Australian Government

National Health and Medical Research Council

A Good Practice Process for Site Assessment and authorisation of clinical trial research

As part of its work to improve the commencement times of clinical trials, NHMRC undertook a consultation on a good practice process for the site assessment and authorisation phases of clinical trial research governance. The Process was developed by a working group comprising stakeholders from the public and private clinical trials sector, as well as academic, industry and state and territory health department representatives.

The purpose of the consultation was to seek views on whether the process represented an approach that would be able to be implemented in Australia and any barriers to its implementation.

Following finalisation of the report, NHMRC will now:

1. Work with the working group to incorporate proposed changes;
2. Test implementation of the process via pilot studies;
3. Consider other proposed initiatives such as the rationalisation or standardisation of governance forms.
4. Work with hospital research directors and Chief Executive Officers to seek uptake of the process.

NHMRC is seeking volunteers to act as sites to test the implementability of the Process. Interested sites should contact riact@nhmrc.gov.au.

For further information please see Clinical Trials | National Health and Medical Research Council or contact the Clinical Trials Section

Prepared for the National Health and Medical Research Council

National Consultation on a 'Good Practice' Process for the Governance Authorisation of Clinical Trials

Final Report

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Executive Summary

In May 2014, HealthConsult was engaged by the National Health and Medical Research Council (NHMRC), to undertake:

> ***"a consultation process to ascertain the views of stakeholders who conduct, or are otherwise involved in the conduct or governance of, clinical trials in Australia with respect to the feasibility of implementation of a redesigned process for the site assessment and site authorisation of clinical trials'***

HealthConsult used a four stage methodology that embraced a broad national stakeholder consultation program which involved face to face meetings, focus groups and an online survey questionnaire to maximise opportunities to gather the views of a representative set of the diverse range of stakeholders involved in the conduct of clinical trials in Australia. Participating stakeholders came from following groupings: private and public hospitals (including stand-alone Phase 1 Trial facilities); state and territory government health departments; pharmaceutical, biotech and medical device industry; peak industry, advocacy and research bodies; cooperative research groups (CRGs), clinical trial alliances, associations and networks including academic groups; clinical trial researchers; institutions including research institutes and universities; and third party trial centres. The consultation program and thematic analysis of stakeholder feedback was structured around the 14 consultation questions as presented in the prepared consultation paper *A 'Good Practice' Process for the Governance and Authorisation of Clinical Trials.*

The Consultation Paper describes a model for the activities and tasks for the individuals and entities associated with the site assessment and authorisation processes for clinical trials in terms of *six phases,* as shown in Figure 2.1. Chapter 2 provides a thematic analysis of the information provided by stakeholders specifically around the *five consultation questions* directed at the first Preparation and Planning Phase for overall clinical trials readiness and is supported by Table of activities (refer to Table 2.1); and Chapter 3 provides a thematic analysis of stakeholder feedback to the remaining *eight consultation questions* directed at the *five phases* from feasibility assessment to site authorisation to be completed on a trial by trial basis and supported by the proposed Process Diagram (refer to Figure 3.1).

There was strong support from stakeholders and all stakeholder groupings that having more upfront commitment as well as national consensus on the roles, responsibilities and activities of key players within research governance for the Preparation and Planning Phase to be "site ready" for any clinical trial was a constructive way forward for clinical trial reform in Australia. In fact, stakeholders considered this a positive step towards a needed national accreditation scheme for "sites" to be accredited as "research mature and able" to perform clinical trials. Stakeholder feedback around specific activities and tasks for all parties has been incorporated to produce a suggested revised listed activities/tasks for the Planning and Preparation Phase (refer to Table 2.2).

There was also strong support from all stakeholders for the Process Diagram in describing a "good practice" set of tasks/activities for the individuals and entities involved in site assessment and authorisation processes for any clinical trial. Stakeholders agreed that the tasks and activities allocated in the Feasibility Assessment Phase were critical in leading to a reduction in delays later in the process. Stakeholder feedback has again been incorporated to produce a suggested revised listed activities/tasks for the Feasibility Assessment Phase (refer to Table 3.1).

One specific area of feedback that the NHMRC may wish to address is the redrawing of the Process Diagram so that the intended timing/sequencing of the tasks/activities is more explicitly reflected. At present, it is the supporting text in the Consultation Paper that clearly indicates that the intention is for research governance processes to be conducted in parallel with, or prior to, ethics approval. Stakeholders indicated that making intended timing more specific would be helpful, and then the Process Diagram could more easily be used to develop the requested associated KPIs. Stakeholders

also unanimously commented that the development of an overall "process" communication plan/map to overlay the Process Diagram that sets out who communicates what and when, as well as indicative time frames and/or benchmarks for key steps/activities in the site governance process would be of great benefit.

Stakeholders advised that the tasks/activities listed for all six Phases of the "good practice" process were broadly applicable to commercial and non-commercial trials. They agreed that, to the greatest extent possible, commercial and non-commercial trials should operate under the same proposed "good practice" process. However, while uniform "national" ethics and governance processes are valued by stakeholders, the processes also need to be appropriate and flexible enough to accommodate the specific nature of some trials, e.g. low risk non-drug trials with fewer requirements should have expedited approval processes whilst paediatric trials may have additional processes to be met.

Stakeholders recognised that while the NHMRC has provided national leadership and significant advances have been made (particularly in agreements reached between Australia's eastern states in regard to mutual acceptance) there were still significant legislative and regulatory barriers to a implementing a truly uniform national approach to clinical trial readiness. They indicated that there was scope to overcome some of these barriers by further development of processes, tools and technologies that allow for greater standardisation of processes, and also for much more ready access to information around the timing of approval and conduct of clinical trials.

Overall, stakeholders viewed this national consultation process and program as an excellent step forward to improve the planning, approval, conduct and research governance of clinical trials and the processes that support them by helping to identify key barriers including the known existing variation in protocols, standards and requirements across State/Territories. They welcomed the proposed 'good practice' processes set out in the Consultation Paper but also openly discussed that there was also an urgent need for larger scale reform to improve Australia's competiveness as a destination for international clinical trials, and to reverse the trend of a declining number of clinical trials conducted in Australia.

Stakeholders did recognise that there were processes already in place to address some of the broader issues raised including the review and development of a new national human research application form, the review and subsequent costing of the revised standard list of items associated with clinical trials, the development of role statements and the analysis of the training needs of research governance officers (RGOs), and the national review of insurance and indemnity arrangements for clinical trials. Many stakeholders stated that they looked forward to a continuation of the clinical trial reform process and to the results of these (and other) development projects coming together in a cohesive way to achieve truly efficient and effective processes for approving and conducting clinical trials in Australia.

Moreover, stakeholders considered it imperative that all parties continue to work together and take on a more "trusted" and "open" partnership approach to agree on common requirements, processes and timelines as part of an ongoing process of clinical trial reform.

1

Introduction

In May 2014, HealthConsult was engaged by the National Health and Medical Research Council (NHMRC), to undertake a:

> ***"a consultation process to ascertain the views of stakeholders who conduct, or are otherwise involved in the conduct or governance of, clinical trials in Australia with respect to the feasibility of implementation of a redesigned process for the site assessment and site authorisation of clinical trials'***

This Chapter presents the project background and objectives; and summarises the methodology used by HealthConsult to conduct the assignment, including the stakeholder consultation program, number of stakeholders consulted and stakeholder groups and organisations that they represented.

1.1 BACKGROUND

Clinical trials are essential for evaluating the effectiveness and safety of medications, services and interventions to help prevent, detect or treat health and medical conditions. Clinical trials also have the potential to bring hundreds of millions of research dollars each year into the Australian economy.

As part of implementing the Government's 2013 election commitment to prioritising and accelerating clinical trial reforms, the NHMRC and the Department of Industry have been undertaking work to provide a nationally coordinated approach to clinical trials and reduce the complexity of the associated ethics and governance processes, one aim being to boost Australia's status as a preferred destination for conducting international trials.

Over the past months, the NHMRC has been working with the State and Territory health authorities, and other key stakeholder groups on progressing a nationally consistent approach to the processes associated with conducting clinical trials. Specifically, the NHMRC has been working with researchers, industry, governments, public and private sector organisations on a good practice process for the governance and authorisation of clinical trials in public and private hospitals that includes streamlined and timely ethics approval, and expedited site assessment and authorisation processes for clinical trials. This work addresses the concern that delays in the site assessment and authorisation processes prior to the start of clinical trials are one reason for Australia's lack of competitiveness in clinical trials research. Reducing delays will help to ensure that Australia remains an attractive destination for clinical trials.

To pursue this objective, in September 2013, the NHMRC hosted a national forum bringing together a cross section of personnel involved in conducting clinical trials in Australia, either at a Hospital CEO, Director of Research, practitioner, administrator, industry or jurisdictional health/government authority representative level. The Forum considered the requirements of a system to enable efficient and effective site assessment and site authorisation for all involved, and represented a call to action for those interested in improving the capacity for the conduct of clinical trials in Australia.

As a result of this Forum, a Research Governance Working Group was established to progress the work. The input of the Group, which met in December, 2013, was used to develop a flow chart of a proposed 'good practice' system for clinical trial site assessment and site authorisation phases. The system, which articulates roles and responsibilities of personnel and entities involved in the process, is

provided in the consultation paper on clinical trial research governance called *A Good Practice Process for the Governance Authorisation of Clinical Trials.*

1.2 PROJECT REQUIREMENTS

The project requirements, as set out in the Request for Offer (RFO) document, stated that the project team was to undertake a national consultation process with key stakeholders about the proposed "good practice" system including allocation of activities to individuals and entities as described in the consultation paper on clinical trial research governance *A Good Practice Process for the Governance Authorisation of Clinical Trials.*

The desired outcome of the consultation was to obtain an analysis of the views of a wide range of researchers, jurisdictional representatives, institutions, and sponsors/CROs from both the public and private sector health industry who conduct or are otherwise involved in the conduct or research governance of clinical trials in Australia, particularly with respect to the feasibility of implementation of the redesigned process for the site assessment and site authorisation of clinical trials.

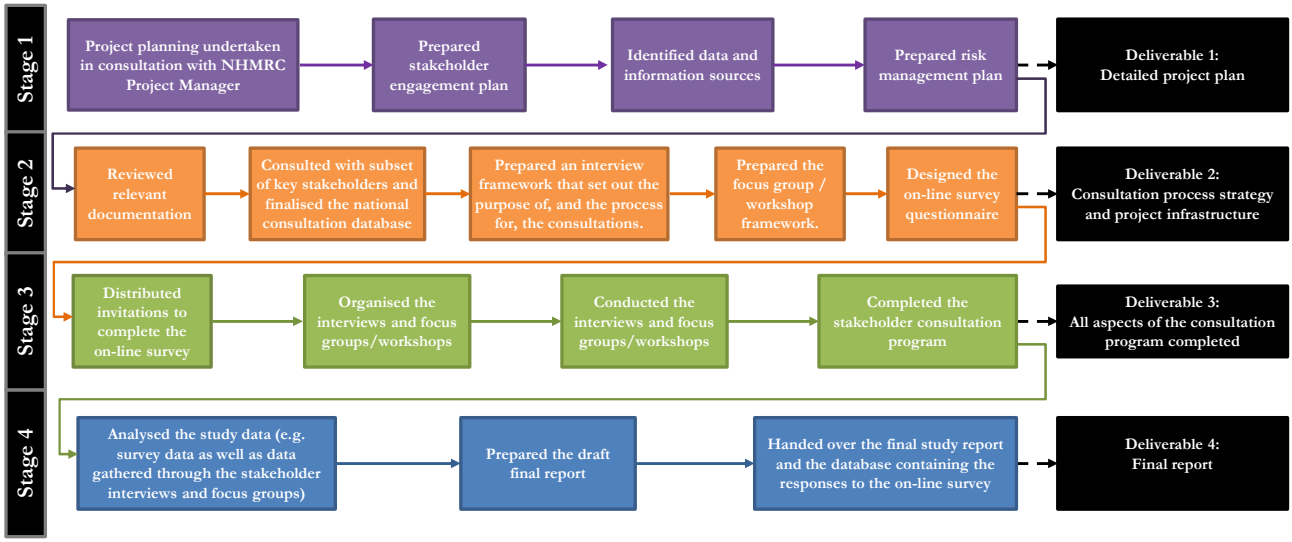
The focus of the consultation was to be on commercially sponsored trials and for the phases from planning and preparation to site authorisation. Specifically, the project team was to:

- review relevant identified background reports and documents;
- identify key organisations and individuals to be consulted (with the assistance of the NHMRC);
- develop an approach and plan for face to face and telephone consultations, as well as design and host an online feedback process e.g. Survey Monkey;
- undertake the consultation process; and
- provide a report on the outcomes of the consultation process to NHMRC that will include an analysis of the feedback and the feasibility of, and barriers to, implementation of a re-engineered site assessment and site authorisation process.

