Developing a human research application form for research involving humans

As a part of its work to increase the efficiency and reduce the complexity of ethics approval processes for human research, NHMRC undertook a consultation on the proposal to develop a national application form for research involving humans. A simplified and efficient form will support nationally consistent ethical review and site-assessment for all human research, in particular clinical trials.

NHMRC developed a proposed structure and indicative content for the form using the expertise of representatives from HRECs, public and private hospitals, academic institutions and commonwealth and state government departments. An advisory group comprising representatives from the academic, public and private hospital, industry and state government sectors advised on this. Stakeholders were asked to provide comment on a number of aspects, including the suitability of key proposed features, the applicability for low risk research, indicative content and any potential technical barriers. It is expected that this redeveloped form will replace NEAF.

NHMRC will now, with the assistance of a content development group:

1. Develop the content of a redeveloped form;
2. Consider the technical aspects of the form, including interoperability with existing institutional systems and including features such as auto-complete and spell checking.

There will be further opportunity for consultation and comment on the form as it is being developed. Further inquiries to riact@nhmrc.gov.au
Building a new application form for use in human research

Report of a consultation conducted on behalf of NHMRC by Roxsolt Pty

September 2014
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## 1 Glossary

### 1.1 Acronyms

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>ACTA</td>
<td>Australian Clinical Trials Alliance</td>
</tr>
<tr>
<td>ANZCTR</td>
<td>Australian and New Zealand Clinical Trials Registry</td>
</tr>
<tr>
<td>ARC</td>
<td>Australian Research Council</td>
</tr>
<tr>
<td>ARCS</td>
<td>Australian Clinical and Regulatory Scientists</td>
</tr>
<tr>
<td>ARPANSA</td>
<td>Australian Radiation Protection and Nuclear Safety Agency</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated Statement of Reporting Trials</td>
</tr>
<tr>
<td>COREQ</td>
<td>Consolidated Criteria for Reporting Qualitative Research</td>
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<tr>
<td>FOR Codes</td>
<td>Field of Research Codes</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>HREF</td>
<td>Human Research Ethics Form</td>
</tr>
<tr>
<td>ICH CGP</td>
<td>International Conference on Harmonisation – Good Clinical Practice</td>
</tr>
<tr>
<td>IRAS</td>
<td>Integrated Research Application System</td>
</tr>
<tr>
<td>LHD</td>
<td>Local Health District</td>
</tr>
<tr>
<td>NEAF</td>
<td>National Ethics Application Form</td>
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<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NMA</td>
<td>National Mutual Acceptance of ethical and scientific review of clinical trials</td>
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<tr>
<td>PHO</td>
<td>Public Health Organisation</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Clinical Trial</td>
</tr>
<tr>
<td>SPIRIT</td>
<td>Standard Protocol Items: Recommendations for Interventional Trials</td>
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<tr>
<td>STROBE</td>
<td>STrengthening the Reporting of OBservational studies in Epidemiology</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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### 1.1.1 Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Jurisdictions</td>
<td>Each Australia State or Territory and their lead agencies involved in human research</td>
</tr>
<tr>
<td>Certified HREC</td>
<td>The HREC of an institution whose ethics review processes have been certified under the NHMRC National Certification Scheme, in support of single ethical review for multi-centre human research</td>
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2 Executive Summary

Scope and objectives
This report summarises the feedback from the National consultation meetings held with stakeholders on the concept Human Research Application Form (HRAF). The consultation forms part of a broader project looking at the redevelopment of a single, national ethics application form, a project that also has linkages to other NHMRC programs around research governance and timeliness of ethical review.

The stakeholders who attended the consultation meetings or provided responses online came from diverse backgrounds and organisations and shared an enormous amount of detail around what makes a good application and review process. Despite the diverse views, the most heavily weighted consolidated feedback in the report is that of researchers completing the form and of HREC members reviewing it. Thought has also been given to the efficient administrative process that support ethics review; however this is not the primary focus of the consultation or the report.

Consultation Findings
The consultation findings presented are those on which there was general agreement. Where there was no agreement or no clear path forward on a preferred option these findings are highlighted for further discussion by NHMRC. Feedback specific to particular areas is highlighted in the report and NHMRC may wish to explore how these matters could be included in the development of the HRAF (or any successor version).

Overall, stakeholders who attended meetings or provided email feedback were overwhelmingly supportive of the principle of the development of a new national ethics form. However, there was reservation from some sectors on the feasibility of a single form and its ability to reflect the needs and language of diverse research disciplines. Jurisdictions varied in their support; but this reticence was mostly due to the perceived budget and resourcing impact of implementing a new form. While stakeholders in the university sector were supportive of the concept, many institutions have invested heavily in developing their own online forms. Therefore, significant engagement will need to occur with this sector. In addition, while the benefits for the health sector, with its increasing number of multi-centre studies, are clear, the benefit to the university sector is not as well articulated. If the form is to be successful as a national form then buy-in and uptake from universities is critical.

The feedback received through the consultation process was rich and highly detailed but there are some key decision points, which will dictate the way the form and the subsequent question logic is developed. For these decision points there is no clear right or wrong path, simply multiple feasible options. Decisions on development may be impacted by other factors out of the scope of this report that may provide a clearer way forward.

General Findings:
The findings are presented in order of priority. Priority is determined by the impact of the finding on producing a single national ethics application form that can be used by all researchers, for all research activities, with minimal duplication and secondly by potential feasibility.

- The consultation indicated that HREC forms are used for multiple purposes – ethical review, as an education process for researchers and for administrative purposes. Any new form must continue to serve these three needs, however there is a significant opportunity to enhance the education aspect through meaningful guidance.
- Beta testing of a draft form by HRECs, researchers and administrators prior to release is essential. This process will identify any issues of language, logic, duplication, functionality and useability that can be resolved prior to roll out. This also allows jurisdictions the option to test and amend their specific questions in the form.
- Developing and testing “proof of concept” (POC) is recommended where there are multiple feasible options for form structure. This will provide concrete feedback from stakeholders as to how the form structure performs in terms of ease of completion, logic of questions and reviewability. POC can be incorporated into technical development and beta testing.
- Stakeholders were supportive of the concept but indicated that ongoing involvement of NHMRC in terms of consultation, training, post-implementation support and responsiveness were important factors in order for HRAF to be successful as a single, national form
- The form should be written with the language of researchers at front of mind. This includes clear, well-defined terminology. Problematic areas of terminology are highlighted in section 6.1.7.
- Stakeholder’s valued guidance and help being built into the form. Help functionality needs to be question specific, provide examples and clearly communicate the purpose of the question.
- Integration of other forms such as ANZCTR, site specific forms and the pre-population of fields is considered essential functionality and should be extended to allow other forms to be pre-populated and completed on the HRAF site. Examples include applications to access or link with large data collections such as cancer registries.
- The HRAF term was not well accepted by stakeholders with comments to the effect that any name or acronym needs to be pronounceable and meaningful. The NEAF terminology was not seen as problematic.

Findings on Form Structure

- Stakeholders liked the proposed structure and the functionality of a dynamic form that only drew in the ethically relevant questions, however they still wished to see the questions that they did not have to answer, even if these were greyed out. Stakeholders consistently suggested that projects that relate to quality improvement or evaluation and that do not seek publication in a journal be directed out of the form at the introduction stage.

- Stakeholders expressed a strong view that the “question-predicting-next-question” approach that relied on tick boxes was limiting in the information it yielded, created presumptive thinking from HRECs and researchers and was overall an undesirable structure for a new form. Researchers and HRECs strongly supported a form structure of open-ended questions that allowed narrative and evaluation from a researcher perspective. This provides the opportunity for the researcher to provide explanation and address areas of grey – the “yes, but” scenarios that the tick box format does not accommodate. Where narrative is provided, HRECs have the opportunity to evaluate the thinking and understanding of the researcher and respond with the appropriate changes, advice and guidance.

- Stakeholders also felt that “not applicable” should be available in response to many questions with an opportunity to explain why the applicant believes this question does not apply to their proposed research. This structure again provides the opportunity for narrative and explanation from the researcher rather than leaving HRECs to fill in the gaps where a question is not adequately answered via the available tick boxes. It creates a far more flexible and readable form.

- There were some areas for which the tick box structure was perceived as useful such as for filtering purposes to identity the questions that should be drawn into the form and where there were common, “acceptable” options or answers for questions, for example there are a few known approaches to “how will consent be sought?”. The option to provide further information should also be included.

- The proposed categories listed in section 2 of the consultation paper were not supported and were not considered useful. The purpose of categorising research was put forward as related to risk assessment and its function in generating distinct ethical questions that are forward-populated in the form, depending on the category of research. The categories proposed in the consultation paper were viewed as unhelpful as they placed too much emphasis on biomedical research and because the distinctions between the categories were unclear. Moreover, it was felt that the ethically distinct questions that might be associated with each category were not apparent and significant overlap was anticipated in the questions to be asked of each category. If it is not possible to use broad categories to trigger ethically distinct questions, then it is questionable what purpose categorisation serves and how activity that could fall into multiple categories would be managed.

- Categorisation was also discussed in the context of risk assessment. The idea that some categories of research pose more risk than others and that this information can be used to default to a low risk review pathway was questioned. Again, categories were seen as too constraining and, if a risk assessment is required to determine review pathway (low risk or full HREC review), then this should be based on what is happening to the participant – something which is
determined by methodology (or combination of methodologies) rather than by a research category.

- The consultation meetings revealed differences in opinion between HRECs, researchers and administrative staff over what is essential information to be captured in an ethics application form. The section in the consultation paper on risk assessment was one such divisive area. There were different understandings of the role and purpose of the risk assessment. HRECs and Ethics Officers consistently felt that this was the role of the HREC and researchers should not be the ones to indicate if their research is low risk, while researchers reported that they should be given the opportunity to justify why their work is low risk. It was also not clear what the purpose of an upfront risk assessment was other than to determine a review pathway. A suggested solution to this is a question at the end of the form that asks if the researcher believes their research is of no more than low risk and seeks justification based on the National Statement. This approach is intended to remove assumptions that research is low risk but ask the applicant to explain their understanding of the risk presented. Although completed last in the application form, this question could be appear first on the submitted form to enable the appropriate review processes.

