions outlined in our response to question 4.

ALTERNATIVE MODEL 3

Question 3.2:

What advantages and disadvantages of this model do you see for you or your organisation if the model was introduced? (For example, what impact would it have on a researcher at your stage of experience? Would it support research in your research area?)

Of all three models, model 3 has the potential to be the most applicable for obtaining **funding for statistics in general**. Similar to questions 1.2 and 2.2, we address relevant topics for the biostatistics' discipline:

1. **Recognition**: The limit of being able to apply for one and hold a maximum of 2 grants at any time would be extremely problematic (see item 1 of our response to question 1.2 for our reasons).

2. **Methodological research**: Although this proposed structure would support applications for funding of methodological research, the difficulty is the subtype and streams that have been proposed since it is unclear to us where methodological research fits into the proposed categories. As mentioned in item 3 of our response to question 1.2, it is very difficult to make a case for the knowledge creation and translation of methodological research in comparison with clinical advances, yet such research is critical to ensure that studies are conducted, analysed and reported to the highest of quality.

3. **Track record**: Specifically with regards to this model, it will be extremely challenging to demonstrate a track record in the knowledge creation or translation subtypes because we feel that methodological research does not fit in.

4. **Funding**: Having a more flexible funding structure as proposed in this model could potentially be more suitable for supporting the biostatistician, as it would enable them to apply for exactly what funds are required for the particular research project, be it an applied or a methodological research project.

Question 3.4:

Could the model be adjusted to optimise its impact? If so, how?

See suggestions outlined in our response to question 4.

GENERAL

Our review has focussed on the role of biostatistics in the NHMRC grant program. Our group is a firm believer that medical research without biostatistical input is a missed opportunity to optimize the design, analysis and reporting of medical research and that insufficient or unprofessional biostatistical input could lead to poor quality medical research. These beliefs are strengthened by the explicit call to respond to the statistical community made by Professor Anne Kelso during the public discussion at the Walter and Eliza Hall Institute of Medical Research, Melbourne.

1. **Recognition**: All proposed models place a severely limiting cap on the number of applications and grants held at any one time. This could be alleviated by setting a separate higher cap for statisticians.

2. **Methodological research**: Although model 2 appears to be the most appropriate for funding for methodological research, it is very hard to see how such research would be supported across any of the proposed models. For example, page 13 refers to the grant program model retaining "support for research across all of the broad research areas i.e. basic, clinical, public health and health services research". Methodological research does not fit comfortably within any of these categories. Methodological research into optimising the design and analysis of studies is critical to ensure that research studies are conducted to the highest of quality and make the most of the available data, e.g. the development adaptive and stepped wedge designs has enabled trials to be conducted which were not previously possible. Given the huge investment in medical research across Australia, it is critical that there is also investment in biostatistical methodology to support such research.

    As an example of how this may be improved, the UK's Medical Research Council (MRC) provides ongoing funding for biostatistics through a network of methodology hubs with the primary goal of promoting and encouraging collaborative methodological research (http://www.methodologyhubs.mrc.ac.uk/). The MRC also has streams within their funding model for methodological research. This means that 1) funding is guaranteed

for methodological research and 2) that statisticians are competing on an even playing field in terms of track record and tangible outcomes.

3. **Track record**: The challenges of a competitive track record for a biostatistician have been outlined earlier. A track record assessment which takes into account the cross-disciplinary and supporting nature of biostatisticians has the potential to alleviate those concerns, for example by placing greater emphasis on the quality of contributions and less on publications metrics (e.g. authorship rank).

4. **Funding**: Model 3 is promising in supporting funding for biostatisticians. For model 1 and 2, we propose that funding is guaranteed by making it mandatory for large grant applications for clinical trials to include a biostatistician as a CI because such studies generally have a complexity that warrants expert statistical advice. Both model 1 and model 2 mention a cross-discipline stream. We strongly support the recognition of cross-disciplinary streams and would encourage new funding models to explicitly incorporate ways of supporting cross-discipline researchers.

Submitted by Dr Katherine Lee
Chair, ACTA STInG Executive Committee