1.3 PROJECT METHDOLOGY

Figure 1.1 presents the *four stage methodology* designed by HealthConsult to achieve the outcomes sought by the NHMRC.

Figure 1.1: Overview of the four stage methodology used



To summarise briefly, the four stages were:

(1) **Stage 1:** Project planning and governance, which included the development of the stakeholder engagement and risk management plans, as well as the monitoring of progress.

(2) **Stage 2:** Review of relevant documentation and, with the assistance of NHMRC, development of a comprehensive national stakeholder database of individuals from the following stakeholder groups and subgroups: private and public hospitals (including stand-alone Phase 1 Trial facilities); state and territory government health departments; pharmaceutical, biotech and medical device industry; peak industry, advocacy and research bodies; cooperative research groups (CRGs), clinical trial alliances, associations and networks including academic groups; clinical trial researchers; institutions including research institutes and universities; third party trial centres, and other clinical trial specialists. A first round of consultations was held with a subset of key stakeholders to inform the development of face to face meeting and focus group frameworks, identification of appropriate key individuals for face to face meetings and finalise the overall stakeholder consultation program.

(3) **Stage 3:** Roll-out of the broad stakeholder consultation program which involved face to face meetings, focus groups and an online survey questionnaire using Survey Monkey to maximise the opportunities to engage all stakeholders. In addition, stakeholders were invited to submit written feedback. All individual stakeholders on the national database were invited to register their interest in attending a focus group session(s) to be held in each State/Territory; and key individuals were identified and contacted for face to face meetings. Depending on the expression of interest for attending the planned focus group sessions, one or two day visits were planned for each State/Territory to conduct the face to face interviews and focus group session(s). The format of the face to face interviews and the focus group sessions was structured around the 14 consultation questions as presented in the Consultation Paper. Stakeholder views were documented during the interviews and focus groups. All stakeholders were advised that they could submit additional feedback subsequent to the meeting if they wished.

(4) **Stage 4:** Analysis of the stakeholder feedback and data to develop the draft report on the outcomes of the national consultation on the prepared consultation paper *A 'Good Practice' Process for the Governance and Authorisation of Clinical Trials* and preparation of the associated report (this document). Finalisation of the report after receiving feedback from the NHMRC's Project Manager.

1.4 CONSULTATION PARTICIPANTS

The stakeholder consultation program was conducted across Australia in the period from 10th July to 22nd August, 2014. From the national clinical trials stakeholder database developed for the purposes of this project, individual email invitations were sent to 513 stakeholders requesting them to register their interest in attending a focus group session(s) in each of the State/Territory's capital cities. Table 1.1 shows that registrations of interest in attending a focus group session(s) were received from stakeholders in all States/Territories except the Northern Territory and Tasmania. Follow-up emails were sent to individuals in the Northern Territory and Tasmania inviting them to participate in either a face to face meeting or telephone interview to provide input into the consultations. This opportunity was not taken up.

Table 1.1shows there were 26 face to face interviews held with a total of 51 attendees (refer to Appendix A for a listing of individual attendees) and seven focus group sessions held with a total of 101 attendees across the five States and one Territory conducted as part of the consultation program (refer to Appendix B for focus group session details and Appendix C for a more detailed breakdown of the number and names of participating stakeholders by the stakeholder grouping). In addition, 79 stakeholders took the opportunity to complete the online survey questionnaire. However, it should be

noted that less than a third of respondents completed every question in the survey (refer to Appendix D for details on the number of respondents who answered each of the survey questions).

Table 1.1: Number of stakeholders involved in consultation process by jurisdiction

State/Territory	Email Invitations	Focus Group Registrations	Focus Group Attendances	Online Survey	Face-to-face interviews (participants)
New South Wales	155	36	15 &15	21	11 (21)
Victoria	116	21	9 &21	23	5(12)
Queensland	81	26	20	15	2 (5)
Western Australia	42	14	13	9	2(4)
South Australia	74	12	8	8	1 (2)
Tasmania	9	0	N/A	0	0
Australian Capital Territory	7	0	N/A	2	4 (7)
Northern Territory	5	0	N/A	0	0
Other (National bodies)*	24	0	0	1	0
Grand Total	**513**	**116**	**101**	**79**	**26 (51)**

*where appropriate representatives from National bodies attended State Focus Groups Sessions or were interviewed face-to-face

As a result of the focus group discussions and face to face meetings, HealthConsult also received six follow-up written submissions relating to the consultation paper *A 'Good Practice' Process for the Governance and Authorisation of Clinical Trials*. Submissions were received from the following organisations: Research Australia; Safety, Quality and Research Branch, Commonwealth Department of Health; GlaxoSmithKline Australia; Victorian Comprehensive Cancer Centre; NHMRC Clinical Trials Centre (University of Sydney); and, Alfred Health Victoria.

The overall consultative process proved to be very wide ranging and gathered the views of a representative subset of the diverse range of stakeholders involved in the conduct and/or governance of clinical trials in Australia. HealthConsult reviewed all the written materials and undertook a thematic analysis of the information and data produced by the comprehensive stakeholder consultative program, the results of which are presented in Chapters 2 and 3.

2

Planning and Preparation Phase

This Chapter provides a thematic analysis of the information provided by stakeholders through the consultation program in response to the prepared consultation paper *A 'Good Practice' Process for the Governance and Authorisation of Clinical Trials* (the 'Consultation Paper') and specifically the *five consultation questions* directed at the preparation and planning phase for clinical trials readiness.

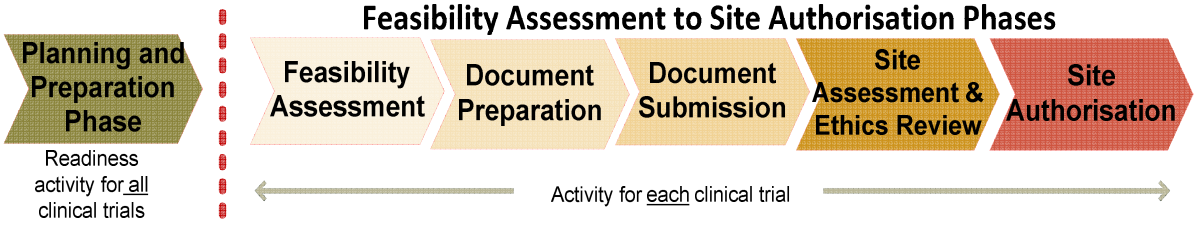
2.1 THE PROPOSED PLANNING AND PREPARATION PHASE

As outlined in the Consultation Paper, the 'good practice' process proposes *two* key improvements that would reduce the time taken to commence clinical trials:

- an increased commitment to planning, preparation and ongoing support for clinical trials within those institutions where clinical trials are conducted; and
- a change to the order in which the activities within the assessment and authorisation process are conducted, whereby key assessment activities occur much earlier.

The Consultation Paper goes on to describe a model for the activities associated with the site assessment and authorisation processes for clinical trials in terms of *six phases,* as shown in Figure 2.1.

Figure 2.1: Activities associated with the authorisation of clincial trials (from the Consultation Paper)



As can be seen from Figure 2.1, the model proposes a planning and preparation phase that comprises activities that apply to *all clinical trials*, and then five phases from feasibility assessment to site authorisation that are intended to be completed on a *trial by trial basis*. The model recognises that, in any institution, upfront planning and preparation to get to a state of "research readiness" to conduct clinical trials is critical to efficient approval of individual trials. The model is supported by a set of activities (see Table 2.1) that are designed to ensure that sites and all personnel involved in the process are ready and available to conduct clinical trials when the opportunity presents.

2.2 STRONG SUPPORT FOR TABLE OF ROLES AND ACTIVITIES

All stakeholders welcomed the increased commitment set out in the Consultation Paper to an upfront planning and preparation phase to get institutions to a state of "readiness" to conduct clinical trials. There was positive discussion that, in effect, the tasks and activities listed in Table 2.1 could be considered as a "minimum set of national requirements" or "a national clinical trial research ready checklist" for all relevant personnel and parties to have in place "prior" (and as an ongoing requirement) to engaging and/or conducting any clinical trial research.

Table 2.1: Roles and activities for individuals and entities involved in the clinical trial planning and preparation

Individual/Entity	Proposed role and activities
Contract Research Organisation/Sponsor	• Agree, having regard to the Independent Hospital Pricing Authority (IHPA) process [LINK: http://www.ihpa.gov.au/internet/ihpa/publishing.nsf/Content/home-1], to the costs of and cost-sharing approach to standard clinical trial items with participating institutions • Agree to use standard research agreements (contracts) • Agree to comply with nationally consistent insurance and indemnity requirements • Develop guidelines and processes to ensure trial protocols are compatible with the Australian context before providing to investigators • Agree to use a suite of nationally agreed standard patient information and consent forms (PICF) templates • Conduct regular audits of institutions, researchers, facilities and patient profiles
All Principal Investigators (including coordinating principal investigator)	• Complete Good Clinical Practice (GCP) training • Complete relevant learning modules • Maintain current CVs in an institutional database • Meet core competencies for clinical trial investigators • Maintain professional registrations • Maintain professional indemnity insurance
Human Research Ethics Committee (HREC)	• Document and promote process to efficiently manage clinical trial applications • Use certified ethical review processes for multi-centre clinical trials and single site trials as appropriate • Utilise the current national ethics application form • Adopt standardised/harmonised ethical review forms, templates and processes • Advertise HREC meeting dates and deadlines • Require use of a suite of nationally agreed standard PICF templates
Institution management and administrative personnel (e.g. Research Director, Research Governance Officer, Delegate for authorisation)	• Maintain certification for ethical review processes related to multi-centre clinical trials and single site trials as appropriate. • Make templates documents available on websites • Complete relevant learning modules • Accept single ethical review without further site-specific ethical review • Establish and communicate research priorities • Promote capacity to conduct clinical trials on web site and via other mechanisms • Comply with national standards and processes for implementing a research governance framework • Ensure all staff participating in clinical trials are appropriately trained • Use nationally agreed electronic site assessment document templates • Use nationally agreed standard contracts • Agree, with reference to IHPA advice, to the costs of and cost-sharing approach to clinical trial items with sponsors • Utilise national standard operating procedures for site assessment • Maintain IT system that enables electronic submission of documents and compliance with national requirements

Reaching a national consensus on the roles, responsibilities and activities of key individuals and entities involved in the proposed planning and preparation phase was seen as a positive step in clinical trial reform for Australia, and also as a potential contribution towards a national accreditation scheme for "sites". Stakeholders considered that having such a national accreditation scheme for a site to be accredited as "site ready" and "research mature" was a possible important next step in clinical trial reform.