- Another area of divergent views was on what information is essential in the core information, most notably the level of detail required on sites. Jurisdictions and stakeholders more experienced in the application of multicentre review processes requested minimal detail on sites – only the name of the site and the investigator in charge. Where as jurisdictions and stakeholders who were less experienced in multicentre research took a more conservative view and wished to know the details of all sites and staff involved. Social scientists presented another view that challenged HRECs view of site as a physical location and sought that any form encompass the changing nature of where research activity takes place.

- Stakeholders required that the form collect information required by NHMRC as part of annual reporting for Certified and registered HRECs.

- The consultation presented two distinct views – that of HREC members reviewing the application and the feedback of useful functionality for researchers completing the application. These two perspectives were often consistent but it was apparent that the most useful structure for completing the form might differ from the best structure to review the form. The technical development of the form should incorporate these two perspectives where possible. For example, it is preferred that contact and site details be entered first from the applicants perspective, however the HREC was less interested in these and wished to see the details of what is happening in the research on the first few pages. Investigator and site details were requested in table summary form, however this may not be the most efficient way to enter this information. Please also see comments on risk assessment and relationship with low risk review.

- One form that encompasses low risk research was supported on the logic that simple proposals will have shorter forms. This assumption will require testing to ensure that it holds true.

- If the purpose of the risk assessment is to determine review pathway, consider placing the risk assessment at the end of the form as a series of simple questions on the researchers perspective regarding why this proposal is no more than low risk. This option removes the need for extensive check boxes in an up-front risk assessment. It also allows risk to be considered in the context of the study and the participants rather than particular responses generating an automatic designation of low risk. Being at the end, if an applicant believes their research is more than low risk they do not have to go through a redundant risk assessment process.

- There is increasing overlap and dependencies between sections 2 – Project Description and Categorisation of Research and Section 3 – Participants. Consideration should be given to combining them to one section which includes the additional information relating to the ethical issues raised by the methodology and participants.
- Stakeholders supported moving the filtering questions to generate the ethically distinct questions relevant to the application to the beginning of the application, potentially before section 1. Potential filtering categories may include:
  
  a) The conduct of research overseas.
  
  b) Drugs or devices either within approved indication, outside of approved indication or unapproved.
  
  c) Unapproved or unvalidated laboratory tests (now require CTN form).
  
  d) Randomisation.
  
  e) Intervention – may be educational, psychological, procedural or any variation from standard practice in a given context.
  
  f) Emergent design
  
  g) Use of deceptive methods, covert methods or non-disclosure of the true nature of research to participants.
  
  h) Collection and use of human tissue.
  
  i) Genetic research.
  
  j) Use of ionising radiation.
  
  k) Obtaining consent, or not.
  
  l) Observational methods.
  
  m) Storing and linking data.
  
- Stakeholders favoured a principle-based approach to determining which ethically distinct questions should be included in the form. As discussed above in the general findings on form structure, the categories outlined in the consultation paper were not supported. A principle-based approach circumvents issues of definition, provides detail to the HREC on what is actually being done as part of the proposal and enables multiple methods to be selected. A single category limits the use of multiple methods and provides a narrow view of the proposal.
  
- Stakeholders were supportive of the inclusion of a research governance or site assessment module as the advantages to completing forms in one location and pre-populating information was a valuable saving of time and effort. However, administrators in particular cautioned against any suggestion that HREC and governance processes were to be combined. Therefore the form and guidance should clearly communicate that they are two separate processes.
  
- The consultation showed consensus that privacy, information management and data governance should be in a separate section (section 4). However careful question development is required to prevent overlap between this section and jurisdictional specific privacy questions.
  
- There is the potential for duplication in questioning where a waiver of consent is sought as federal and some jurisdictional privacy laws also cover this process. Stakeholders supported aspects of privacy related to participants and consent to be included in section 3, with links to section 4 as appropriate. However it is imperative that there is no duplication of questioning between the two sections.

**Findings on Form Functionality**

- Researchers requested a contact database that pre-populated HRAF be included as part of the form functionality. This functionality would significantly reduce the time spent entering the same information. An example of this is the IRAS contact database. (See Integrated Research Application System Forms, Functions and Governance)
  
- To understand the question logic decision points, it was felt useful to have a visual “question tree” that outlined all the questions but greyed out those that are not required. This enables backtracking if an incorrect selection is made. An example of this can be seen in the IRAS screenshots in appendix 7.3)
The form requires the ability to manage both electronic signatures/declarations and signatures to accommodate the variation in submission processes between electronic and hard copy submission.

Jurisdictions that use AU RED expressed concern about the potential loss of functionality that currently exists when applications are submitted via ethicsform.org/au. Currently researchers can include attachments as part of their submission in a one step process. Jurisdictions were unclear on how this would occur with a single HRAF portal without introducing a two-step process. It is suggested that NHMRC develop a communication strategy to continue to seek feedback from Jurisdictions and other stakeholders as part of the form build and testing.

Options and Issues for Consideration by NHMRC

General Feedback

- Stakeholders expressed an interest in nationally consistent amendment and reporting forms. This lead to further discussion on where amendments sit in the review process, particularly where HRAF requires updating as a result of an amendment. NHMRC should consider the role of amendments in the scope of HRAF and the development of nationally consistent forms where appropriate.
- Extending on the discussion of amending the HRAF is the issue of how long will the NHMRC retain data in the HRAF portal for and how long will forms be available to duplicate or amend.
- Two options arose for accommodating jurisdictional specific requirements. Option (b) was favoured by the majority of stakeholders.
  a. Jurisdictional Specific Module: This approach has the potential for duplication between the main form and specific modules as well as duplication where multiple jurisdictions are selected. An advantage to having a separate module for each jurisdiction is that the development of the content and maintenance of this information can be placed with the jurisdictions, ensuring their requirements are met and
  b. Embedded jurisdictional-specific questions in the relevant sections of the form where the questions are then expanded for nominated jurisdictions. This option may introduce less duplication but will require maintenance by NHMRC, consultation with the jurisdictions and testing to ensure accuracy.
- Suggestions have been made above on how to accommodate triage of applications to low risk review pathways. This suggestion is based on an assumption that the purpose of the risk assessment is administrative. NHMRC may wish to reconsider this depending on the purpose of the risk assessment and consideration of the value that it adds to the HREC review process. Any risk assessment should not introduce overlap or duplication with the role of the HREC in reviewing risk to participants; these questions must be included in the form itself. The risk assessment was an area of confusion as to its purpose and intended outcome.

Alternative Structures for consideration:

- An alternative structure presented was a three-module approach, which included the HREC application, an administrative module and governance module. This approach should be further considered and potentially incorporated in the question logic, particularly highlighting data collected for reporting purposes. Researchers individuated that while duplicating information was frustrating, it would be better understood if the purpose of the duplication was clear (eg one set for HREC review, the other for specific data reporting categories).
- A third structure identified was a core module that is completed by applicants with additional modules for drugs and devices, establishing and using biobanks/ genetic research, use of radiation, establishing and using data collections.

Project Description

- Stakeholders held slightly different views as as to the purpose of the project description and in developing this document NHMRC will need to establish the purpose of project description as this will in turn influence the headings and content. Stakeholders queried if the purpose of the project
descriptions is as the ‘recipe’ or roadmap to enable the running of the study or as an outline for review by the HREC?

• Building on the purpose of the project description is clarification by the NHMRC of its intended audience. Is the document a technical document or written in lay language? With the potential for the document to be used for multiple purposes, researchers and clinical trial sponsors felt that writing for a single audience may be challenging.

• The concept of the project description and cross referencing with the HRAF was well supported, however in developing these templates it must be clear what information should be included in HRAF, what should be included in the project description and where potential areas of overlap exist.

• Two suggestions were put forward for presenting the project description with researchers preferring option (a) due to the ease of updating the project description without amending the HRAF, while HREC members were split in their preference.
  a) Project description as a word document attachment, NHMRC also to consider technical solution to attaching/uploading documents to HRAF. This approach also enables the use of images in the document.
  b) Including the project description as part of the form to create one document that includes the project description headings.

• Stakeholders requested that NHMRC develop clear templates and examples to assist completion of the project description. The variability in language between research areas needs to be accommodated and tested with researchers. This may require different templates for different methodologies.

• Clinical trial sponsors and investigators were strongly of the view that the clinical trial protocol should be submitted rather than a project description with the argument that any other approach will duplicate this source document and potentially introduce bias or effort. HRECs were split in their view as to the acceptability of this proposal with no prevailing preference. A number already receive the clinical trial protocol while others felt that this was too onerous a document to review, particularly for lay members. In providing guidance on the use of the project description it would be useful if the NHMRC considered including advice on navigating this requirement as a consistent approach to the position description was the preference of all researchers. This discussion may also extend to the attachment of other types of research plans, perhaps with the addition an index table that references the protocol or research plan to the project description headings.

Site assessment and research governance

• Universities were largely unfamiliar with the concept of research governance and site assessment but on further exploration of the intention of the site assessment, thoughts emerged on how this might be used by universities to capture institution-specific requirements (e.g., how will researchers address Open Access requirements of funding bodies and journals). As most university research is single site, the HREC process is used to capture administrative and other information. A number of the university representatives were interested in exploring if each university could include a specific form in the HRAF portal if the IRAS “repository of forms” concept is adopted. NHMRC may wish to consider the scope of HRAF as to whether it remains just an ethics form or if it is expanded to end user (university or jurisdiction) maintained governance assessment forms.

• A limiting factor was identified during the consultation with regards to the Australian Radiation Protection and Nuclear Safety Agency guidelines (ARPANSA guidelines) for the use of Ionising Radiation in Research. While radiation safety is widely accepted by HRECs and administrators as an institutional governance matter, the guidelines place responsibility for radiation safety with the HREC. This structure is no longer viewed as appropriate or workable with the national approach to single ethical review and National Mutual Acceptance NMA, as sites wish to revisit radiation safety based on their local equipment which essentially duplicates an aspect of ethical review.

• A number of attendees across several jurisdictions pointed out that there should not be a need to auto-populate information in site assessment forms as there should be no overlap between the HREC application and the site assessment other than basic linkage of information such as title and chief investigator. NHMRC may need to consider recommendations for minimum data set or policy to limit duplication between governance and HREC applications.
3 Introduction

Roxsolt was engaged by the NHMRC in March 2014 to undertake the stakeholder consultation on the concept of and content for a new National form for Human Research Ethics Applications. The report focuses on stakeholder views on the structure and content of the form as outlined in the NHMRC paper, “Building a new application form for use in human research” (the consultation paper). The face-to-face consultation meetings took place in June and July 2014 and were held in all Australian Capital Cities. and the feedback reflects the diversity of stakeholder experience and feedback across the country.

