CONSULTATION ON CLINICAL TRIAL RESEARCH GOVERNANCE

A Good Practice Process for the Governance Authorisation of Clinical Trials

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RESEARCH AUSTRALIA
AN ALLIANCE FOR DISCOVERIES IN HEALTH

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A GOOD PRACTICE PROCESS FOR THE GOVERNANCE AUTHORISATION OF CLINICAL TRIALS

INTRODUCTION

Research Australia welcomes the consultation by the NHMRC on 'A Good Practice Process for the Governance Authorisation of Clinical Trials' and on the other elements of clinical trials including the identification of standard clinical trial items and the redesign of the National Ethics Approval Form (NEAF).

The COAG Standing Committee On Health (SCOH) has agreed to work on facilitating clinical trials in Australia.

> ***Multi-jurisdiction clinical trials***
> *Ministers endorsed work to identify ways to enhance clinical trial activity in Australia by implementing a national approach to clinical trials. They agreed to ask the Australian Health Ministers' Advisory Council to conduct a scoping exercise, in consultation with the National Health and Medical Research Council, to report back on practical approaches to enhancing clinical trials activity.*[1]

This represents an excellent opportunity to improve the approval, conduct and governance of clinical trials and the processes that support them, as one of the key issues is variation in protocols, standards and requirements across state and territory boundaries. Research Australia expects the outcomes of the NHMRC consultations will, where appropriate, feed into the scoping exercise to be undertaken by the Australian Health Ministers' Advisory Council for SCOH.

[1] COAG, Standing Council on Health, Communiqué 11 April 2014

UNIFORM AND 'TRIAL APPROPRIATE' APPROACH TO CLINICAL TRIALS

The keys to improving the governance of clinical trials are uniform and 'trial appropriate' approaches to clinical trials across all Australian jurisdictions and the greater use and acceptance of multi site ethical approvals.

Uniform approval and governance of clinical trials across jurisdictions

The Roles and Activities Table in the Consultation paper (Table 1) makes several references to the use of 'nationally consistent' and 'nationally agreed' documents and templates. While the NHMRC has provided national leadership and significant advances have been made (particularly in agreements reached between Australia's eastern states) there are still legislative and regulatory barriers to a truly uniform national approach.

The following is provided as just one such example of specific Victorian requirements in addition to use of the National Ethics Approval Form (NEAF):

> ***Victorian Specific Module (VSM)***
>
> *In Victoria there is a requirement to comply with legislation relevant to human research involving information privacy, health information and the use of ionising radiation.*
>
> *Consent under circumstances where the Guardianship and Administration Act 1986 and the Mental Health Act 1986 apply must meet legislative requirements in Victoria. The VSM addresses Victorian legislation. It must be submitted with the NEAF for all research projects involving a site in Victoria.*
>
> *For projects involving the use of ionising radiation, a complete 'Section 4: Use of ionising radiation' for each participating site must also be submitted with the NEAF (information for the lead site is included in Section 4 of the VSM).*[2]

Research Australia recognises that these requirements are imposed by the Victorian Government and are beyond the control of the NHMRC. It nonetheless serves to highlight the need to engage the state and territory governments in the reform process, and to consider specific jurisdictional requirements in developing the Good Practice Process for the Governance Authorisation of Clinical Trials.

The document *Jurisdictional Legislative Requirements National & State Statutory and Administrative Frameworks for Ethical Review of Multi-centre Clinical Trials* provides further examples of impediments to a uniform national approach.[3] Despite its title it goes beyond matters specifically affecting ethical approval to broader governance issues including financial accountability, privacy and confidentiality requirements.

Trial appropriate processes

While uniform national processes are valued, the processes also need to be appropriate to the nature of the clinical trial. For example, non-drug clinical trials are typically lower risk and have fewer requirements than clinical trials for drugs; pediatric clinical trials can have additional, specific requirements that must be met. Any system of uniform national approvals and governance must be flexible enough to allow for 'trial appropriate' variations of this nature.