Stakeholders did comment on the importance of expanding the definition and terminology box (refer to page 4 of Consultation Paper) to also include standard definitions on who the actual key parties and personnel are in clinical trial research governance. For example, the word "Sponsor" was raised by many stakeholders as being ambiguous and requiring clear definition. In terms of "CRO/Sponsor" being used in the Table stakeholders suggested that this grouping be replaced by the term "Sponsors including sponsor agents". The alternative was to be all inclusive and the grouping be replaced by a full listing of relevant organisations including contract research organisations (CROs), academic research

organisations (AROs) pharmaceutical, medical device and biotechnology companies, academic institutions and hospitals. Stakeholders specifically commented that it would be helpful to have a standard definition as well as a generic position description of what constitutes a Research Governance Officer (RGO).

Moreover, stakeholders highlighted the importance and usefulness of consistent "standard" research governance information and terminology in a document to supplement any such Table, particularly for internal and external organisational education purposes. Stakeholders commented on the lack of understanding and/or knowledge in the system about the importance of research governance including in how it differs from clinical governance as well as ethical review processes.

2.3 QUESTIONS 1 AND 2 – CORRECT SET OF TASKS AND ALLOCATION

The *first* consultation question was "Does the table describe the correct set of tasks?" and the *second* consultation question was "Are the tasks allocated to the correct individual(s) or entity?" Given their logical relationship, stakeholder feedback on these questions is reported concurrently, based on analysis of the feedback on the specific tasks and activities allocated to individuals and/or entities, as listed in Table 2.1.

Broadly speaking, the majority of stakeholders (including 73% of the survey respondents) agreed that Table 2.1 described the correct set of tasks for individuals and entities involved commercially sponsored clinical trials on which this consultation was focused. Specific feedback on the activities listed against each stakeholder group is provided in the following sections.

2.3.1 Contract Research Organisation (CROs)/Sponsors

The great majority of stakeholders agreed that the allocation of listed tasks for CROs/Sponsors was correct, as reflected by 94% of the respondents to the online survey questionnaire.

Stakeholders were supportive of standardised insurance and indemnity requirements and agreeing to "comply with nationally consistent insurance and indemnity requirements". However, it was noted that stakeholders perceived that there were significant differences between the States and Territories in these requirements. They commented that hopefully variations would be addressed as the result of the national review that was in progress on indemnity and insurances arrangements for clinical trials.

Industry stakeholders, in particular, raised concerns about the wording of the task to "develop guidelines and processes to ensure trials protocols are compatible with the Australian context before providing to investigators" as most protocols were already written by the time they had reached Australia i.e. they had been "globally" designed and approved. A more appropriate wording of the activity was suggested, i.e. that CROs/Sponsors are responsible for "review trial protocols to ensure that they are compatible with the Australian context before providing to investigators".

Concerns were also raised by industry about agreement to "use a suite of nationally agreed standard patient information and consent forms (PICF) templates" as the current templates do not cater for some individual sponsor privacy requirements (i.e. specific data/tissue banking information via taking biological samples and access to this information that is sponsor specific), as well as not taking into account the existence of different State/Territory laws and regulations. Equally, feedback, particularly from the public sector, raised concerns about this activity and confirmed very few CROs/Sponsors elected to use PICF templates but rather submitted global templates that contained information not relevant to Australian law and the conduct of research in Australia. Overall, this process resulted in much time being wasted, in particular by HREC and RGO personnel in rewriting and renegotiating with Sponsors/CROs to amend templates, which led to long delays to ethics approval and study start up time.

Many stakeholders commented that the "conduct of regular audits of institutions, researchers, facilities and patient profiles" by CROs/sponsors on an ongoing basis when it is not related to a particular trial could become very onerous and perhaps this activity maybe more appropriate under "institution management and administrative personnel" where high quality random and planned audits should be core business of any institution conducting research. Gathering this type of data and information was seen as very resource intensive and an alternative activity maybe to enable a single national database of site specific capabilities (refer to Section 3.8).

It was noted by a few stakeholders that in agreeing to IHPA's process to the "costs of and cost-sharing approach to standard clinical trials items", there did not seem to be coverage of private hospitals and/or other private institutions, which may have alternative methodologies to cost clinical trial activities. These stakeholders felt that there may be some bias introduced into setting clinical trial budgets if the IHPA costs are used. There was also some confusion about what was meant by "cost sharing", as stakeholders observed that the IHPA determination did not appear to take any position on "cost sharing", but rather simply published a table of standard costs. Nonetheless, most stakeholders accepted that it was valuable to have a reference point such as the IHPA determination in negotiating clinical trial budgets.

2.3.2 All Principal Investigators (including Co-ordinating Principal Investigator)

Stakeholders strongly made the point that this grouping also needed to include Clinical Trial Co-ordinators, Trial Managers and Research Co-ordinators as, a number of the activities listed that were considered to be the "responsibility" of the Principal Investigators in this planning and preparation phase, were usually performed by these personnel. Specifically, "maintaining current CVs in an institutional database" was usually delegated to these personnel, and other stakeholders thought that may also be a more appropriate task for Institutional Management and Administrative personnel.

Stakeholders commented that there should be a "consistent standard CV template" made available electronically for use by parties that was considered more of a "fit for purpose" CV for commercially sponsored clinical trial research. Stakeholders agreed that having access to a shared database of standard CV templates as well as standard Principal Investigator CVs would allow for improved consistency and efficiency. A number of stakeholders advised that this was one of the initiatives currently being pursued by the global non-for-profit organisation TransCelerate BioPharma (referred to as "TransCelerate").

There was consistent stakeholder feedback that the task "complete Good Clinical Practice (GCP) training" was also ambiguous and would be perhaps be better worded as "maintain a current GCP certification", which removes an implication of GCP training needing to occur for each new trial. Feedback from industry groups indicated that global trends had moved toward a two or three year (non-sponsor specific) GCP certification. Stakeholders were very supportive of the NHMRC making an accredited online-GCP training available. They again highlighted TransCelerate initiatives that address common criteria for mutual recognition of GCP training, as well as the collection of generic information about study sites which could help streamline activities in the proposed planning and preparation phase.

There was also feedback that the activity "complete relevant learning modules" was considered ambiguous by stakeholders, and that more details and a specific definition was required. It was noted that this activity also appears under the Institution Management and Administrative Personnel sections, but it was not clear whether it is the same or different learning modules that are being referenced.

Stakeholders also commented on the need for further clarification of what was meant by "meet core competencies for clinical trial investigators" including how this activity would be demonstrated, assessed and/or measured, and by whom. Some stakeholders wanted a clear definition of the core competencies for a clinical trial investigator, before expressing a view on this activity.

2.3.3 Human Research Ethics Committee (HREC)

The majority of stakeholders indicated that the list of activities allocated to HREC was correct, as reflected by the 97% of the respondents to the online survey. However, stakeholders did note that with the current NHMRC consultation on, and potential changes around, the NEAF that the activity "utilise the current national ethics form" task may need to be reviewed and updated.

Stakeholders again commented that current differences in State/Territory laws and regulations would make it difficult for HRECs to be able to "use a suite of nationally agreed patient information and consent (PICF) forms" Clear examples of this barrier were not obtained in the focus group context, but there was certainly discussion around differences in privacy and biosafety requirements (see Section 2.5 that provides feedback on barriers). However, it was noted that the position for moving forward could be that HRECs would "require use of a suite of nationally agreed patient information and consent (PICF) forms" i.e. the suite is likely to include at least one that met with all jurisdictional requirements.

2.3.4 Institution management and administrative personnel (e.g. Research Director, Research Governance Officer (RGO), delegate for authorisation)

There was common concern from stakeholders that this was too broad a grouping. It was felt that grouping all institution management and administrative personnel together resulted in a lack of role clarity between higher level and general administrative tasks.

The majority of stakeholders agreed that "maintain certification for ethical review processes related to multicentre clinical trials and single site trials" although tasked as an institutional responsibility, was more appropriately listed as part of the HREC set of tasks as it was more common practice for the RGO to only check that the relevant site is listed on the HREC approval letter rather than maintaining the certification level of the HREC. Stakeholders advised that this task was commonly performed by the Secretariat or Executive Officer of the HREC.

Stakeholders commented that, to better inform CROs/Sponsors on a site's clinical trial readiness to be selected for commercially sponsored studies, it was very important that institution management "establish and communicate research priorities" and "promote capacity to conduct clinical trials on web site and via other mechanisms". They also stated that these activities required more explanation particularly as the responsible group was so broadly defined. For example, who was responsible for "establishing research priorities" versus who was responsible for "communicating research priorities". One part of this task was clearly thought to be at the level of the CEO/Board whilst the other part of this task was administrative. Stakeholders understood that in addition to outlining departments and services, hospital websites should also clearly promote their capacity to conduct clinical trials including having content on the hospitals research areas/fields of interest. Stakeholders suggested having access to examples of what constitutes a "good" research capability statement would also be of benefit such as that prepared by the UK's Guy's and St Thomas' NHS Foundation Trust. However, a number of stakeholders commented that this type of information should be maintained centrally and not at an individual institution level, to improve efficiencies in the planning and development phase for the CROs/Sponsors.

The majority of stakeholders commented that to "ensure all staff participating in clinical trials are appropriately trained" was a task better aligned to the Principal Investigator's responsibility as part of conducting a clinical trial (unless it was a reference only to attaining and maintaining GCP certification, which can be done independently of any one clinical trial).

Finally, there was strong stakeholder feedback and discussion around what was inferred by "maintain an IT system that enables electronic submission of documents and compliance with national requirements". All stakeholders commented that clinical trial research did not independently operate from a specific site/hospital's funded IT system and infrastructure, so for this activity to occur as

stated, there would be need to be a commitment of independent funding and support. Consistent with feedback around other activities, stakeholders requested some clarity about what was meant by "national requirements".

2.4 QUESTION 3 – ADDITIONAL ACTIVITIES

The *third* consultation question was "Is there more that can be done in planning and preparation and if so, what and by whom?"

Stakeholder feedback around improvements to the activities listed in the planning and preparation phase mostly focussed around creating/improving enablers to ensure that appropriate training/education and communication processes occurred across all stakeholders involved, and that there were tools (templates, software, databases, etc.) available that supported sites to become "clinical trial ready".

In terms of specifics, for the CROs/Sponsors grouping, stakeholders suggested that a task be included as "accept a nationally accredited approach to GCP training" as discussed under Section 2.3.2. In addition, there was consistent feedback that it was imperative for CROs/Sponsors to "maintain adequate training and an experienced research team" as it was noted by many that there was a burgeoning CRO market and a reduced internal clinical trial monitoring capacity within the larger industry organisations. Also, for clarity it was suggested by stakeholders that the task "adhere to national TGA requirements" be added to the list.

In particular, for sites to be seen as "research ready" for multi-centre clinical trials, stakeholders commented that HRECs could become more empowered in making decisions by undertaking activities such as "complete certified training in legislation around privacy laws as well as *Guardianship and Administration Acts* for all States and Territories". It was seen as important for all HREC members, current and new, to receive this mandatory initial training, and for this training to be ongoing with regard to updates on any legislative changes.

There was considerable discussion around the need for institutional management and administrative personnel to be charged with the responsibility to "ensure effective communication (for example via public institutional websites) of up to date information on internal research governance processes and policies". This information would include: the contact details of who in their organisation are responsible for research governance; outlining who can provide approvals and the relevant delegated officers; relevant HREC and Research Governance meeting dates; and current Standard Operating Procedures (SOPs).

All stakeholder groups raised the importance of institutional management and administrative personnel in developing and reporting on a set of agreed KPIs and other measures of accountability for incorporating clinical trials research as core business. Benchmarking and publication of data on performance against these KPIs was seen as a very important enabling activity.