This report provides a summary of the feedback from stakeholders on their views, requirements and suggestions for building a functional, streamlined and user-friendly ethics application form.

It is acknowledged that at the time of this consultation, NHMRC was conducting parallel consultations on an IT system solution for the HRAF, and on clinical trials research governance. This report only touches on these areas, as they relate to project dependencies or significant stakeholder feedback.

3.1 Background

Applications for ethics review of research projects involving humans use a variety of forms and formats. The one common, underpinning factor is the need for all applications for human research to demonstrate that the proposal is designed and will be conducted in accordance with the National Statement of Ethical Conduct in Research Involving Humans (2007) (the National Statement).

With respect to application forms for human research, there has only been one effort to develop a national form. NHMRC developed and launched the NEAF in 2005. Its intended purpose was for it to be an online form that could be used for all forms of research involving humans. Uptake of the form varied significantly with Jurisdictions such as Western Australia and Northern Territory rarely using the form, to wide implementation on the Eastern seaboard as part of a Memorandum of Understanding between Queensland, New South Wales and Victorian Health Departments. There is some commonality with Organisations and Institutions that are actively involved in National Mutual Acceptance (NMA), with most requiring the use of the current National Ethics Application Form.

Stakeholder feedback indicated that those involved with multicentre health and medical research were mostly familiar with the NEAF. Where the form was too complex, Institutions developed alternatives that better suited their needs. This is particularly true in the case of university research. Universities have invested heavily in integrated research management systems that accommodate online submission and HREC review with many developing their own ethics application forms.

Researchers who work in multicentre research environments continued to express frustration at the inconsistent requirements of HRECs. Not all committees adopted NEAF and some requested additional project descriptions and supplementary questions for each institution¹.

Further complexity was introduced with the licensing of NEAF to the online portal www.ethicsform.org/au to enable integration with AU RED, a system used by a number of state health departments. This created two methods of completing and exporting the form and the relationship between the two systems was not necessarily clear. A number of stakeholders reported being unaware of the NEAF portal until this consultation process.

Stakeholder feedback indicated that NEAF was too complex to be used to apply for approval to conduct routine or low risk research. As a result, state-specific and institutional-specific low and negligible risk forms were widely implemented to fill this gap created by NEAF and to provide a simpler application pathway for low and negligible risk proposals.

Despite challenges with the implementation of NEAF, there generally remains broad support for a single ethics application form that elicits the ethical issues and considerations applicable to a wide range of research activities. The Human Research Application Form (HRAF) is proposed to supersede NEAF and function as an application to meet the needs of HREC members, researchers and institutions. This includes the required information to apply the National Statement and to provide researchers with a simple application form without repetition.

### 3.2 Project Scope

The project was undertaken in keeping with the parameters outlined in the Request for Offer, **Building a new application form for use human research, RFO 14/007**. The scope of this project and this report is limited to the structure and content of the proposed form. The developments of the technical aspects of the form are addressed in a separate project.

The purpose of this project was to seek the feedback and views of stakeholders on the proposed structure and content of a new HREC Application Form to support nationally consistent ethical review for all human research. The new application form is intended to supersede the current NEAF and feedback is required on its application of different research methods, useability by researchers and HREC members as well as interoperability to the systems and requirements already in place in each Australian State or Territory (the jurisdictions).

The project priorities as outlined in the RFO include:

1) Elicit feedback from stakeholders on the structure and content of the form that is populated by the NHMRC with example proposals. The focus of the consultation meetings was on structure, content, usability and identifying additional functions or features that may be useful. The consultation meetings also considered jurisdictional requirements, research governance/site specific assessment and how this information might best be captured as part of the application process.

2) Consultation with State and Territory health departments (or lead research agencies) on the proposed application form, identification of jurisdictional needs and interoperability with existing IT platforms used by government organisations, private sector, hospitals, research institutes and universities.

The development of the technical aspects of the proposed application form are out of scope of this project, however the consultation process was designed and conducted with and the knowledge of current potential technical limitations.

### 3.3 Consultation Methodology

It was critical in this project to canvas a diverse range of views from researchers that represented different research areas and also institutions in order to establish the needs of researchers, institutions and HRECs and to discuss how a form might respond to any specific requirement. It was also acknowledged that a number of issues fall under the broad banner of “ethical review”. Some of these are related to the application form, others to institutional policy, site-specific issues or culture and history of the HREC. As such, face-to-face consultation was preferred over written responses to ensure high quality feedback, specific to the proposed form concept.

The view of the Jurisdictions on the proposed form was sought through structured meetings with the key personnel. These meetings were primarily held with State Health Departments except for NT and Tasmania where the universities largely hold responsibility for ethical review on behalf of PHOs. These meetings sought to understand any local concerns, limitations and potential barriers as well as an understanding of specific local requirements that may need incorporation.

Although requiring additional resources, meeting in person with stakeholders allows the opportunity to better evaluate their operating context and tease out concerns and potential solutions. The risk of written consultation responses only, is that feedback may be off topic and clarification is difficult to seek. However the timeframe for consultation meetings was limited so an online consultation response was developed to capture feedback from those unable to attend the scheduled meetings. This two pronged approach to feedback elicited a wide range of feedback from diverse stakeholders.
Identifying attendees

In the Project Initiation meeting, a number of key organisations to be involved in the consultation were identified. The Australian Research Council assisted in identifying additional professional organisations that may wish to be involved. The complete list of stakeholder groups that were invited to attend consultation meetings can be found in appendix 8.1. The consultation meetings were further publicised in the NHMRC Tracker.

Roxsolt also sent invitations to all HRECs registered with the NHMRC, Medical Research Institutes and Research Offices where contact details were available. In addition, contact was made with each of the jurisdictions and it was requested that the invitation be circulated through their networks.

The invitation process sought to include a broad range of stakeholders such as:

- Researchers in public and private health settings
- Researchers in non-biomedical fields
- Universities
- Medical Research Institutes
- State agencies involved in conducting or administering research, quality assurance or evaluation projects (e.g. health departments, patient safety agencies)
- Lead agencies for the management of research systems on a state-wide basis (e.g. health departments)
- HRECs, public and private
- Sponsors of clinical trials
- Collaborative research groups
- Public and private hospitals and health services in the community
- Institutions with HRECs certified by NHMRC as part of the National Approach to Single Ethical Review.

Each location for the consultation meetings presented different perspectives, processes and mix of research activities. The local considerations are outlined below:

<table>
<thead>
<tr>
<th>Focus Group Locations</th>
<th>Consultation Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adelaide</td>
<td>Central concentration of health services and Universities in Adelaide, expanding research sector with the commissioning of the South Australian Health and Medical Research Institute. Opportunity to consult with private ethics committee.</td>
</tr>
<tr>
<td>Perth</td>
<td>Strong experience in bio banking and specialist child health research institute. Does not use NEAF, but it can be accepted.</td>
</tr>
<tr>
<td>Darwin</td>
<td>Provides the opportunity to seek focused input from stakeholders conducting research involving Aboriginal and Torres Strait Islander peoples. Research in remote and regional communities. Does not use NEAF, but NEAF can be used if supplemented with NT Modules.</td>
</tr>
<tr>
<td>Melbourne</td>
<td>Concentrated biomedical research precinct, specific considerations for health privacy in HREC applications, high levels of research activity in the health and University sectors.</td>
</tr>
<tr>
<td>Aust. Capital Territory</td>
<td>Large government sector holding data accessed for research purposes.</td>
</tr>
</tbody>
</table>
Attendees were requested to register via email or Google form. Attendees were asked to provide information on the role in which they were attending, as well as the experience they had in the specific methods or vulnerable participant groups as outlined in the National Statement. The purpose of collecting this information was to ensure a broad range of experience and to weight the input of particular organisations or research sectors.

Conducting the Consultation Meetings

The consultation meetings were designed to meet the stated project outcome – seek feedback and views of stakeholders on the proposed structure and content of an application form to support nationally consistent ethical review and site assessment processes for all human research and, in particular, clinical trials. The meetings were supported by the Consultation Paper, which outlined a number of consultation questions. A number of these were expanded to clarify areas of diverse views or where there were potential requirement conflicts. A full list of consultation questions can be found in the consultation paper.

The consultation meetings are grouped to address the ethical and process considerations specific to research methods or fields as outlined in the National Statement. At least one meeting was scheduled in each Capital City to discussion the application of the form from the following perspectives:

<table>
<thead>
<tr>
<th>Meeting purpose</th>
<th>Proposed Invitees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead agency for research in each jurisdiction to seek feedback on current submission processes and how the NEAF is used. Feedback was sought on the proposed ethics application form, how it might integrate with existing technology platforms and its ability to meet State specific legislation or regulatory requirements.</td>
<td>Key agency staff including: Directors, Policy Staff, Business Analysts and Data Managers.</td>
</tr>
<tr>
<td>Consultation meeting – use of proposed form in clinical trials and interventional research, human genetics in the clinical context.</td>
<td>+ Researchers in public and private hospitals Nursing and Allied Health Researchers + Clinical Academics + Representatives from Industry sponsors + Representatives from collaborative research groups + University based researchers + Independent Medical Research Institutes</td>
</tr>
</tbody>
</table>
Consultation meeting – use of the proposed form in databanks, human bio specimens in laboratory research, human genetics.

• Researchers in public and private hospitals
• Clinical Academics
• University based researchers
• Independent Medical Research Institutes
• Basic science researchers
• Bio bank/databank managers

Consultation meeting - use of the proposed form in qualitative and observational methods, use of the proposed form in low risk research and quality assurance activities.

• Researchers in public and private hospitals
• Nursing and allied health researchers
• Clinical Academics
• University based researchers
• Higher degree students
• Representation from non-health, medical or scientific faculties of universities. E.g. Law, humanities, business researchers

Consultation meeting – HREC members and Ethics Officers.

HREC members and support staff from the public, private and university sector. This includes public hospitals and public agencies that provide data for research purposes.

Consultation Meeting Online Response
To ensure the maximum opportunity to provide feedback, an online consultation response was set up by the NHMRC via Survey Monkey. The questions largely mirrored those discussed in the face-to-face meetings. The online response was designed without compulsory questions to provide respondents the opportunity to only comment on relevant aspects of the consultation paper.