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[2] Victorian Government, Department of Health, *Streamlining Clinical Trials in Victoria*

[3] http://docs.health.vic.gov.au/docs/doc/D7635CEE1368C91FCA257AC90079AE63/$FILE/Jurisdictional%20Legislative%20Requirements%2030%20Oct%20.pdf

Facilitate single ethical approval for multi site, multi jurisdiction trials

There are a number of different barriers to single approval for multi site and/or multi jurisdiction approvals. Much of the existing framework for approval is based on individual site approval and this needs to be overhauled if clinical trials are to be streamlined. As an example, all states and territories have agreed to implement the National Radiation Protection Standards and there is a specific standard for the use of radiation for research purposes. However, the standard assumes/requires site specific ethics approval, as the below extract illustrates.

> ***2. Responsibilities***
>
> *2.1 RESEARCHER*
>
> *2.1.1 The researcher must obtain the approval of the Human Research Ethics Committee of the relevant institution for the research.*[4]

Identifying and amending State, Territory and National standards and protocols to eliminate a requirement for (or bias in favour of) single site ethics approval is an important step in improving clinical trials processes.

Several states have implemented intrastate ethics approval, but we need to progress to single ethics approval across state and territory borders. The agreement between NSW, Victoria and Queensland in relation to 'National Mutual Acceptance' is a significant advance but needs to be extended beyond these states and their publicly funded health services to achieve its full potential.[5]

Commercial and non-commercial clinical trials

To the greatest extent possible, commercial and non-commercial trials should operate under the same processes. Research Australia is aware that in addition to the current NHMRC consultations on NEAF, action has also been taken by the pharmaceutical industry to develop standard application forms and processes. It is imperative that the various organisations work together to agree on common requirements, processes and timelines if we are to achieve truly efficient and effective clinical trials practice in Australia.

A Single National Electronic Approval System

A national register of accredited sites for clinical trials has been proposed as a useful addition to the existing process. This register would include not only details of accredited sites but evidence of their accreditation, and would assist in initial selection of candidate sites.

A more ambitious but worthwhile initiative would be to develop a single national electronic database and application system:

- holding information about all sites and their accreditation,
- in which electronic 'smart' forms for clinical trial applications could be created, submitted, tracked and authorised,
- providing a standard, uniform national approach to clinical trials with visibility of the system and progress of applications through the approval process available to stakeholders.

[4] Australian Radiation Protection and National Standards Authority, Radiation Protection Standard (RPS)No. 8 , Section 2, page 3.

[5] Further information is available at http://www.health.vic.gov.au/clinicaltrials/mutual-acceptance.htm

RESPONSES TO SPECIFIC CONSULTATION QUESTIONS

Q.3: Is there more that could be done in planning and preparation and, if so, what and by whom?

Consideration should be given to charging institution management and administrative personnel with responsibility for providing information about the appropriate contact people at the institution, outlining who can provide approvals and providing indicative timelines for when decisions will be made from the date documents are provided.

They should also be responsible for communicating any requirements that are specific to the institution and or the state/territory so that these can be considered by the Contract Research Organisation/Sponsor at the earliest possible stage.

Q.9 Are there any points at which the process could be made more efficient?

The process diagram could be enhanced by the addition of information about who will make and communicate decisions relating to the feasibility assessment, and to whom the decision will be communicated. Indicative timelines for the making of decisions should also be developed and communicated.

In addition, the process would be enhanced by identifying specific 'Go/No Go' points in the process at which decision will be made as to whether the clinical trial will be approved.

Q11: Are you aware of any institutional, state, territory or national law or binding rule that would prevent your or your institution from implementing the tasks in this phase as proposed?

There are rules and requirements that impose additional obligations. The Victorian example is given above where requirements are imposed in addition to the use of the NEAF. Research Australia recommends that a thorough review of the national, state and territory forms and requirement be undertaken to identify other impediments to the adoption of a uniform national system.

CONCLUSION

Research Australia recognises that this submission goes beyond consideration of the proposed Good Practice Process for the Governance Authorisation of Clinical Trials to broader issues relating to the adoption of national uniform approaches to approval. We also recognise that the current consultation is only one of a number of initiatives currently being undertaken to facilitate clinical trials in Australia and is supportive of these measures. In doing so our aim has been to highlight some of the barriers to the adoption of the nationally agreed templates and research agreements described in the consultation document.

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