2.5 QUESTION 4 – BARRIERS TO IMPLEMENTATION

The *fourth* consultation question asked "Are you aware of any institutional state, territory or national law or binding rule that would prevent you or your institution from implementing the tasks in this phase as proposed"?

Stakeholders in Victoria particularly raised that radiation safety activities are currently a parallel process that need to be included in research governance activities. Implementation of a mutual acceptance program for radiation safety could be considered, however there are legal implications due to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Codes (no.8).

Stakeholders also commented on the current differences between State/Territory Privacy Laws as well as with laws relating to Guardianship which allow clinical trial research to occur in cases where a patient lacks capacity to consent. As discussed in Section 2.3.1, stakeholders again raised the current situation with the variable State and Territory indemnity and insurance arrangements.

2.6 QUESTION 5 – SUITABILITY FOR NON-COMMERCIAL TRIALS

The *fifth* consultation question asked stakeholders "Generally, are the tasks, roles and responsibilities suitable for non-commercially sponsored and academic trials? If not, which tasks/roles/responsibilities are not and why not?"

Overall, there was strong support from stakeholders that the tasks, roles and responsibilities were generally suitable for non-commercially sponsored and academic trials, as reflected by 73% of respondents to the online survey.

As discussed in Section 2.2, to be more suitable for non-commercially sponsored and academic trials, the grouping CRO/Sponsor would need to be amended and/or more clearly defined to include other parties such as Academic Research Organisations (AROs), Public Hospitals, or an Academic Institution.

Also, a number of stakeholders made the point that "agreeing to the Independent Hospital Pricing Authority (IHPA) process to the costs of and cost-sharing approach to standard clinical trial items with participating institutions" was an activity that non-commercially sponsored and academic trials were not required to comply with, but noted that the IHPA costings of standard clinical trial items may be useful in developing grant application budgets.

2.7 SUMMARY

Overall, stakeholders were very supportive and welcomed the increased commitment by entities listed in Table 2.1 to greater and ongoing planning and preparation for the conduct of clinical trials to help improve timelines of the site feasibility and authorisation process.

Specifically, stakeholder feedback was unanimous in support of, where possible, taking a more coordinated approach to becoming "site ready" by having in place "nationally agreed or standard" frameworks, systems, training, education, information (including standard documents and templates). Stakeholders recognised that while the NHMRC has provided national leadership and significant advances have been made (particularly in agreements reached between Australia's eastern states in regard to mutual acceptance) there were still significant legislative and regulatory barriers to a implementing a truly uniform national approach to clinical trial readiness.

To this end, stakeholders noted that the roles and activities (in Table 2.1) made several references to the use of "nationally consistent" and "nationally agreed" documents and templates, as well as to "national standard" processes, documents or procedures. There was common discussion in all forums around what constitutes "standard" and "nationally consistent/agreed", and stakeholders commented that, at this stage, an activity/task incorporating this wording was unable to be truly agreed to and/or required the additional information to be added to the activity for further clarification.

In support of working towards a "national consistent" process, stakeholders recognised the important the work of the Southern Eastern Border States (SEBS) Panel in trying to standardise, as far as possible, the terms and conditions of the Medicines Australia Clinical Trial Research Agreements (CTRAs) in an effort to streamline the administrative management of contracts for Sponsors and public

health organisations who are parties to the agreement. Stakeholders welcomed the existence of the SEBS centralised Schedule 7 or 4 special conditions review process for SEBS jurisdictions.

In light of the above discussion, stakeholders therefore suggested that it would be more appropriate and precise to have as an activity "use the Medicines Australia standard research agreement with only pre-approved and evidenced Schedule 7 or 4 wording". However, it was noted Western Australia had directed the "mandatory use" of its own developed standard research contract to its public health organisations, so at present this change could not apply nationally.

In order to give effect to the specific stakeholder feedback, Table 2.2 reflects a suggested revised set of tasks and activities associated with the planning and development phase for consideration by NHMRC.

Table 2.2: Suggested revised* roles and activities for individuals and entities involved in the clinical trial planning and preparation phase (* revised text and/or additional roles/tasks are underlined)

Individual/Entity	Proposed role and activities
Sponsors (including Sponsor agents)	• Agree, with reference to the Independent Hospital Pricing Authority (IHPA) advice where applicable, to the costs of standard clinical trial items with participating institutions • Review trial protocols to ensure that they are compatible with the Australian context before providing to investigators • Maintain adequate training and an experienced clinical trial research team • Adhere to national TGA requirements • Agree to use a suite of nationally agreed standard patient information and consent forms (PICF) templates • Agree to use standard research agreements • Agree to comply with nationally consistent insurance and indemnity requirements
Principal Investigators (including Coordinating Principal Investigators), Clinical Trial Coordinators/Managers and Research Coordinators	• Maintain a current Good Clinical Practice (GCP) certification • Complete relevant learning modules • Maintain current "fit for purpose" CVs in an institutional database • Meet and maintain core competencies for clinical trial investigators • Maintain professional registrations • Maintain professional indemnity insurance
Human Research Ethics Committee (HREC)	• Maintain certification for ethical review processes related to multi-centre clinical trials and single site trials as appropriate. • Maintain certified training in legislation for all States/Territories • Document and promote process to efficiently manage clinical trial applications • Use certified ethical review processes for multi-centre clinical trials and single site trials as appropriate • Utilise the current national ethics application form • Adopt standardised/harmonised ethical review forms, templates and processes • Advertise HREC meeting dates and deadlines • Require use of a suite of nationally agreed standard PICF templates

Individual/Entity	Proposed role and activities
Institution management and administration personnel (e.g. Research Director, Research Governance Officer, Delegate for authorisation)	• Complete relevant learning modules, including those on clinical trial research governance • Disseminate up to date information on current research governance processes and polices (e.g. SOPs) • Communicate agreed clinical trial research priorities and objectives • Develop and report on clinical trial research KPIs • Make templates documents available on websites • Accept single ethical review without further site-specific ethical review • Promote capacity to conduct clinical trials on web site and via other mechanisms • Comply with national standards and processes for implementing a research governance framework • Use nationally agreed electronic site assessment document templates • Use nationally agreed standard contracts • Agree, with reference to IHPA advice when applicable to the costs of clinical trial items with sponsors • Utilise national standard operating procedures for site assessment • Maintain IT system that enables electronic submission of documents and compliance with national requirements

As discussed earlier, the Table would benefit from an accompanying document, which would include an expanded glossary and definition section as well as provide more detailed information to help clarify any ambiguities in the interpretation of the activities/tasks listed as dot points. Stakeholders were keen to see that the list of activities and responsibilities in this Table become nationally recognised and raised the possibility of a mandatory checklist to be somehow centrally monitored before receiving a "Research Passport" to engage in clinical trial research.

3

Site Assessment and Authorisation Phases

This Chapter provides a thematic analysis of the information provided by stakeholders through the consultation program in response to the prepared consultation paper *A 'Good Practice' Process for the Governance and Authorisation of Clinical Trials* (the 'Consultation Paper') and specifically the *nine consultation questions* directed at the remaining *five phases* (as shown in Figure 2.1) that are intended to be completed on a trial by trial basis.

3.1 THE PROPOSED SITE ASSESSMENT AND AUTHORISATION PHASES

These remaining *five phases* are presented in more detail in the diagram shown in Figure 3.1. In this diagram the roles of individuals or entities, and the activities for which they are responsible, are presented in a 'swim lane' style (hereafter referred to as the 'Process Diagram').

The Process Diagram represents the proposed high level processes and activities for the *five phases* (columns) and responsibilities for individuals or entities (rows) considered necessary for the assessment and authorisation of each clinical trial. The *five phases* are:

- Feasibility Assessment;
- Document Preparation;
- Document Submission;
- Site Assessment and Ethical Review; and
- Site Authorisation.

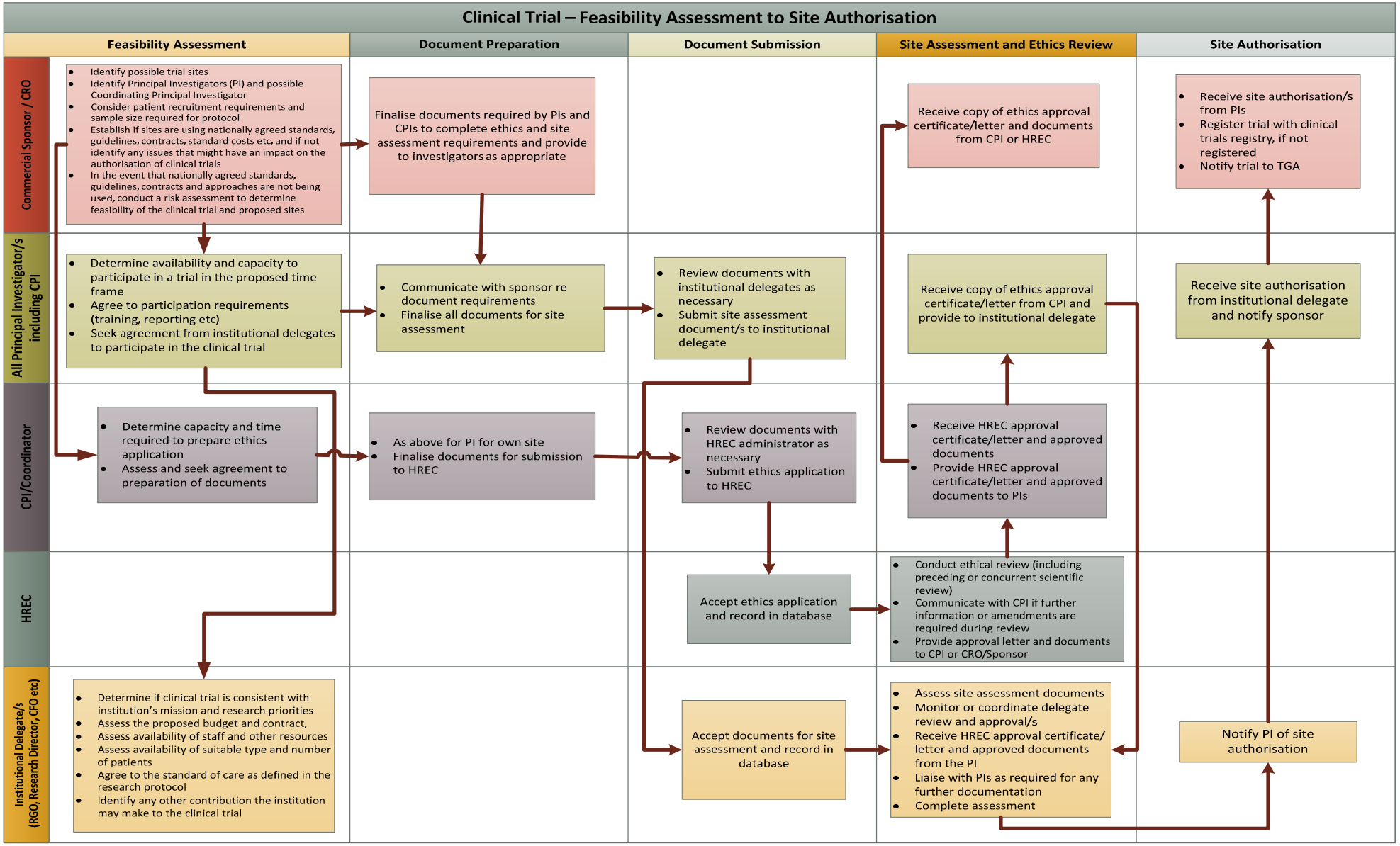
The *five individual(s) or entities* that are allocated roles are:

- Contract Research Organisation (CRO)/Sponsor;
- All Principal Investigator(s) (PI);
- Coordinating Principal Investigators (CPI);
- Human Research Ethics Committee (HREC); and
- Institutional Delegate/s.