44 responses (55% response rate) were received via the online consultation response. These comments are included in the discussion on the consultation findings in section 6.

Meeting with Jurisdictional Representatives
Prior to the consultation meetings in each Capital City, a face-to-face meeting was conducted with each lead jurisdictional agency responsible for research. The purpose of this meeting was to understand any jurisdiction-specific requirements, technology requirements and how the proposed ethics application form may integrate with existing systems and processes. Jurisdictional representatives often chose to attend the consultation meetings to gain an understanding of the views within their jurisdiction.

3.4 Summary – Response and Attendance
The call for interested individuals to attend the consultation meetings or complete the online response received 492 individual responses. 80 respondents indicated they were unable to attend a face-to-face meeting and wished to receive the survey. The remaining 412 respondents indicated their preference for meeting times and locations, with a small number indicating a preference to attend multiple meetings in the same location.

A total of 404 registered attendees participated in the consultation meetings. There is some duplication in this number as some individuals attended multiple meetings and their attendance is counted at each meeting. However there were a number of attendees who did not register and whose details are not counted in the participant analysis. The number of 404 attendees is therefore an under-estimation of participants. The dropout rate was anticipated to be as high as 50% but this turned out to be an over-estimation. The HREC member sessions were often over-subscribed with more attendees than registrants. These sessions were the best attended followed by the meetings on the use of HRAF in clinical trials and interventional research. The highest non-attendance rate was for the meetings on the use of HRAF in biobanking and databanking. This was primarily due to those nominating these meetings attending an earlier meeting and raising any comments in that forum.
Demographics of Respondents

It was logistically difficult to collect information on attendees during the consultation meetings due to the tight timeframes, late arrivals and a number of unregistered attendees. This data is intended to demonstrate the range of respondents, their roles, organisations and experience in the participant groups and methods outlined in the National Statement. Given that the majority of respondents provided input, either in meetings or by online response it would be reasonable to assume that this data also applies broadly to the attending respondents.

Respondents were asked to nominate the category that their role was closest to when using the ethics application forms and processes. Multiple categories could be chosen, however the most common combined category was that of HREC member and researcher. The term “research manager/administration” was used on both the organisational management side (ethics, governance and research integrity), as well as on the research activity side (clinical trial co-ordinators and project managers). These two categories were further split using job title and organisation to better establish the perspectives of these groups.
Researchers were asked to self-report their experience with the fields or methodologies outlined in the National Statement. The question provided the ability to nominate more than one response and the question did not seek to clarify the level of experience or expertise. The question asked researchers to “Please indicate if you have experience in any of the following”:

- Qualitative methods
- Interventions and therapies, including clinical and non-clinical trials, and innovations
- Human biospecimens in laboratory based research
- Human genetics
- Databanks, data bases and data linkage

Researchers that also sat on HRECs generally indicated they had experience in all the categories of research outlined in the National Statement. This suggests that this question was interpreted by as nominating their review experience rather than their experience in conducting research in these categories. As a result these questions are likely to overstate the depth and expertise of experience in some areas, however the graph shows that respondents self-reported experience that covered the breadth of categories in the National Statement. In addition, all research areas were represented in some way in all jurisdictions.
Other areas of experience reported were:

- Role play scenario experiments
- Fine arts
- HREC submissions
- Interviews and surveys
- Statistics and geospatial modelling
- Medical and research ethics
- Regulatory, Quality Assurance and Pharmacovigilance
- Coronial research
- ART
- Devices
- Cross sectional and longitudinal surveys
- Psychosocial screening
- Epidemiology
- Ethnography

To further understand the research experience of attendees, researcher respondents were also asked their experience with the specific participant groups outlined in the National Statement. Those who reported working with people in unequal relationships were also more likely to report experience in working with people who were highly dependent on medical care. The experience of working with Aboriginal and Torres Strait Islander was centralised in the Northern Territory, Western Australia and QLD.
Other areas of researcher expertise with consideration of specific participant groups include:

- Healthy volunteers
- Culturally and linguistically diverse communities
- Staff and students
- Cancer patients
- School teachers
- Defence Personnel
- Police officers and other personnel from the criminal justice system
- Sexual assault support services
- Substance abuse/addiction medicine

The full consultation schedule, including meeting attendance by location and meeting type is outlined in appendix 8.1.

3.5 Limitations of the Methodology and Report

The following limitations on the methodology and data collection are noted:

Availability of stakeholders and bias in stakeholder engagement: Invitations to attend the consultation meetings were circulated as wide as practicable, however it is known through the stakeholder meetings that some academic sectors felt that the consultation would not be relevant as it would focus on health research. The views expressed in this report comprise those who attended the meetings and who are arguably already interested or engaged with the process. This is likely to lend some bias to the report. The view of less engaged stakeholders is clearly missing and it is likely that opposing views will arise further into the consultation and implementation process.
Distribution of the Online Consultation Response: The online consultation response was circulated to individuals that indicated they wished to participate in this manner and to those unable to attend the consultation meetings. The online consultation response lacked the clarity of the face-to-face meetings and the quality and utility of the responses were far more variable than those gained in the consultation meetings. As such, this data is only included and analysed where relevant.

4 Local and International Approaches to Ethics Submission

4.1 Literature Scan

A brief literature scan was performed to canvas the current processes and proformas associated with the submission of ethics applications. The search platforms included Google and a number of journal databases such as Proquest and Expanded Academic. Search terms were limited to the past 3 years to ensure only recent literature was reviewed. The literature scan sought both theoretical and empirical sources that consider the relationship between form design, review quality and application quality. The literature scan was also expanded to risk assessment of research activity, which returned one relevant article. Risk assessment of research is discussed further in Section 6.2.3 – Project description and categorisation of research.

Limited articles were identified, the majority of the literature focused on ethics committee decision-making processes rather than application processes. There was also little information on change management approaches or what makes a successful submission process in terms of quality and timeliness.

The literature scan did provide a number of International approaches to standardised reporting which are expanded further in section 4.1.1 and guidance to international approaches to submission, most notably the United Kingdom (UK) system which is discussed in further detail in section 4.2.

A Google search yielded a number of University application forms that are good examples of how other institutions have dealt with using a single application in the review of all research activity involving humans.

4.1.1 Project Description/Protocol Templates

The Consultation Paper proposes that all applications for ethical review will be supported by a project description. As part of the literature scan a search was undertaken to identify international or commonly used standards that may be used as project description templates. The scan showed that the health and medical research sector is the most mature in this area, while there are a number of key articles that guide the design and reporting in the arts, social science and humanities. There is little available in the way of commonly agreed templates, however the existing checklists or templates may be modified to ensure appropriate language that is accessible to the social sciences.

None of the standardised templates specifically address the emerging methodologies such as action research or emergent design. However, there is scope to use standard templates and provide guidance on how these newer methods may be accommodated.

Standards of reporting results/project descriptions in Qualitative Research

No single or well-accepted international standard for reporting of results were identified in the literature scan. Tong and Craig (2007) completed a review of checklists and failed to identify any consolidated reporting frameworks for any type of qualitative design. As a result, the 32-item consolidated criteria for reporting qualitative research (COREQ) was developed through the consolidation of the 76 items identified in the partial checklists. The COREQ focuses on interviews and is largely referenced by health and medical literature. It sets standards across three domains (i) research team and reflexivity (ii) study design and (iii) analysis and findings. It is unclear from the article if reporting standards in social sciences were considered in developing the checklist.

The full checklist can be reviewed in appendix 10.2

The American Psychological Association also has a body of work on reporting standards for psychology. However, there is little to support that the Journal Article Reporting Standards for information for manuscripts that report new data collection (regardless of research design) are widely adopted\(^3\).

CONSORT Statement

The CONSORT Group is an international group of medical journal editors, clinical trialists, epidemiologists, and methodologists\(^4\) that have convened since 1996 to develop and refine a checklist of items that authors should include when reporting the results of Randomised Clinical Trials (RCT). The first Consolidated Standards of Reporting Trials (CONSORT) Statement was first published in 1996.

The CONSORT Statement is an evidence-based, minimum set of recommendations for reporting randomised trials\(^5\). It offers a standard way for authors to prepare reports of trial findings, facilitate their complete and transparent reporting and aid their critical appraisal and interpretation. The CONSORT 2010 Statement comprises of a 25-item checklist. The CONSORT Statement is endorsed by over 50% of the core medical journals listed in the Abridged Index Medicus on PubMed\(^6\).

The limitations of the CONSORT Statement include its focus on health and medical research, however it was developed with all randomised clinical research in mind and is not limited to clinical trials. The CONSORT statement also addresses a number of issues of interest to HRECs that are addressed in the National Statement including blinding, implementation of randomisation, funding, data collection and storage.

The CONSORT 2010 checklist is attached as appendix 8.2.

STROBE Statement

STROBE is an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of STrengthening the Reporting of OBservational studies in Epidemiology\(^7\).

STROBE publishes checklists for a number of observational methods:

- Cohort, case-control, and cross-sectional studies (combined)
- Cohort studies
- Case-control studies
- Cross-sectional studies

Although applied to observational research, The STROBE statement is set in a health research context and uses language most commonly associated with qualitative research. It is also heavily referenced by key medical journals such as JAMA and the BMJ. This focus on the health and medical research sector may limit its accessibility to the Arts, Social Science, and Humanities research areas.

TransCelerate

TransCelerate Biopharma Inc is an international collaborative, largely of commercial pharmaceutical and biotechnology companies that seeks to resolve inefficiencies in commercial research and development\(^8\). In 2013 TransCelerate launched a global initiative to create a common clinical trial protocol template\(^9\). This project is in progress and NHMRC should review the outcome when available, mapped against other available standards.

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\(^4\) http://www.consort-statement.org/about-consort/history, accessed 28\(^{th}\) July 2014


\(^6\) http://www.consort-statement.org/about-consort/endorsers accessed 28\(^{th}\) July 2014

\(^7\) http://www.strobe-statement.org accessed 28\(^{th}\) July 2014


SPIRIT 2013

SPIRIT stands for “standard protocol items; recommendations for interventional trials”. SPIRIT is an international collaboration with the objective to improve the quality of clinical trial protocols through defining an evidence-based set of objectives that need to be addressed. These objectives include scientific, ethical and administrative elements that should be included in clinical trial protocols. SPIRIT takes a broad definition of a protocol:

“[a clinical trial protocol] is defined as a document that provides sufficient detail to enable understanding of the background, rationale, objectives, study population, interventions, methods, statistical analysis, ethical considerations, dissemination plans, and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial’s scientific and ethical rigor from ethics approval to dissemination of results”10.