The Process Diagram presented is considered a significant paradigm shift from the way in which site assessment and authorisation processes are usually conducted in *two* ways: firstly, that the majority of site assessment activities can be conducted not just in parallel with, but prior to ethical review being undertaken; and secondly, that some key site assessment activities can be substantively completed in the Feasibility Assessment Phase and then formalised in documentation rather than be delayed until all documentation is submitted.

As can be seen from Figure 3.1, the model recognises that for any clinical trial there is a series of steps that needs to be completed to authorise the conduct of a trial at a specific site. Although timing is not specifically indicated in the Process Diagram, the Consultation Paper makes it clear that the intent is for ethics approval and site authorisation activities to proceed largely independently, rather the predominant historical practice where site authorisation work only started after ethics approval had been obtained.

Figure 3.1: Activities associated with the phases from Feasibility Assessment to Site Authorisation of clinical trials (from the Consultation Paper)



3.2 QUESTIONS 6 AND 7 – CORRECT STEPS AND ALLOCATED ROLES

The *sixth* consultation question asked of stakeholders was "Does the process diagram identify the appropriate high level process steps?" and the *seventh* consultation question was "Are the high level activities matched to the correct responsible person/s and or entities?" As with the planning and preparation phase, and given their logical relationship, stakeholder feedback on both these questions is reported concurrently, based on analysis of the feedback on the high level process steps/activities allocated to individuals and/or entities as outlined in the Figure 3.1.

Overall, there was strong support from stakeholders across all key groups that the appropriate high level steps/activities had been identified in the Process Diagram, as reflected by over 84% of respondents to the online survey. Similarly, over 83% of respondents to the online survey agreed that the high level activities were allocated to the correct responsible persons/s or entities.

Almost all stakeholders noted, and were pleased, that the Process Diagram did not indicate a two-step review (i.e. scientific committee and then the ethics committee) and included a simultaneous or parallel governance process rather than a governance process subsequent to the ethics review.

The discussion at interviews and focus groups concentrated mainly around clarifying the activities/tasks for each party within the Feasibility Assessment Phase. Stakeholders viewed that this Phase and its associated activities/tasks were the most critical in helping to reduce delays to completing the research governance activities later in the process.

Stakeholders commented that the current activities/tasks listed in the Feasibility Assessment Phase seemed to imply that all required documents (including contracts, protocols) had already been prepared or developed. Many of them had the view that this Phase also needed to include what they referred to as "early stage" Feasibility Assessment Phase activities/tasks.

Specifically, stakeholders suggested that additional "early stage" Feasibility Phase activities for CROs/ Sponsors could include "develop/provide research protocols and draft budgets" and "recommend standard of care definition(s) in the research protocols". For the Principal Investigator(s) stakeholders suggested that "identify lead HREC and ensure it had required clinical expertise" was a needed additional activity. Stakeholders also commented that it was important for Principal Investigators to "determine availability and capacity to participate in a trial in the proposed timeframe" in consultation with Institutional Delegates(s).

Stakeholders also identified a key step in the Feasibility Assessment Phase for the Institutional Delegate(s) was to "notify the intent to conduct a clinical trial" in a particular area to relevant institutional internal stakeholders. Also, this group should be responsible for "communicating any special requirements that are specific to the institution and/or States/Territories" so that these could be considered by the CRO/Sponsor at the earliest possible stage of the Feasibility Phase.

3.3 QUESTION 8 – PROCESS DIAGRAM REFLECTS "GOOD PRACTICE"

The *eighth* consultation question was "Does the process diagram reflect 'good practice' throughout the phases?"

Stakeholders agreed that the process diagram reflected 'good practice' throughout the phases, as reflected by over 92% of respondents to the online survey.

However, stakeholders considered that in any process where timing was a critical element in defining "good practice", there should be some specific references to timeframes in the Process Diagram. A number of stakeholders went further and suggested that the diagram needed to include a time

dimension and guidance around reasonable expected timelines for implementation of key activities/processes.

Similarly, stakeholders thought that effective and ongoing communication between all parties on where the clinical trial approval process was up too was also a critical enabler of "good practice". Parties needed to establish open lines of communication from the inception of the research proposal to underpin the resolution of any issues that may arise in the completing site assessment and authorisation requirements. Specifically, stakeholders suggested that a core responsibility for the Institutional Delegate(s) was the "effective negotiation and open communication with support Departments and/or disciplines" that need to be involved in the clinical trial (e.g. with medical records, pharmacy, pathology and radiology), and that these activities must occur early on at the Feasibility Assessment or Document Preparation Phases.

Some stakeholders also commented that the individual arrows within the Process Diagram may not be required and that the "swim lane" columns containing the individual boxes of essential activities with some guidance around expected timeframe for each steps, may constitute a better representation of "good practice" (the report authors have a different view, and suggest retention of the arrows).

3.4 QUESTION 9 – SUGGESTIONS FOR IMPROVEMENTS TO PROCESS

The *ninth* consultation question was "Are there any points at which the process could be made more efficient?"

There was considerable stakeholder discussion around possible points at which the site assessment and authorisation processes could be made more efficient. Stakeholders unanimously commented that the Process Diagram would be enhanced by the addition of information about who will make and communicate decisions (and for this process to be done electronically) relating in particular to the Feasibility Assessment Phase, as well as to whom the decision would be communicated. Stakeholders further suggested that the inclusion of indicative timelines for the making of decisions should also be developed and communicated. Many stakeholders felt that having open and ongoing communication with all parties throughout the process would also assist with transparency and understanding.

Stakeholders indicated that all sites should have a clear clinical trial program mission and set of priorities, and that the Feasibility Assessment Phase would be far more efficient if all departments and personnel involved including the (prospective) sponsor knew the institution's objectives with regard to hosting clinical trials, as this knowledge would also enable more rapid decisions on participation. Furthermore, to improve efficiency, stakeholders also suggested that sites should have established electronic mechanisms to quickly and accurately predict recruitment numbers (based on retrospective data or current patient population data).

A number of stakeholders raised that having a nominated 'single point" of contact for the CRO/Sponsor and the "site" to liaise with internal staff and respond to issues as they arise would streamline the overall process. Two particular frustrations were often noted, one was that once the CRO/Sponsor had prepared and/or assisted with the preparation of the ethics approval documents, there was either limited or no opportunity to engage with the ethics review process. The other was that stakeholders thought that site authorisation could be made more efficient and effective by encouraging direct communication between the institution delegates (mainly the Research Governance Officer) and the CRO/Sponsor.

3.5 QUESTION 10 – DOES NOT COMPROMISE GOVERNACE PRINICIPLES

The *tenth* consultation question was "Does the proposed process compromise or nullify any important governance principles that should be maintained?"

There was minimal stakeholder feedback on this question. The was a very small minority view that undertaking site assessment and authorisation activities before an ethics submission had been approved was inappropriate, as it may result in wasting valuable resources if the research was not approved. However, most stakeholders commented that in their experience ethics approval was always obtained, even though, on many occasions, additional information needed to be provided.

3.6 QUESTION 11 – POTENTIAL BARRIERS TO IMPLEMENTATION

The *eleventh* consultation question was "Are you aware of any institutional, State, Territory or national law or binding rule that would prevent you or your institution form implementing the proposed approach?"

As discussed in Section 2.5, stakeholders commented on differences between State and Territory legislation and regulations particularly around Privacy and Guardianship with respect to clinical trial research. The comments about differences in insurance and indemnity, and biosafety requirements across States and Territories were also reiterated.

Stakeholders also indicated that most individual institutions had their own confidentiality, privacy, intellectual property and responsible conduct of research type policies that also needed to be taken into consideration in implementing any proposed process.

3.7 QUESTION 12 – RELEVANT NATIONAL AND INTERNATIONAL INITATIVES

The *twelfth* consultation questionwas "Are you aware of any national or international initiatives that are relevant to any of these phases and that should be considered?"

A number of national and international initiatives were raised by stakeholders as being relevant for consideration to the proposed "good practice" approach to site assessment and authorisation.

The Victorian Department of Health have recently produced a handbook *Research Governance and Site specific Assessment – Process and Practice* with the purpose of providing guidance to all sectors involved in clinical trials to understand the processes used to meet the regulatory requirements for clinical trial research in Australia. Stakeholders also raised the NSW Ministry of Health's Office of Medical and Health Research (OMHR) *Health and Medical Research Governance Discussion paper* and the ongoing review process as a potential source of relevant information.

Stakeholders noted other relevant NHRMC initiatives occurring at this time including a consultation process on the structure and content of a new Human Research Application Form (HRAF) to support nationally consistent ethical review and site assessment in particular for clinical trials research; a review of State/Territory insurance and indemnity arrangements and, by the Department of Industry, a consultation process to support the development of educational materials and guidance targeted for relevant audiences in clinical trials research governance.

A number of stakeholders highlighted the work done by the Health Research Council of New Zealand in centralising site authorisation and assessment processes using a portal and shared party tracking system. As discussed in Section 2.3.2, stakeholders also raised the potential benefits of a number of TransCelerate initiatives to improve these processes as well as to improve communication between sponsors and clinical trials sites including the creation of a shared, cross-industry, web-based, investigator platform with capabilities, for example, in document exchange, site feasibility surveys as well as with management of site and investigator information.

Strong positive feedback was received from a number of stakeholders about the potential learnings for Australia from the National Institute for Health Research (NIHR) reforms which focus on improving clinical trial research in the UK by focusing on patient access to trials and outcome data (through the recently established the UK Clinical Trials Gateway), attracting more biomedical investment, and by removing barriers to clinical trials through establishing a network approach (the NIHR Clinical Research Network(CRN)) as well as by providing nationally approved standard agreements and other standardised tools/resources including a template for costing clinical trials.

Other international initiatives raised by stakeholders included the newly formed 3CTN (Canadian Cancer Clinical Trial Network) formed by the federally funded Canadian Partnership Against Cancer that also takes a network approach to delivering efficient research services to support clinical trials and their rapid translation into clinical practice.

3.8 QUESTION 13 – SUITABLE FOR NON-COMMERCIALLY SPONSORED TRIALS

The *thirteenth* consultation question asked of stakeholders was "Generally, are the identified task, roles and responsibilities suitable for non-commercially sponsored and academic clinical trials? If not, which task/roles/responsibilities are not and why not?"

Stakeholders agreed that the identified tasks, activities, roles and responsibilities were also suitable for non-commercially sponsored and academic clinical trials, as was reflected by 87% of respondents to the online survey.

Again, discussed in Section 2.2, stakeholders highlighted that to be more suitable for non-commercially sponsored and academic trials, the grouping "Sponsor/CRO" would need to be amended and/or more clearly defined to include other parties such as Academic Research Organisations (AROs), Public Hospitals, Principal Investigator or an Academic Institution. To this end, if a hospital was a "sponsor" of a trial then stakeholders indicated that the Institutional delegate(s) grouping would need more involvement in the Feasibility Phase to gain a clear understanding of the role(s) of the hospital in the trial including gaining transparency of any additional required resources upfront (as there will be no funding from any other party).

3.9 QUESTION 14 – TABLE OF TASKS FOR INDIVIDUALS AND ENTITIES

The *fourteenth* consultation question asked of stakeholders was "Could the process be further modified to support the expedited assessment of 'low risk' clinical trials? If so, how?"

Firstly, it should be noted that a number of stakeholders were unclear about what was meant by, or what constitutes, a "low risk" trial. Stakeholders suggested that having a better shared understanding of what was meant by "low risk" including some developed criteria for designating "low risk trials" would be greatly beneficial.

Broadly speaking, those stakeholders who were familiar with "low risk" trials agreed that such trials should use expedited site assessment and authorisation processes, and that some institutions already deploy such a process.