The concept of the protocol means the production of a cohesive document that provides the required narrative for the IRB [HREC] to fully understand the context and elements of the trial. It is a document subject to change but requires approval and ongoing amendment with the approving IRB [HREC]11.

SPIRIT 2013 also takes a broad definition of clinical trial:

“The SPIRIT 2013 Statement applies to the content of a clinical trial protocol, including its appendices. A clinical trial is a prospective study in which 1 or more interventions are assigned to human participants to assess the effects on health-related outcomes. The primary scope of SPIRIT 2013 relates to randomized trials, but the same considerations substantially apply to all types of clinical trials, regardless of study design, intervention, or topic”12.

The intention of SPIRIT 2013 is to promote transparency and a full description what is to occur as part of a particular trial. Much of this information is of interest to a HREC in determining research merit but also includes information to enable consideration of the risks and benefits to the participant. SPIRIT 2013 is not specific to clinical trials of drugs and devices and can be applied to all studies within its definition. SPIRIT is ICH-GCP consistent13 and supports international registration of clinical trials.

The full list of protocol items is included in appendix 10.2

4.2 Integrated Research Application System

The Integrated Research Application System (IRAS)14 is the online application system used to apply for the majority of permissions and approvals for research in health and social care in the UK. IRAS is managed by the National Research Ethics Service (NRES) on behalf of all the participating agencies. The objective of IRAS was to develop a single point of access for researchers wishing to undertake health and medical research in the UK. IRAS acts as a repository of forms for the regulation of research in the UK with the objective of streamlining the application process. The ethics application is just one of a number of forms in the system. IRAS also includes site governance forms for across the UK, hosting over 200 individual forms for different Trusts and organisations.

IRAS is an open system to which anyone in any location can login and register. Once a study is registered on IRAS, an initial checklist is required to be completed, allowing IRAS to determine the type of study and which approvals are necessary. The first question establishes if a HREC application is required, filtering out quality assurance activities. Applications for all health and medical research in the UK must be completed and submitted via IRAS. Many Universities accept IRAS but it is not widely used in the University sector due to its limited scope of health and medical research. UK University ethics

11 Ibid
12 Ibid
committees are unable to approve health research activity, as NRES HREC must approve it and therefore submission via IRAS is a requirement.

IRAS features include:

- A contact database that enables researchers to save their contact details and qualifications, as well as those of common co-investigators. The database is searchable and contacts in the IRAS database can be added to any application.
- Pop up help at a general and question specific level
- Project filter that determines what forms need to be completed in IRAS
- Common project dataset that enables pre-population of common information between forms.
- Visual representation of what questions are not required and what questions require completion
- Electronic and hard copy submission, depending on the requirements of the receiving body

Several challenges of implementing IRAS are relevant to HRAF and the proposed collecting of information to submission to other organisations. Most notably was the challenge IRAS had in obtaining agreement on the standard Project Dataset that enabled pre-population of information in other forms. This took extensive consultation but is the data that underpins this key functionality is critical to system operation and would only be successful with the buy in and agreement of all organisations involved.

Another potential barrier is version control and determining who can make changes in the system. IRAS underwent significant changes and modelling to get the functionality and processes right. The challenge was achieving a balance between agency-controlled content, efficient use of resources in maintaining IRAS, and consistency in language, look and feel. Options for accommodating jurisdictions and potentially universities in an IRAS type system include allowing each jurisdiction to control their local content such as site specific forms, or forms for local agencies such as radiation protections. For consistency a final signoff by NHMRC may be helpful. An alternative is for all changes to be made centrally by the NHMRC on submission of change requests from jurisdictions. However this creates an ongoing commitment from NHMRC to the maintenance of jurisdiction specific content and processes.

Full details on the functionality and governance of IRAS can be found in appendix 7.3

4.3 Australian Approaches to Ethics Submission

4.3.1 Bellberry E-Protocol

During the consultation meetings, a number of attendees spoke highly of the Bellberry review process. Located in South Australia, Bellberry, a not-for-profit incorporated entity, provides ethical review services across a range of research areas. Historically clinical trials have dominated the review workload, however the organisation is seeing increasing numbers of applications from other parts of the health and academic research sectors. Bellberry’s ethics review processes have been certified by the NHMRC.

The Bellberry application consists of seven screens of questions, a number administrative in nature. Bellberry accepts applications on a wide variety of application formats (including NEAF) and relies primarily on source documentation such as clinical trial protocols or grant applications. Using source documentation reduces transcription errors and provides a comprehensive overview of the study and the documentation that researchers will be running the study from. The source documentation is seen as the study roadmap and there is little value in duplicating this in other forms. Inadequate documentation becomes apparent in the review process. Bellberry is not tied to any institution and is required to consider a proposal in its entirety rather than in an institutional or geographical context.

Rather than using a form with specific, detailed questions that seeks to elicit detail from the researcher of the application, Bellberry HRECs use a checklist to ensure the breadth of issues in the National Statement have been considered in the review of the proposal. The checklist is formatted against the

15 Interview of Bellberry Processes and e-Protocol demonstration, July 2014 between Tegan Cox and Kylie Sproston
National Statement and provides evidence of issues considered. The Committee confirms that the proposal is consistent with the application or seeks clarification as required. This process puts increasing onus on the HREC and secretariat to understand and apply the National Statement, rather than trying to tease out its application in a detailed form.

**e-Protocol**

e-Protocol is an “off the shelf” product from a US based vendor, although Bellberry have invested heavily in developing the platform to meet local needs. Each researcher registers, which creates a profile of their studies and relevant contacts. E-protocol outlines a simple application form that is used primarily for administrative purposes. This form collects information on\(^{16}\):

- Personnel involved including contact details.
- Study sites with questions that differentiate between multicenter studies with multiple investigators and studies involving the one investigation team working across multiple sites.
- Sponsor details including global and local sponsors.
- If the study is a first time in humans study.
- A brief overview of the study (maximum 2000 characters).
- Ability to nominate additional study objectives such as tissue banking, pharmacokinetic or pharmacodynamics sub-studies.
- Power calculation and specified margin for non-inferiority studies.
- Details on the publication and dissemination of results.
- Participants; including worldwide and Australian recruitment numbers and how will they be recruited.
- Questions regarding radiation safety and requirement for a report from a Medical Physicists.
- Risks and indemnity – will Medicines Australia Guidelines apply? If no, the opportunity is given to provide justification.
- Other HRECs that the study has been reviewed by and any rejections.
- Declarations that consent processes are compliant with section 5.2.16 of the National Statement, conflicts of interest have been addressed as per 3.3.4 of the National Statement and the proposal is compliant with state-specific legislation.
- Confirmation that the Investigator Brochure is current and its date of last review.

Some questions trigger reminders to attach documentation. For example, the questions on the use of radiation will trigger a need to attach the report and include these details in the consent documentation.

The principle investigator agrees with the declarations through a series of tick boxes and subsequent submission. This process of declarations encourages the investigator to review the National Statement to ensure consistency prior to submitting as opposed to relying on a form to elicit the required information.

In discussions with Bellberry senior management, their view was that the strength of e-protocol is in its collaboration tools rather than online submission alone. e-Protocol has a number of communication functions including the ability for the HREC to comment, for researchers to be able to provide responses to queries and a history log including approval, amendments, email correspondence and HREC queries and responses. These collaboration tools contract the timeframes for communication within the HREC itself and between the HREC and researchers.

**Potential Limitations:**

Not all stakeholders were supportive of the Bellberry Model. HREC members in particular felt that the review of clinical protocols was too onerous a task while others were concerned that information was easily missed or omitted if not guided by an application form.

5 Consultation Findings – Jurisdiction

Meetings took place with the jurisdictional representatives in each State and Territory. Primarily these meetings took place with State Health Departments except in Tasmania where the University of Tasmania undertakes ethical review on behalf of Public Health Organisations (PHOs) and the Northern Territory where the Department of Health has a limited role in research and ethics—this is now largely the responsibility of the newly formed Local Health Districts (LHDs). Conversations with the jurisdictions indicated varying levels of maturity with respect to multicentre research. The eastern states, having a well-established model, raised few issues with the structure and features outlined in the consultation paper, while SA, ACT, WA and NT expressed concern around HRECs having to review unfamiliar forms and the loss of autonomy in asking questions in a particular style. This concern is attributed to unfamiliarity with common forms and concerns of HREC adaptability. These jurisdictions all request support or advice on helping their HRECs adjust to the proposed major change.

Jurisdictions were asked to describe their structure, relationship with PHO’s, universities and the private sector as well as outline their current HREC application structure, information systems and local policy or legislative requirements. The meeting also discussed the impact of implementing a new form and what support and resources would be required.

With the exception of Tasmania and the Northern Territory, most jurisdictions have a clear separation between the health and the university sector, often with little communication between the two. The jurisdictions generally expressed a desire to work with and consult more with university colleagues but in practice there was little that brought the two together. Jurisdictions generally had poor understanding of the forms, processes and IT platforms in the university and private sector which is in keeping with their narrow remit of research in PHOs.

All jurisdictions accepted NEAF for multicentre research, primarily multicentre clinical trials, however only NSW and QLD had implemented the single form for all research greater than low risk. In the other jurisdictions a mix of forms are used. In NT, WA, ACT and Tasmania, none of which are part of the NMA scheme, the NEAF is uncommon and the local form is the primary application form of the Health Department or University.

Consistent findings:

- Form must collect information required by NHMRC as part of annual reporting of Certified and registered HRECs.
- All jurisdictions requested to be involved in further consultation and beta testing.
- All jurisdictions sought ongoing support with implementation including training, responsive answers to questions and a mechanism for providing feedback.
- All jurisdictions reported a degree of lack of confidence in the support of the NHMRC in rolling out HRAF. The biggest concern about this is in WA and the NT, who feel their visibility is low when it comes to hands-on or face-to-face support.
- HRECs need to be aware of changes, consulted and given sufficient lead time to implementation
- All jurisdictions were concerned around the potential cost of implementation including resources and amendments to information systems.
- Jurisdictions were cautious of any discussion suggesting that ethics and governance processes be combined. This is due to the time spent to date trying to clearly articulate two separate processes, although it was broadly acknowledged that HREC review is one part of a research governance framework. An attempt by QLD Health to introduce a statewide governance process for statewide projects such as surveys coordinated by the department was met with resistance from sites and was ultimately unsuccessful.
- Jurisdictions using AU RED expressed concern about losing current functionality if HRAF is not licensed to Infonetica, and the risk of more duplication for researchers in exporting and importing forms. The eastern states have invested heavily in information management and engaging local stakeholders in this process. There is concern that this investment may become redundant or that it will involve significant costs to the jurisdictions that were early supporters of NEAF. Workflow is well established and it is unclear how HRAF will impact on these processes.
• Data must be collected in a format that can be used for reporting to Institutions and internally within state government. Open text fields should be limited to questions that require explanation; otherwise fields should be a required format (e.g. standard date format, standard numerical format).

• Jurisdictions have already invested significant resources in developing their own forms or information systems and it is unclear how HRAF will fit with this. Jurisdictions such as WA and NSW are currently developing or going to tender on their systems and are advanced in the requirements analysis process. Therefore, jurisdictions will need to have access to the minimum data set and fields to map HRAF to their existing information systems. Deviating from this may be costly and the HRAF is unlikely to be supported if it is at odds with jurisdictional processes and objectives. Likewise, Universities have also invested heavily in forms and technology to enable the HREC submission process with many moving to entirely online submission. The benefit of using HRAF needs to be clearly articulated and communicated to the stakeholders that have previously acted independently and the value proposition of the HRAF made clear. At the moment, jurisdictions and their university counterparts question why they should invest time and resources into adopting a new form.

Variable findings:

• How the jurisdictions felt privacy should be best dealt with varied. QLD was not in favour of state-specific modules and felt that privacy information should be incorporated in the form based on selecting jurisdiction. In contrast, WA strongly held the view that a WA specific module is essential. Victoria also shared this strong sentiment and wish to retain their specific module. Given the conceptual nature of the HRAF, if it can be demonstrated how jurisdictional specific information can be incorporated into the form without additional modules, most jurisdictions would be open to reviewing this.

• Some jurisdictions suggested that local legislative issues could be dealt with as part of research governance during the local implementation of the study, thereby removing the need for all HRECs to be familiar with the specific legislation of other jurisdictions. This view was more common in jurisdictions currently using National Mutual Acceptance, whereas other jurisdictions were of the view that to be ethically sound a proposal must also be legally sound. There are also some legislative requirements for the HREC to review the study.

• There was no consistent position from jurisdictions on the need for a specific low and negligible risk form (LNR). The Eastern States are used to using a low and negligible risk application form and some wished to retain it. Others felt that it was not a requirement, as it was developed to fill a gap created by NEAF. Victoria and NT were not supportive of a separate LNR form while WA felt a separate form was important to quickly triage applications to low risk review processes.

• Victoria currently uses NHMRC Field of Research (FOR) Codes in AU RED and has requested this be included in the new form. Other jurisdictions were unclear on the value of the FOR codes in categorising research.

• The smaller jurisdictions such as ACT, NT and Tasmania that do have sophisticated information systems expressed an interest in a centrally co-ordinated system that was subscriber-based. This would offer the advantage of removing the cost of each jurisdiction undertaking system development and provide support for a nationally consistent, central system. NSW also supported this subscription-based approach and that the upcoming NSW tender opportunity could be the basis of building a national system.

Specific Findings:

• Timing of the development and roll out of HRAF is critical to NSW due to the impending tender for the Research Ethics and Governance Information System. They are not in a position to wait for a lengthy development process and are looking to work with NHMRC to see what synergies are possible in the development of HRAF and ReGIS.

• Privacy and guardianship issues in the NT require specific consideration. The NT Privacy Act and Guardianship Act fail to deal with kinship issues. For example, in Indigenous communities, individuals can have multiple fathers, mothers, grandparents, aunties and uncles. This challenges
the guardianship concept of a single “person responsible” and it is difficult to establish hierarchy using guardianship criteria.

6 Consultation Findings – Stakeholder Meetings

This section discusses the detailed findings of the consultation process. The feedback from the online consultation response and the face-to-face meetings are combined under the relevant sections. The findings are presented overall and include specific suggestions where appropriate. The findings or feedback was generally consistent between consultation meetings and jurisdictions unless highlighted otherwise. The consultation meetings were attended by a variety of stakeholders with a breadth of experience. Feedback that is not applicable to the development of a national form has been omitted from the discussion.

Stakeholders were overwhelmingly positive about the initiative and supported the concept of a common form. While support for the concept was tested through the consultation, the willingness or commitment to implement HRAF was not canvased. The feedback was that the consultation paper was given a lot of thought and that the face-to-face consultation process was highly valued. While many stakeholders found it challenging to consider the concept of the form and not specific questions, by the end of the meetings they welcomed consultation at this early stage.

6.1 Key Proposed Features For A Standard Human Research Application Form

GENERAL CONSULTATION QUESTIONS

1. Are the proposed key features of the new form appropriate? If not, what alternative or additional features would you suggest?

Overall the key features were seen as comprehensive. The concept of an intelligent, dynamic format that only shows relevant questions was highly desirable. Many stakeholders noted that this is what NEAF attempted to do but in the process added a great deal of complexity with the number of questions. Some stakeholders found the consultation paper too conceptual and were unable to comment on the features without a more concrete draft. Many stakeholders felt that the project scope was too narrow and that a more comprehensive electronic submission and management system was highly desirable. Although out of scope of this project, these suggestions are captured in Appendix 7.4 – Future Development and Extension of Functionality.

There was a degree of confusion over section 2.5 – option of a site assessment/research governance module – with regards to what exactly was proposed. Researchers favoured the single form approach to ethics and governance while research managers were strongly opposed to this suggestion due to the difficulty in separating the two processes to date.

All were supportive of the proposed feature of being able to complete as many forms as possible in one location. This is discussed in further detail in section 2.5.

The majority of stakeholders felt that a form did not go far enough and that an integrated electronic submission processes was logical. There was a view that “forms” were an outdated concept and that this form review should be extended to the development of a system, as many universities have already done. There was significant concern from AU RED users about the potential for loss of functionality that currently exists in AU RED, as it was not clear how the two systems would interrelate.

Beta testing was considered essential and the majority of stakeholders indicated their willingness to be involved in the testing of the form. The summary of attendees can be used to seek expressions of interest for beta testing as the project progresses.

An extensive list of additional functionality or additional requirements emerged from the meetings:
6.1.1 Functionality

Technical Functionality Suggested by Stakeholders

- Enable the form be downloaded, completed and uploaded. Internet access in remote areas is not always adequate to allow online submission.
- Include the ability to attach documents such as consent documentation.
- Stakeholders and jurisdictions wish to retain functionality in online forms/AU RED and the ability to attach documents.
- The ability to duplicate forms and select a different HREC where a study requires review by more than one HREC.
- Ensure that the form is be optimised for smart phones and tablets.
- The form and project description need to have the ability to insert tables, images, Visio files, and graphic content.
- Each HRAF application should not be “locked” but able to be duplicated and amended so that it is a living document.
- The ability to integrate with existing systems including importing data and attachments.
- Ensure that the output of application is suitable for electronic distribution and electronic agendas.
- Ensure that the form is accessible to people with a visual impairment. NHMRC should consider developing the form in a W3C compatible format.
- The ability to print out a blank form to go through with researchers and provide advice on how to complete.
- Provide easy navigation between section, e.g click on a section and it opens (see e-tax as example) and the ability to move back and forth between sections even if a section is not completed. (See Figure 1 Edith Cowan University worklist showing completed and non-completed sections (ECU 2014).
- The form should be shareable so that collaborators can provide input on the content.
- Include a decision tree that visually shows key points that expand, or contract points in the nested form. This could be achieved through a + icon that indicates an expansion point and greys out the questions that are not applicable.
- Include a checklist of requirements such as for the attachment of the project description/ protocol and the capacity to prevent the application from being finalised or submitted unless the application is complete.
- The ability to add sites to currently approved studies – links with comments on managing amendments
- The form needs to be compatible with older operating systems and older versions of web browsers that are still commonly used in some organisations. Also requires compatibility with Safari, Chrome, Firefox and other common browsers.
- Ability to complete local jurisdictional forms for working with children checks and criminal record checks.
Functionality for amendments and version control

Many stakeholders raised issues about the practical functionality of version control of the application, and how amendments to the application should be managed. This is linked with discussion on the project description and the overall purpose of the form. Some HRECs require the HREC application to be kept current, while others consider the application to be a starting point. The approach to amendments and version control can be brought back to the current system – how does it work now? Does HRAF create any additional barriers? HRECs currently have their own processes for dealing with amendments that most likely could be transferred to a new form. Many of the suggestions here arise from the desire to extend the functionality of HRAF beyond a form that only deals with the approval process, to that of a system that facilitates ongoing management.

- Import and export function to bring back into HRAF portal to duplicate or amend.
- How long will NHMRC hold applications? How long can you amend the application form for, how long will it be in the HRAF portal?
- Additional module on the HRAF portal for amendments and for addition of sites.
- Nationally consistent amendment form in the portal that covers additional sites and personnel, administrative and major study amendments.

Use of guidance text embedded with in the form.

Stakeholders all requested that guidance text be embedded in the form. The most popular option was a help button with a pop-up box. Hover text (where you hover your cursor and the help text pops up) were also suggested, however this option has some limitations for cutting and pasting if you need to expand on the suggestions in the text.

Types of guidance to be included:
• Details on the intention of the question—why is it being asked? Understanding the intention of a question and how the information may be used can take the sting out of the "why are they asking this, it has nothing to do with ethics" frustration.

• Link to or text of the relevant section of the National Statement. This alone is insufficient, as it does not explain to the applicant why the information is required.

• Advice on what the HREC is looking for.

• If there are "right" answers to particular questions, e.g. retention periods of data storage as a minimum of 5 years, include this in the guidance text.

6.1.2 User Experience

There was vast support for a visually simplified form and this was identified as an easy place to start making the form more user-friendly through the use of white space, clear icons, one-click actions, fast page loading and the ability to easily navigate between sections.

Suggested features relating to the user interface include:

• An outline of the question framework providing a pathway of what has been completed and what questions are outstanding.

• The use of dashboard traffic lighting to indicate risk level/review pathway and completion status.

• Avoid the use of drill down numbering, it creates long references to questions and is difficult to document in correspondence.

• When selecting jurisdictions where the study will take place, the form only needs to show the jurisdictions that are ticked, not those that are not.