Specifically, stakeholders shared learnings of how expedited assessment could be facilitated, particularly at the HREC level: firstly, a checklist would need be completed to determine if the clinical research met "low risk" criteria; the chairperson/deputy chairperson and one or more HREC members would then review the submission within a rapid time line and, finally the submission would be approved on submission to the Research Governance Office and then ratified at a subsequent HREC meeting (if there were no issues to be discussed). Some stakeholders took the view that ratification should not be a "rate limiting" step prior to commencement of the trial.

Stakeholders also commented that this type of expedited review pathway for "low risk" clinical trials was already being implemented in New Zealand as described in the Ministry of Health's *Standard Operating Procedures for Health and Disability Ethics Committee (2014).*

3.10 SUMMARY

Stakeholders were highly supportive and welcomed the Process Diagram as a positive step forward in describing a "good practice" set of tasks/activities for the individuals and entities involved in site assessment and authorisation processes for any clinical trial.

As already discussed, most of the specific feedback on the documented tasks/activities was about the "critical" Feasibility Assessment Phase. To give effect to that feedback, Table 3.1 reflects a suggested revised set of tasks/activities for the Feasibility Assessment Phase for consideration by NHMRC.

Table 3.1: Suggested revised* roles and activities for individuals and entities involved in Feasibility Assessment Phase (* revised text and/or additional roles/tasks are underlined)

Individual/Entity	Proposed role and activities
Sponsors (including Sponsor agents)	• Identify and decide on possible trial sites • Develop/provide research protocols and draft budget • Recommend standard of care definition(s) in research protocols • Identify lead HREC and ensure it has required clinical expertise • Identify Principal Investigators (PI) and possible Coordinating Principal Investigator (CPI) • Consider patient recruitment requirements and sample size required for protocol • Establish whether sites are using nationally agreed standards, guidelines, contracts, and approaches • In the event that nationally agreed standards, guidelines, contracts, and approaches are not being used, conduct a risk assessment to determine feasibility of the clinical trial
Principal Investigators (including Coordinating Principal Investigator), Clinical Trial Coordinators/Managers and Research Coordinators	• Determine availability and capacity to participate in a trial in the proposed time frame in consultation with Institutional Delegates • Agree to participation requirements (training, reporting, etc.) • Seek agreement from institutional delegates to participate in the clinical trial
Coordinating Principal Investigator	• Determine capacity and time required to prepare ethics application • Assess and seek agreement to preparation of documents
Human Research Ethics Committee (HREC)	Nil
Institution(al) delegates	• Notify intent to conduct a clinical trial to institutional stakeholders • Engage early with relevant support departments and/or disciplines • Communicate any special requirements that are specific to the institution and/or jurisdiction to the Sponsor • Determine if research complies with institution's mission and research priorities • Provide in-principle agreement to the proposed budget, contract, and availability of staff and resources • Assess availability of suitable type and number of patients • Agree to standard care as defined in the protocol • Identify any other contribution the institution may make to the clinical trial

One specific area of feedback that the NHMRC may wish to address is the redrawing of the "swim lane" Process Diagram so that the intended timing/sequencing of the tasks/activities is more explicitly reflected. At present, it is the supporting text in the Consultation Paper that clearly indicates that the intention is for research governance processes to be conducted in parallel with, or prior to, ethics approval. Stakeholders indicated that making intended timing more specific would be helpful, and then the Process Diagram could more easily be used to develop the requested associated KPIs.

That said, stakeholders did recognise and agree that central to "good practice" was that the majority of site assessment and authorisation activities be conducted not just in parallel with, but prior to, ethical review (i.e. the site becomes "clinical trial ready"). In fact, there was consistent stakeholder feedback that many sites already run governance processes in parallel with, and/or prior to, ethical review. Furthermore, stakeholders agreed that a number of key site assessment activities can be substantially completed in the Feasibility Assessment Phase and then formalised in the Document Preparation Phase, rather than be delayed until all documentation was submitted.

Stakeholders commonly agreed that major causes of delay in the site assessment and authorisation process included that budget discussions were not commenced early enough and that there were often unclear processes at "sites" for budget approval and sign off. Similarly, upfront research protocol discussions including the trial specific interpretation of "standard of care" did not commence early enough and that discussion did not always involve the "right" parties. Added to this, stakeholders, usually RGOs, indicated that submissions and other documentation received were often of poor quality and incomplete.

Another key theme was that stakeholders considered that ensuring ongoing easy access (via websites) to any relevant and current local/national information, policies, documents, frameworks and guidelines about conducting clinical trials should be a key feature of any "good practice" process. Many stakeholders also thought that the development of an overall "process" communication plan/map to overlay the Process Diagram that sets out who communicates what and when, as well as indicative time frames and/or benchmarks for key steps/activities in the site governance process would be of great benefit.

4

Broader Strategic Issues

Although stakeholders welcomed the proposed 'good practice' processes set out in the Consultation Paper as a positive step forward in clinical trial reform, many of them indicated that there was a need for larger scale reform to improve Australia's competiveness as a destination for international clinical trials, and to reverse the trend of a declining number of clinical trials conducted in Australia. Although the broader issues raised were largely outside the scope of obtaining stakeholder feedback to the Consultation Paper, this Chapter briefly summarises the issues raised so that they can be considered by the NMRC.

The feedback obtained essentially fits into two main categories. The first category covers a set of strategic issues specifically around building and maintaining an improved research culture. The second category covers the development of enabling processes, tools and technologies (e.g. single ethics review; standardised documentation; national databases for measuring KPIs around time to clinical trial start up, etc.) to support the implementation of the "good" practice clinical trial research governance process and ethical approval processes. This Chapter summarises stakeholder views on each issue.

4.1 BUILDING A RESEARCH CULTURE

Stakeholders commented that there needs to be both behavioural and organisational change, particularly in the health services sector, so as to improve the understanding of why clinical trial research is important. Change strategies would include: transparent and appropriate resourcing of "good practice" research processes; encouraging and rewarding a "culture" of research from the bottom up; understanding that an embedded culture of research attracts and maintains a "better" healthcare workforce; and that good quality research is "core" business for any healthcare institution or organisation, and ultimately the patients.

Stakeholders also commented that a key of part building research culture change was having a skilled, competent and sustainable research management workforce to support a timely, efficient and high quality process. Feedback was consistent around the under-resourcing and lack of general support for research governance particularly within the public sector. Stakeholders commented that many public sector institutions may have only one staff member in the Research Governance Office (and often only part-time) with various extra responsibilities (e.g. for ethics committee support), without consistency in training or qualifications, with no Research Manager or Director of Research, no delegated "back up" and commonly with no obvious lines of accountability or reporting.

As a result, in some cases, clinical trials management and any related administrative tasks have become solely the Research Governance Officer's responsibility regardless of his or her background or training, and the workload becomes difficult to complete in a timely fashion. Stakeholders commented that the Research Governance Officer often received poor quality and incomplete submissions and other documentation particularly from non-commercially sponsored trials which inevitably soaked up resources and resulted in significant time delays. Stakeholders advised that these delays would largely be from non-commercial trials, and there often would be knock on effects to commercial trials (even though the standard of documentation for these trials was usually better).

Moreover, stakeholders commented on the lack of overall understanding in the system of what constitutes, as well as differentiates, the activities of a Research Governance Officer/Manager vs Ethics Officer and that there was often what appeared to be "blurred" lines and/or a duplication of work.

Furthermore, stakeholders held the view that Research Governance Officers have simply "evolved" in the system without consistent terms of reference and varying degrees of management views about their in importance and understanding. To this end many stakeholders commented that there may be benefits of having a separate specific grouping for Research Governance Officers/Managers and their specific activities/tasks in the in particular in preparation and planning phase listed in the Table 2.1.

Numerous stakeholders postulated that the reason that the Research Governance Officer in public hospitals is often under-resourced was that it relies on the revenue stream obtained from clinical trials to fund positions (and this revenue has been decreasing as the number of trials decrease). Many stakeholders argued that the funding for research infrastructure that was imbedded in public hospital budgets has been eroded over the years as hospitals have had to cope with increasing activity levels and pressure to generate efficiency dividends to balance capped budgets. A few stakeholders expressed the view that the application of activity based funding (ABF) to funding research infrastructure in public hospitals would make the funding more transparent and hence allow appropriate resources to be allocated to Research Governance Offices.

4.2 DEVELOPING ENABLING PROCESSES, TOOLS AND TECHNOLOGIES

Stakeholders commonly noted that the proliferation of ethics committees has made multicentre trial research unwieldy for all parties. They thought that efficiency could be improved by moving towards more centralised reviews and fewer accredited committees. Stakeholders lamented the barriers faced in attempting to obtain approval to conduct a trial at a single site in the context of multi-site trials. They observed that much of the existing framework for approval is based on individual site approval. Identifying and amending State/Territory protocols to eliminate the need for individual site ethics approval was viewed by stakeholders as a critical prerequisite to improvement. Stakeholders were aware that several States had implemented single approval processes, and the National Mutual Acceptance Agreement between NSW, Victoria and Queensland (and recently South Australia) was seen as significant in progressing to single ethics approvals for multi-centre trials in public health organisations that cross jurisdictions. But, stakeholders did observe that this approach would need to be extended nationally and beyond the public sector to achieve its full potential.

Some stakeholders went even further and suggested that an "enterprise" approach to research governance approval could be taken, similar to what has been done in the UK, where governance review is undertaken once for a groups of sites rather than individually by each site. There is then reciprocal recognition of that governance approval across all involved sites. Stakeholders considered that there is certainly potential to implement this approach on a large scale for public hospitals in a single jurisdiction, given that they are all under the same accreditation processes, funding and reporting schemes, and that the insurance and indemnity arrangements are also the same. It was recognised that national implementation would be considerably more difficult in Australia's State and Territory based public hospital system.

In respect of enabling tools and technologies, stakeholders provided a consistent message that 'good practice' processes must include reliable indicators of performance that can be measured and bench-marked. Most stakeholders thought that KPIs at site level must be established in order to make clinical trial research more visible and increase its priority. By setting KPIs and monitoring them, an institution would have an obligation to properly resource (human and financial) its clinical trials program. Poor performance on the KPIs may well result in increased institutional funding, commitment and support being provided to the clinical trial program, with consequential improvements in timeliness.

There was also considerable discussion during the consultation process about the need to create centralised and national systems to help streamline processes associated with establishing and conducting clinical trials. There was common feedback around creating a national register of accredited sites for clinical trials. Such a database, which could be a single application system and/or website

portal would hold information about all sites and evidence of their accreditation; it could allow electronic smart forms for clinical trials applications could be created, submitted and authorised and for the current status to be visible to all parties. The database would therefore allow KPIs around timing to be generated and monitored while tracking the progress of applications through to the approval processes, with the details available to all stakeholders as real time data at any time. Stakeholders advised that a database with these features had been a clinical enabler to improvement in clinical trials approval timing in New Zealand.

Finally, stakeholders recognised the need for continuing standardisation in the infrastructure associated with clinical trials. There was recognition that progress had been made, but there was also a need expressed for further progress in areas such as further standardisation of the ethics application form and approval letter, the annual report format to ethics committees as well as site governance documentation. The need to improve (simplify) the standardised PICF, the current standardised contracts, including creation of jurisdiction specific modules that deal with the unique requirements of each State/Territory were also expressed. Other potential improvements included the development of standard templates for investigator CVs, the publication by potential trial host sites of information about research interests and specialisations, capability and capacity to conduct clinical trials, and the refinement of the standard list of items associated with clinical trials including the development of a standing costing template.

Stakeholders did recognise that there were processes already in place to address some of these issues including the review - and development of a new national human research application form, the review, and subsequent costing of the revised standard list of items associated with clinical trials, the development of role statements and the analysis of the training needs of Research Governance Officers, and the national review of insurance and indemnity arrangements for clinical trials. Many stakeholders stated that they looked forward to a continuation of the clinical trial reform process and to the results of these (and other) development projects coming together in a cohesive way to achieve truly efficient and effective processes for approving and conducting clinical trials in Australia.