• Include for each question the purpose or intent behind asking the question and advice on what information should be included in the answer, including examples and links to the National Statement.

• Tools for spelling and grammar. NEAF requires spell checking of each box, which is time consuming, HRAF needs to have the functionality to spell check the entire application.

• A find function that applies to the entire document, rather than question by question.

• The printed version should look as reader-friendly as the online version.

• Any guidance text and instructions should not be included in the final printed version whether printed to hard copy paper or printed to PDF.

• Ability to format text in the form to improve readability including colour, bolding – a ‘What You See Is What You Get’ text editor.

• Use different fonts, colour or bolding to differentiate the questions from the answers.

• The ability to save work to date and complete later.

• Examples and samples available for download – Stakeholders saw the form as an opportunity to educate researchers and enhance their thinking on ethical matters.

• Provide advice where there are clear and known acceptable answers to the HREC.

• Ensure that the application can only be finalised when all indicated documentation is attached, such as the project description.

• No character limits in the form.

• The form needs to provide sufficient guiding information for inexperienced users, but also be dynamic enough to respond to experienced users. This may include the ability to skip through the introduction or guidance information and begin completing the application. Or to provide help as a “click through” rather than including text in the form itself.
6.1.3 Declarations and Signatures

A declarations section needs to be incorporated in the form, logically at the end. There was overwhelming demand for signatures to be electronic and to move away from a requirement of wet signatures. The collection of physical signatures was highlighted as a major cause of delays to getting HREC applications submitted, exacerbated with national and international collaborations.

Declarations may take the form of a “terms and conditions” approach where the chief investigator declares their compliance with no actual signature required; this may include jurisdictional specific requirements. This process puts the onus on the investigator to be aware of what they are agreeing to. Additional suggestions to enable this include:

- Email link to approver that can be clicked through to approve.
- Electronic signatures, or allow emailed approval or endorsement. E.g. UWA accept an email from an investigator’s UWA email address as evidence that they are happy to be involved in the study, or an endorsement from the Head of Department.
- Electronic signatures for declaration, definition and rules of use.
- Tick box declarations against federal and state legislative requirements.
- Move to a “terms and conditions” approach.
- Declarations that the PI has read and understood the National Statement and the Australian Code for the Responsible Conduct of Research.

6.1.4 Reporting requirements

The jurisdictions that use AU RED for the review of health research are moving towards more sophisticated approaches to performance reporting. They were acutely aware of how data may be collected in HRAF and encouraged the technical development of HRAF to think ahead as to how information might be used in reporting and what format best facilitates this. Reporting from free text fields is very difficult and standard formats provide consistent data.

HREC members and administrators held a very strong view that the HRAF must include the reportable data that the NHMRC expects in its reports from registered and certified HRECs. Currently these reports do not reflect the information collected in NEAF. Reporting is also required on the application of Section 95 and 95A guidelines and this information is not easily collated through NEAF. Consideration may be given to expanding reporting requirements to include other data collections such as the ABS Survey on Research Expenditure and to jurisdictional privacy commissioners.

Reportable data may be included as a separate section that includes the reportable fields. This may be technically less complex than trying to import information from other parts of the form. Researchers indicated they were okay with this option as long as it was clear why the information was being asked, although auto-population wherever possible was preferred.

6.1.5 Jurisdictional specific requirements:

A number of jurisdictional differences of relevance to HREC review were identified during the consultation. There was variation in views as to how this information might be integrated into the form. Two main options arose:

1. Additional forms for each jurisdiction indicated.
2. Embedding the jurisdictional specific questions in the relevant part of the form. Filtering by jurisdiction in section 1 or 2 will bring these questions into the form.

Most jurisdictions favoured option 2 – embedding jurisdictional specific requirements within the form. A number of jurisdictions and researchers discussed their challenges with the Victorian Specific Module and wished to move away from this approach. Other jurisdictions, such as NSW and QLD, have indicated that they have had few issues with using the NEAF as a national form and establishing other processes to review local legislative and policy requirements. Jurisdictions also identified that despite some differences in legislation there is also a degree of commonality, particularly between State and Federal Privacy Legislation and it may well be feasible to have one set of questions that meets the requirements of most
States, limiting the number of jurisdictional-specific questions or prompts required and reducing duplication in asking very similar questions.

### 6.1.6 Impact of implementation

**What impact would a simplified human research application form have on HRECs and researchers?**

The anticipated impacts include faster time to approval, less resources invested in completing forms (particularly for multicentre research) and more uniformity in terms of quality of application and feedback from HRECs. To understand if these impacts eventuate, and ultimately if the objectives of the project are met, an evaluation process should be considered at 12-18 months post-rollout.

**Support for Implementation**

The feedback on the support required in implementing a new form in the health and medical research context varied depending on the maturity of the organisation and jurisdiction. Those involved in multicentre research and already using NEAF saw few major issues to implementation. However, universities were reluctant to comment on commitment to the HRAF if they had already invested heavily in the development of their own forms.

The most commonly cited area of support was around IT interoperability including the importing and exporting of data. PHOs that use AU RED were concerned about the loss of functionality that is currently available through the online form’s portal and AU RED if everything must be completed in the HRAF portal. Other suggestions include:

- Evaluation of the HRAF project 18 months after implementation to establish if the form is on target to meet objectives.
- Provide a survey/feedback pop-up on completing application to respond to technical and interface issues early in the implementation.
- Change management support from NHMRC for administrators, HREC members and researchers.
- NHMRC to note limited resources for implementation at hospitals.
- Institutions and jurisdictions need to consider ongoing management and update of local systems – who pays for the change-over costs and development costs? This was a concern for jurisdictions due to the unknown budget implications.
- NHMRC to provide support for implementation and training.
- NHMRC to involve stakeholder in ongoing communication and consultation as the implementation progresses. The introduction of a new form is a big change for HRECs and researchers that requires support and resources.
- Summary or map of changes from NEAF would be useful, e.g. if addressed in part (a) of NEAF now question (y) in HRAF.
- NHMRC to provide guidance or a look up table on interstate modules or legislative/policy requirements. HRECs did not consider it a reasonable expectation that they understand the nuances or application of policy or legislation in other jurisdictions.
- NHMRC to work with data registries to use HRAF rather than their own forms for applications for data linkage.
- Designate a phase-in period for the new form.
- e-Learning modules including very short videos (2 minutes maximum) at the start of the form to introduce new users to the form including the sections and logic of the form, how to complete, how to get help and how to submit.
- Helpdesk either by phone or online (that is helpful to both researchers and administrative staff).
- National roadshow and training package (on-site) to introduce researchers and HREC members to the form, its functions and to provide training.
6.1.7 Challenges and barriers to implementation

**Buy-in from the universities**
While the majority of stakeholders were supportive of efforts to develop a national form, the support for its actual update was less clear. Universities in particular have invested heavily in technology and development of their own forms and it was difficult for them to see the “carrot” to encourage uptake. There will need to be incentive and significant consultation to ensure buy-in from the university sector and the advantages of using HRAF are clear for them given that the majority of research reviewed by universities is single-site and that they do not seek certification. At present universities perceive very little advantage in having their HRECs certified by NHMRC or participating in the National Approach to Single Ethical Review.

This barrier may be ameliorated through data mapping to allow universities to import HRAF fields into their existing systems. A number of stakeholders, primarily on the researcher side, suggested that if institutions receive NHMRC funding they should be required to use the national form in the same manner that other NHMRC policies require implementation to receive grant funding.

Respondents located in remote and regional locations noted the assumption of an internet connection to complete the form, which is not a reliable assumption in non-metropolitan areas. Options need to be considered for offline completion of the form.

**Language and Terminology**
The consultation meetings highlighted the inconsistent use of terminology and the opportunity to use HRAF to bring consistency between ethics and grant processes. Feedback from those involved in the development of NEAF indicated that a lesson learnt was that the form needs to reflect the language that researchers actually use, rather than the language of HRECs. This is important to make the form accessible to all disciplines of research. A number of stakeholders would like to see inversion of the current framework – humanities and social sciences language form the basis of the questions, except in specific areas limited to health and medical research such as drugs, devices, human tissue and genetic research.

Stakeholders involved in the conduct and review of arts, humanities and social science research consistently raised the issue that NEAF and the National Statement are interpreted and reviewed from a biomedical perspective. The development of HRAF provides an opportunity to write a user-friendly form from a researcher perspective that reflects and respects the language of the diverse research disciplines.

Terms need to be clearly defined to ensure they are applicable to the different types of research activity. The following were subject to discussion on their scope and applicability:

- Site – suggests a single physical location for procedures and is limiting with the expansion of descriptive and observational methods. Further discussion on this area in section 6.2.2 – Section 1 Core Information.
- Clinical Trial – conflict between the World Health Organisation Definition and the TGA definition. Both definitions would lead to a different set of questions if a clinical trial were of standard interventions as opposed to a clinical drug trial of an unapproved therapeutic good.
- Lead site – is used in NMA, State Policy and Operating Procedures and NHMRC grants with slightly different meanings.
- Principal Investigator – terminology should be consistent with other NHMRC programs and grants that use the term Chief Investigator.
- Sponsor – is this the TGA/GCP definition? Who is the sponsor in the situation of grant funding distributed to multiple organisations? Term needs to be defined along with responsibilities of the sponsor.
- Databanks and Biobanks – what are the defining features and definitions? Not all databases are databanks. When do tissue collections become a biobank?
- Study completion – this is a subjective term but has impact on project closure. Maybe when database is locked, when follow up is complete or at the end of data collection. A standard definition will aid in reporting and the administrative requirements of HRECs to close and archive files.
• Legal terminology and privacy – clear, consistent definitions of identified, de-identified and potentially identifiable information. Information that is coded (such as look-up codes to identified data) is not considered de-identified. Also clear definition of what is personal information.

Cost of implementation
Jurisdictions and organisational representatives raised concerns about meeting the cost of implementation. These costs were anticipated to be associated with local system mapping and changes to accommodate the new form as well as resources associated with training and additional phone and email traffic associated with any major system change. Health organisations in particular were not confident of extra resources during the implementation period, and this raises the risk for NHMRC of a longer implementation period. No suggestions were put forward as to how the matter might be managed, however stakeholders did request that NHMRC initiate discussions with major providers such as InfoEd, Infonetica and Research Master to assist with the transition processes.