Appendix A – Face-to-face meetings

State	Who	Title	Organisation	Venue, date and time
NSW	Mr. Omar Khan	Industry Policy Manager	Medicines Australia[c]	HealthConsult boardroom, 86 Liverpool St., Sydney, 4th June, 10.00-11.00
NSW	Mr. Gary Burgess	Director of Regulatory Affairs	Medical Technology Association of Australia[c]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July, 11.30-12.30
NSW	Ms. Susan Hopkins	Clinical Research Manager	Johnson and Johnson[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July, 11.30-12.30
NSW	Mr. Falk Thiele	Director, Clinical and Regulatory Affairs	Biotronik[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July, 11.30-12.30
NSW	Ms. Catherine Bourgeois	Vice President Field Clinical Affairs	St. Jude Medical (Asia-Pacific and Japan)[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July, 11.30-12.30
NSW	Prof. John Simes	Consultant Medical Oncologist	NHMRC Clinical Trials Centre, University of Sydney[g]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July 14.00-14.30
NSW	Ms. Thalia Hambides		NHMRC Clinical Trials Centre, University of Sydney[g]	HealthConsult boardroom, 86 Liverpool St., Sydney, 10th July, 14.00-14.30
NSW	Ms. Anne O'Neill	Associate Director, Office of Health and Medical Research	Ministry of Health[a]	Level 5, Conference Room 2, Office of Health and Medical Research, 11th July, 14.00-15.30
NSW	Mr. James Cokayne	Principal Policy Officer, Research Ethics and Governance	Ministry of Health[a]	Level 5, Conference Room 2, Office of Health and Medical Research, 11th July, 14.00-15.30
NSW	Ms. Sharon Falleiro	Senior Policy Officer, Research Ethics and Governance	Ministry of Health[a]	Level 5, Conference Room 2, Office of Health and Medical Research, 11th July, 14.00-15.30
NSW	Ms. Joan Torony	Central Operations and Research Manager	Trans Tasman Radiation Oncology Group[c]	HealthConsult boardroom, 86 Liverpool St., Sydney, 11th July, 11.30-12.30
NSW	Ms. Lucy La Cioppa-Perrett	Clinical Research Manager	Roche Products[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 11th July 10.00-11.00
NSW	Ms. Candice Fitzgerald	Country Head	Roche Products[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 11th July, 10.00-11.00
NSW	Ms. Jenelle Quick	Head of Research	Seventh Day Adventists[f]	HealthConsult boardroom, 86 Liverpool St., Sydney, 11th July, 16.00-17.00
NSW	Dr. Marisa Peterson	Managing Director	George Clinical (George Institute for Global Health)[g]	HealthConsult boardroom, 86 Liverpool St., Sydney, 14th July, 14.00-15.00
NSW	Ms. Marliea Gonzales	Clinical Operations Manager	Eli Lilly[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 14th July, 11.30-12.30

State	Who	Title	Organisation	Venue, date and time
NSW	Ms. Sibyl Masterman	Clinical Operations	Eli Lilly[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 14th July, 11.30-12.30
NSW	Ms. Marisia Carr	Clinical Operations	Eli Lilly[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 14th July, 11.30-12.30
NSW	Ms. Zoe Armstrong	Executive Director, Clinical Research	Merck, Sharp and Dome[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 15th July, 16.00-17.00
NSW	Ms. Julie Charlton	Research Governance Manager	Lifehouse[f]	HealthConsult boardroom, 86 Liverpool St., Sydney, 15th July, 16.00-17.00
NSW	Mr. Mitch Kirkman	Development Quality Assurance Manager	Novartis Pharmaceuticals[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 9th August, 9.30-10.30
NSW	Ms. Sarah Tohill	Clinical Operations Process and Training Manager	Novartis Pharmaceuticals[b]	HealthConsult boardroom, 86 Liverpool St., Sydney, 9th August, 9.30-10.30
QLD	Ms. Sue Hooper	Director, Health and Medical Research	QLD Health Department[a]	Room 2-1, Level 2, 15 Butterfield St Herston, 6th July, 8.30-9.30
QLD	Ms. Sara Gray	Principal Policy Maker, Health and Medical Research	QLD Health Department[a]	Room 2-1, Level 2, 15 Butterfield St Herston, 6th July, 8.30-9.30
QLD	Prof. Christian Gericke	Chief Executive Officer	Wesley Research Institute[c]	UnitingCare Health, Level 5, 193 North Quay, Brisbane, 6th August, 10.00-11.00
QLD	Mr. Richard Royle	Executive Director	UnitingCare Health[f]	UnitingCare Health, Level 5, 193 North Quay, Brisbane, 6th August, 10.00-11.00
QLD	Dr. Christian Rowan	Deputy Chief Medical Officer	UnitingCare Health[f]	UnitingCare Health, Level 5, 193 North Quay, Brisbane, 6th August, 10.00-11.00
Victoria	Ms. Jo Phipps-Nelson	Head (Acting) Centre for Biostatistics and Clinical Trials	Peter MacCallum Cancer Centre[g]	Level 2, 10 St Andrew's Place, East Melbourne, 22nd July 11.30-13.00
Victoria	Mr. Paul Fahey	Development and Project Manager, Centre for Biostatics and Clinical Trials	Peter MacCallum Cancer Centre[g]	Level 2, 10 St Andrew's Place, East Melbourne, 22nd July 11.30-13.00
Victoria	Ms. Sophie Mepham	Department Head, Clinical Trials Unit	Peter MacCallum Cancer Centre[e]	Level 2, 10 St Andrew's Place East Melbourne, 22nd July, 11.30-13.00
Victoria	Ms. Marianne Hundling	Clinical Trials Program Manager	Peter MacCallum Cancer Centre[e]	Level 2, 10 St Andrew's Place East Melbourne, 22nd July, 11.30-13.00
Victoria	Ms. Rhiannon Tate	Executive Officer	Australian Clinical Trials Alliance[c]	Monash Department of Epidemiology and Preventive Medicine, Level 6, 99 Commercial Rd., Melbourne, 22nd July, 10.00-12.00
Victoria	Prof. John Zalcberg	Medical Oncologist	Australian Clinical Trials Alliance[c]	Monash Department of Epidemiology and Preventive Medicine, Level 6, 99 Commercial Rd., Melbourne, 22nd July, 10.00-12.00

State	Who	Title	Organisation	Venue, date and time
Victoria	Prof. John McNeil	Professor and Head, School of Public Health and Preventive Medicine, Monash University	Australian Clinical Trials Alliance[c]	Monash Department of Epidemiology and Preventive Medicine, Level 6, 99 Commercial Rd., Melbourne, 22nd July, 10.00-12.00
Victoria	Mr. Carlo Macarrone	Associate Director, Clinical Research	GlaxoSmithKline Australia[b]	Level 4, 436 Johnston St., Abbotsford, 23rd July, 13.30-15.00
Victoria	Mr. Alex Dimitroff	Operations Science Leader and Senior Clinical Research Associate	GlaxoSmithKline Australia[b]	Level 4, 436 Johnston St., Abbotsford, 23rd July, 13.30-15.00
Victoria	Mr. Darryl Carrington	Clinical Research Manager	GlaxoSmithKline Australia[b]	Level 4, 436 Johnston St., Abbotsford, 23rd July, 13.30-15.00
Victoria	Dr. Suzanne Hasthorpe	Manager, Coordinating Office for Clinical Trial Research	Health Review and Regulation, Department of Human Service[a]	Department of Human Services, 50 Lonsdale St., Melbourne, 23rd July, 12.00-13.00
Victoria	Dr. Anne Lavelle	Chief Executive Officer	Ausbiotech[b]	Ausbiotech Suite 4, Level 4, 627 Chapel St, South Yarra, 23rd July 10.30-11.30
WA	Dr. Gary Geelhoed	Chief Medical Officer	WA Health Department[a]	Level 2, C Block, 189 Royal St., East Perth, 31st July, 11.00-12.00
WA	Dr. Tarun Weeramanthri	Chief Health Officer	WA Health Department[a]	Level 2, C Block, 189 Royal St., East Perth, 31st July, 11.00-12.00
WA	Ms. Katherine Coltrona	Senior Policy Officer, (Research Governance)	WA Health Department[a]	Level 2, C Block, 189 Royal St., East Perth, 31st July, 11.00-12.00
WA	Prof. Nik Zeps	Group Research Coordinator, St John of God Healthcare	St. John of God[f]	Miss Maudes, 97 Murray St, Perth, 31st July, 8.00-9.00
SA	Mr. David Van Der Hoek	Senior Policy Officer, Office for Research Development	SA Health Department[a]	Citi Centre Building 11 Hindmarsh Square Adelaide 1st August, 13.30-14.30
SA	Ms. Heather Petty	Acting Manager, Officer for Research Development	SA Health Department[a]	Citi Centre Building 11 Hindmarsh Square Adelaide, 1st August, 13.30-14.30
ACT	Prof. Paul Gatenby	Professor Emeritus	ANU Medical School, Canberra Hospital Campus[h]	ANU Medical School Building, Level 2, Building 4, Canberra Hospital, 11th July, 13.30-14.30
ACT	Ms. Maria Travers	Director of the Research Investment Section	Safety, Quality and Research Branch, Acute Care Division, Department of Health, Australian Government[a]	Department of Health, Level 6 Scarborough House, Atlantic Street, Woden, 11th July, 12.15-13.15
ACT	Mr. Alan Groth	Policy Director, Workforce Development	Universities Australia[k]	Universities Australia, 1 Giels Court, Deakin, 11th July, 10.30-11.30
ACT	Ms. Sara Brown	Policy Director, Research and Innovation	Universities Australia[k]	Universities Australia, 1 Giels Court, Deakin, 11th July, 10.30-11.30
ACT	Mr. Renne Kyle	Policy Analyst, Research and	Universities Australia[k]	Universities Australia, 1 Giels Court, Deakin,

State	Who	Title	Organisation	Venue, date and time
		Innovation		11th July, 10.30-11.30
ACT	Prof. Colin Thompson	Academic Leader: Law and Ethics	Graduate School of Medicine, University of Wollongong[h]	Silo Bakery, Kingston, 11th July, 15.00-16.00

a=Government; b=Pharmaceutical and medical device industry; c=Peak bodies and professional organisations; d=Clinical Trial Networks; e=Public hospitals; f=Private hospitals; g=Third party trial centres, associations and other clinical trial specialist; h=Research institutes and universities; i=CRO

Appendix B – Focus group sessions

State	Session	Venue, Date and Time	Number of Attendees	Organisations Represented
New South Wales	Session 1	The George Institute for Global Health, Sydney 8th August 14:00	15	Ambulance Service of NSW[a] Amgen Australia[b] ARCS Australia Ltd[c] Bayer[b] Cancer Institute NSW[a] Eli Lilly[b] James Cook University (QLD)[h] Kinghorn Cancer Centre[e] Macquarie University[h] NHMRC Clinical Trials Centre[g] Pfizer[b] Quintiles Pty Ltd[i] South Eastern Sydney Local Health District[a] South Western Sydney Local Health District[a] Sydney Children's Hospital Network[a] Sydney Local Health District (Royal Prince Alfred Hospital)[a] The George Institute for Global Health[c] Westmead Hospital[e]
	Session 2	Westmead Hospital, Westmead 14th August 11:00	15	
Victoria	Session 1	The Alfred Hospital, Melbourne 21st July 14:00	9	Amgen Australia[b] Austin Hospital[e] Australasian Sarcoma Study Group[d] Baker IDI Heart and Diabetes Research Institute[h] Barwon Health[a] Bristol-Myers Squibb[b] Burnet Institute[h] Cancer Council Victoria[a] Cancer Trials Australia[d] Celgene Australia[b] Centre for Eye Research Australia[h] Deakin University[h] Eastern Health[a] IPSEN Pty Ltd[b] Melbourne Health[e] Monash Health[e] Nucleus Network[d] Orygen Youth Health Research Centre[h] Peter MacCallum Cancer Centre[e] PPD Australia[i] Research Australia[c] Royal Children's Hospital Melbourne[e] Victorian Comprehensive Cancer Centre[a]
	Session 2	Murdoch Childrens Research Institute, Parkville 22nd July 14:00	21	
Queensland	Session 1	Queensland Department of Health, Herston 5th August 14:00	20	Gold Coast University Hospital[e] Griffith University[h] Mater Research Office[h] Metro North Hospital and Health Service[a] North Coast NSW Human Research Ethics Committee (NSW)[a] Prince Charles Hospital[e] Princess Alexandra Hospital[e] QIMR Berghofer Medical Research Institute[h] Qpharm[i] Royal Brisbane Women's Hospital[e] Royal Children's Hospital Brisbane[e] West Moreton Hospital and Health Service[a]
Western Australia	Session 1	Sir Charles Gardner Hospital, Nedlands 30th August 16:00	13	Curtin University[h] Department of Health (WA)[a] Graylands Hospital[e]

State	Session	Venue, Date and Time	Number of Attendees	Organisations Represented
				Harry Perkins Institute of Medical Research[h] North Metropolitan Health Service[a] Primary Care Collaborative Cancer Clinical Trials Group (PC4)[d] Princess Margaret Hospital for Children[e] Sir Charles Gardner Hospital[e] St John of God Health Care[f] St John of God Hospital Subiaco[f] Telethon Kids Institute[h]
South Australia	Session 1	Royal Adelaide Hospital, Adelaide 1st August 09:30	8	Calvary North Adelaide Hospital[f] Central Adelaide Local Health Network[a] IDT CMAX Ltd[i] Murdoch Children's Research Institute[h] Quintiles Pty Ltd[i] The Queen Elizabeth Hospital[e] The University of Adelaide[h] Women's and Children's Health Network[a]

a=Government; b=Pharmaceutical and medical device industry; c=Peak bodies and professional organisations; d=Clinical Trial Networks; e=Public hospitals; f=Private hospitals; g=Third party trial centres, associations and other clinical trial specialist; h=Research institutes and universities; i=CRO

Appendix C – Stakeholder survey

Section 1: Demographics

1. What state/territory do you work in?
   - ☐ New South Wales
   - ☐ Victoria
   - ☐ Queensland
   - ☐ South Australia
   - ☐ Western Australia
   - ☐ Northern Territory
   - ☐ Tasmania
   - ☐ Australian Capital Territory
   - ☐ Other (please specify) _____

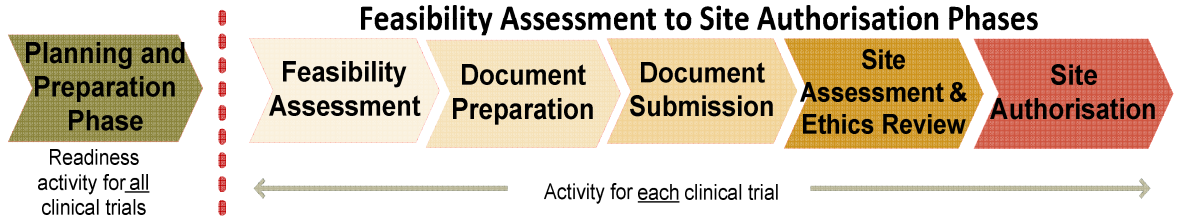
2. What sector do you work in?
   - ☐ Public
   - ☐ Private
   - ☐ Not for profit
   - ☐ University
   - ☐ Other (please specify) _____

3. What industry do you work in?
   - ☐ Pharmaceutical
   - ☐ Medical devices
   - ☐ Jurisdictional health authority
   - ☐ Clinical trial network
   - ☐ Public hospital
   - ☐ Private hospital
   - ☐ Research body (e.g. university)
   - ☐ Clinical trial association
   - ☐ Other (please specify) _____

4. What is your role in your organisation?
   - ☐ Coordinating Principal Investigator
   - ☐ Principal Investigator
   - ☐ Member of Human Research Ethics Committee (HREC)
   - ☐ Senior Executive in trial host institution (e.g. Hospital Chief Executive, Research Director)
   - ☐ Research Governance Manager/Officer in trial host institution
   - ☐ Clinical Governance Manager/Officer in trial host institution
   - ☐ Clinical Trial Researcher
   - ☐ Work for Trial Sponsor Organisation (industry)
   - ☐ Work for Trial Sponsor Organisation (research and/or clinical trial collaborative)
   - ☐ Work for Contracted Research Organisation
   - ☐ Other (please specify) _____

The questions in the following sections are based on the consultation paper developed by NHMRC.

Please refer to the following figure for the proposed phases leading to site-authorisation of a clinical trial.



Section 2: Planning and preparation for clinical trials readiness

5. Does Table 1 (Roles and activities for individuals and entities involved in the clinical trial planning and preparation phase) in the consultation paper describe the correct set of tasks?

☐ Yes
☐ No

If answered No, please provide comments.

_____
_____

6. Are the tasks allocated to the correct individual(s) or entity?

Correct individual(s) or entity	Yes	No
Contract Research Organisation / Sponsor		
All Principal Investigators		
Human Research Ethics Committee (HREC)		
Institution (Research Director, Research Governance Manager/Officer, Delegates etc.)		

If answered No, please provide comments

_____
_____

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

Correct individual(s) or entity	Yes	No	N/A
Contract Research Organisation / Sponsor			
All Principal Investigators			
Human Research Ethics Committee (HREC)			
Institution (Research Director, Research Governance Manager/Officer, Delegates etc.)			

If answered Yes, please provide comments on what more could be done.

_____
_____

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

Law or binding rule	Yes	No	N/A
Institutional			
State/Territory			
National			

If answered Yes, please provide comments.

_____

_____

9. Generally, are the identified tasks suitable for non-commercially sponsored and academic clinical trials?

Type of trial	Tasks	
	Yes	No
Non-commercially sponsored		
Academic		

If answered No, please provide comments.

_____

_____

10. Generally, are the identified roles and responsibilities suitable for non-commercially sponsored and academic clinical trials?

Type of trial	Roles and responsibilities	
	Yes	No
Non-commercially sponsored		
Academic		

If answered No, please provide comments.

_____

_____

Section 3: Key activities for assessment and authorisation of each clinical trial

The following questions relate to all tasks involved in the assessment and authorisation of each clinical trial. This involves the tasks outlined in the *Clinical Trial- Feasibility Assessment to Site Authorisation* process diagram, which comprises the following phases of the process: Feasibility Assessment; Document Preparation; Document Submission; Site Assessment & Ethics Review; and Site Authorisation.

11. Does the swim lane flow chart (Attachment A – Process Diagram) in the consultation paper identify the appropriate high level process steps for each phase?

Phase	Yes	No
Feasibility Assessment		
Document Preparation		
Document Submission		
Site Assessment & Ethics Review		
Site Authorisation		

If answered No, please provide comments.

_____

_____

12. Are the high level activities matched to the correct responsible person/s?

Responsible person/s	Yes	No
Contract Research Organisation / Sponsor		
All Principal Investigators (PI)		
Coordinating Principal Investigator (CPI)		
Human Research Ethics Committee (HREC)		
Institutional Delegate/s		

If answered No, please provide comments.

_____

_____

13. Does the process diagram reflect 'good practice' throughout the phases? Please identify any phases that do not reflect 'good practice'.

Phase	Yes	No	N/A
Feasibility Assessment			
Document Preparation			
Document Submission			
Site Assessment & Ethics Review			
Site Authorisation			

If answered No, please provide comments.

_____

_____

14. Are there any points at which the process could be made more efficient? Please identify in which phase the efficiency could be gained.

Phase	Yes	No	N/A
Feasibility Assessment			
Document Preparation			
Document Submission			
Site Assessment & Ethics Review			
Site Authorisation			

If answered Yes, please provide comments.

_____

_____

15. Does the proposed process compromise or nullify any important governance principles that should be maintained?

☐ Yes
☐ No

If answered Yes, please provide comments.

_____

_____

16. Are you aware of any institutional, State, Territory or National law or binding rule that would prevent you or your institution from implementing the proposed approach?

Law or binding rule	Yes	No	N/A
Institutional			
State/Territory			
National			

If answered Yes, please provide comments.

_____

_____

17. Are you aware of any national initiatives that are relevant to any of these phases that should be considered?

Phase	National initiative	
	Yes	No
Feasibility Assessment		
Document Preparation		
Document Submission		
Site Assessment & Ethics Review		
Site Authorisation		

If answered Yes, please provide comments.

_____

_____

18. Are you aware of any international initiatives that are relevant to any of these phases that should be considered?

Phase	International initiative	
	Yes	No
Feasibility Assessment		
Document Preparation		
Document Submission		
Site Assessment & Ethics Review		
Site Authorisation		

If answered Yes, please provide comments.

_____

_____

19. Generally, are the identified tasks suitable for non-commercially sponsored and academic clinical trials?

Type of trial	Tasks	
	Yes	No
Non-commercially sponsored		
Academic		

If answered No, please provide comments.

_____

_____

20. Generally, are the identified roles and responsibilities suitable for non-commercially sponsored and academic clinical trials?

Type of trial	Roles and responsibilities	
	Yes	No
Non-commercially sponsored		
Academic		

If answered No, please provide comments.

_____

_____

21. Could the process be further modified to support the expedited assessment of 'low risk' clinical trials?

☐ Yes

☐ No

If answered Yes, please provide comments.

_____

_____

End of survey – Thank you

Appendix D – Survey respondents per question

Question Number	Question	Respondents
	Section 1	
1	What state/territory do you work in?	79
2	What sector do you work in?	79
3	What industry do you work in?	79
4	What is your role in your organisation?	79
	Section 2	
5	Does Table 1 (Roles and activities for individuals and entities involved in the clinical trial planning and preparation phase) in the consultation paper describe the correct set of tasks?	33
6	Are the tasks allocated to the correct individual(s) or entity?	34
7	Is there more that could be done in planning and preparation and if so, what and by whom?	33
8	Are you aware of any institutional, state, territory or national law or binding rule that would prevent you or your institution from implementing the tasks in this phase as proposed?	32
9	Generally, are the identified tasks suitable for non-commercially sponsored and academic clinical trials?	30
10	Generally, are the identified roles and responsibilities suitable for non-commercially sponsored and academic clinical trials?	29
	Section 3	
11	Does the swim line flow chart (Attachment A – Process Diagram) in the consultation paper identify the appropriate high level tasks for each phase?	27
12	Are the high level tasks matched to the correct responsible person/s?	26
13	Does the process diagram reflect 'good practice' throughout the phases? Please identify any phases that do not reflect 'good practice'.	26
14	Are there any points at which the process could be made more efficient? Please identify in which phase the efficiency could be gained.	25
15	Does the proposed process compromise or nullify any important governance principles that should be maintained?	26
16	Are you aware of any institutional, State, Territory or National law or binding rule that would prevent you or your institution from implementing the proposed approach?	27
17	Are you aware of any national initiatives that are relevant to any of these phases that should be considered?	26
18	Are you aware of any international initiatives that are relevant to any of these phases that should be considered?	25
19	Generally, are the identified tasks suitable for non-commercially sponsored and academic clinical trials?	23
20	Generally, are the identified roles and responsibilities suitable for non-commercially sponsored and academic clinical trials?	23
21	Could the process be further modified to support the expedited assessment of 'low risk' clinical trials?	24