6.1.8 Additional comments on form and questions structure

Stakeholders were mostly supportive of the proposed dynamic form structure but wished to see changes in the question structure away from questions-predicting-next-question approach, to evaluative and open-ended questions where applicants are asked to explain or describe aspects of their proposal. It was felt that when discussing methods, participants, risks to participants and consent, that tick-boxes introduced presumptive thinking and removed the ability to answer not applicable or provide a "yes, but" explanation. One researcher commented that the role of the applicant was to provide the HREC with reassurance as to their skills, experience and methods, and that they had through their risks and mitigation strategies, but this could only be achieved through narrative.

Tick-boxes were felt to be appropriate for filtering purposes or where there are often repeated “acceptable” responses to questions. E.g. how is data being secured, why is consent not being sought? An “other” response is also required with the opportunity to provide explanation.

The ability to indicate that a question is not applicable, perhaps with an explanation as to why, was also considered valuable by researchers and HRECs. It is important that the form is able to accommodate areas of grey and explanations as opposed to the extensive binary questioning in NEAF. Broad questions were perceived to elicit rich detail rather than closed questions where it isn’t obvious where you put the explanation.

Researchers requested a tree or road map on what questions are not required to be completed and where decision-points are made regarding which questions are brought into the form, to enable backtracking if the incorrect selection is made.

Several alternative structures that were suggested are expanded further in the discussion in section 1.2. In reviewing HREC applications, HREC members largely wished to see the project details with investigator details being far lower priority.

A three-module approach was suggested as an alternative:

• HREC Review Module with specific questions related to the National Statement and references to the Project Description, prior HREC or scientific review, sponsorship and funding.
• Administrative Module with information on contact details, duration, FOR codes, data used for reporting purposes, declarations.
• Governance Module including Site-Specific Assessments/Institutional Requirements and Jurisdictional-Specific requirements.

Another suggestion for the structure of the form is a modular approach with a core module applicable to all applications that would include all the relevant ethical questions and modules particular to specific types of research. Suggested modules include:

• Core Module (all to complete).
• Drugs and Devices.
• Establishing and using biobanks.
• Establishing and using data banks and datalinkage (may overlap with biobanks).
• Use of radiation.

This approach is less complex and provides less room for error in selecting yes/no options. Researchers would only be required to complete the relevant modules or tick their requirement to bring them into the form. This approach does not accommodate the risk assessment but leaves that for determination by the Ethics Officer and the HREC. Ideally, simple studies should result in short forms.

There was strong support for a clear data dictionary and common terms to enable forward populating of common information where questions are repeated between forms. Only completing information once will remove a great deal of frustration from the application process.

2. Do you support using the new form to encompass low risk research? If not, why not?

There was consistent support for the form to be used to encompass low risk research. There was little agreement on the best approach to risk assessment and if the form should be a single form or two forms – one for low risk and one for greater than low risk. Institutions currently use a mix of both. Administrators generally expressed reluctance to move away from low risk forms as this was seen as the most efficient way to triage applications for the full or expedited review process. The issues raised specific to risk assessment and low risk research are addressed further in section 2.3

Variable Findings:
There was no firm agreement on whether the HRAF should be one form that populates questions based with consideration of risk, or two forms – one for low risk and one for greater than low risk where the applicant self-selects the pathway. This finding appears to be largely informed by familiarity with low risk forms currently in place in universities and used by the eastern states in health and medical research. There was also significant support for a single form, with the understanding that a dynamic form will result in a shorter form for less complex proposals. In order for a single form to be widely accepted, it must technically deliver short forms for simple projects. Stakeholders suggested that a single form would be acceptable on this proviso.

Key Decisions required?
• Where will amendments fit in the workflow process? HRAF portal side or HREC side?
• How long will NHMRC retain data in the portal for? How long will forms be available to duplicate or amend?
• Where will jurisdictional requirements be located in the form? Options put forward include separate modules for nominated jurisdictions or embedded in the relevant sections of the form where the questions are expanded for nominated jurisdictions. Both options introduce the opportunity for duplication of questions where requirements are similar between jurisdictions.
• Do the alternative structures require any further exploration?

6.2 Proposed Structure and Content of the New Form

6.2.1 Introduction to the form

3. What other information would be useful in the Introduction?

The introduction is the opportunity to succinctly communicate why ethics approval is required. Not just from a historical perspective, although link to key documents such as the National Statement and the Declaration of Helsinki will be useful, but also to promote ethically good human research and to ensure participants are given due respect and protection17.

The preference was to keep the introduction simple and easy to skip through for experienced users. It was suggested that the introduction include tasks that should be completed prior to commencing the

application, most notably that the project description should be written and completed prior to starting the HREC application, as this is critical to inform the responses. Other tasks included reviewing the National Statement, seeking peer review or feedback on the project description and having completed any participant consent documentation or advertising materials.

Stakeholders consistently suggested that projects that relate to quality improvement or evaluation and that do not seek publication in a journal be directed out of the form at the introduction stage. Screening questions to establish that this proposal actually requires ethics approval was supported.

The introduction should explain how the form works, a brief outline of each section, how to seek help (institutional guidelines and ethics staff) and where information can be found (such as the information radio buttons). It should also cover what researchers should expect to see as they travel through the form. E.g. IRAS shows what aspects are completed by greying questions out. The Edith Cowan University Form has a summary side bar with green/red dashboard indicators for completeness. Questions that are not applicable could have a grey indicator.

The introduction is the best place to introduce and provide information on how low risk research is identified, assessed and how questions are populated in the form. This content is dependent on key decisions relating to risk assessment outlined in section 2.3, as this will depend on whether a low risk pathway is determined by self-assessment or by a risk assessment within the form itself.

The introduction can also set up the expectation of applicants that HREC forms are used for multiple purposes – HREC review and compliance with jurisdiction requirements as well administrative functions such as reporting and ongoing monitoring of the study. Early explanation aims to increase understanding of why questions are asked. This also needs to be included in the pop-up help associated with each question.

6.2.2 Section 1 – Core information

3. Is there other core information that should be included?

The requirement for core information was largely dependent on the consultation meeting. HREC members, for example, were not interested in reviewing investigator contact details but, to researchers, entering these details first seemed logical. In the technical build, consideration needs to be given to the most logical and convenient way to complete the form. This may differ significantly from the most logical and convenient way to review the application.

The first item for completion and review should be the lay summary. HREC members require an understanding of what is being proposed, the nature of the research, the participants and the process. HREC members also wished to gain an understanding of the beneficence of the proposal to the individual, community or broader society.

Investigator Details

A contact database was a highly desirable feature to limit repetitive data entry where research teams or collaborators remain consistent. Researchers in clinical trials in particular would like to be able to look up and add investigators in other states or sites. Many researchers proposed a profile similar to, or the ability to link with, RGMS. The use of ORCID was an option but is not one that is widely used. The ability to either link with RGMS or maintain a single, national researcher profile was seen as a more convenient approach. An example is the IRAS contact database.

HRECs experienced in NMA and multicentre research were less concerned about specific site details. For clinical trials they were most interested in the Co-ordinating Principal Investigator and Lead Investigators at each site. The form requires the functionality to add or remove investigators with ease.

HRECs required clarity on who was responsible for the overall running of the project at each site rather than full details of all sub-investigators. Where the project is to be conducted overseas, HRECs were interested in the details of local contacts. For social science researchers and HRECs, who was doing the research was less important than what is happening in the research. Often formal qualifications are not required for conducting surveys but credentialing is a critical consideration in procedures in health and medical research.
HRECs consistently requested that investigator details be moved from the front of the application to the back of section 1, or even to the back of the entire application. HREC members generally do not want contact details first; they wish to know what the study involves. From a capability perspective, HRECs only required that full range of skills be demonstrated, and will then consider how collective experience adds up. A summary of investigator details was preferable and CVs were not required, this is considered a local governance matter.

The summary table might include the following fields
- Name
- Qualifications, experience (including CGP training).
- Role in this proposal (e.g. seeking consent, study procedures/observations, data analysis, follow up phone calls).
- What training will be provided/is required for this particular study.
- Details of any conflicts of interest.
- If track record is critical, details of five most relevant publications to this research.

HRECs and Ethics Officers required that there be clear distinction between the Chief Investigator and primary contact, if different to Chief Investigator. A primary contact must be nominated for all proposals.

The terminology describing investigators also demonstrated high variability between HRECs, researchers, universities and health organisations. The terminology of investigator, chief investigator or principal investigator requires definition and harmonisation with other NHMRC policies and grant applications. It should also be defined that the term “coordinating principal investigator” and “lead investigator” are terms unique to NMA and multicentre review models.

Therefore an early question may be:

<table>
<thead>
<tr>
<th>Will this study be conducted at multiple sites in Australia?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>↓</td>
</tr>
<tr>
<td>Will each site have its own investigation team?</td>
</tr>
<tr>
<td>Yes -&gt; provide details of site chief investigator/principal investigator</td>
</tr>
<tr>
<td>No -&gt; details of project team</td>
</tr>
</tbody>
</table>

HRECs required details of conflicts of interest and researchers favoured a simple approach with the opportunity to default to none. This information could be transposed to the investigator details table.

Please provide details of any declarations of interest:

☒ None

**Students**

The policy differs between universities as to whether or not students can be Chief Investigators with the Group of 8, with the exception of UQ, now allowing student CI’s. Other institutions recognise that the student researcher is not always inexperienced, and may be an expert in a field seeking a higher qualification. Therefore it may be appropriate for them to be CI. Universities define students by their enrolled status, however they may also be undertaking research in their workplace, which may not require enrolment in a degree programme.

All HRECs supported the functionality to allow students to be the primary contact for their study, however increased transparency is required on who has supervisory responsibilities, and their role in the event of multiple supervisors. HRECs are interested in the involvement of students and what support and training will be available to them to ensure the completion of their research.

Are students involved in this project?
Undergraduate research:
A number of Universities queried how the HRAF would manage course-wide approval from the HREC for a particular subject or course. Many institutions have developed their own teaching forms for this purpose. These projects are often low risk with undergraduate students collecting information and reporting. Approval is sought on a course-wide level due to restricted time frames, common projects and student project teams. An option may be to include course-wide approval as an option under student projects.

Site Information

The concept of the ‘site’ provided challenging and was considered to be somewhat outdated in some research activity areas as it was felt to be a term that was defined by multicentre clinical trials. The concept and relevance of the site is often unclear in social science and humanities research where the activity may take place in any number of places including homes, businesses, public space, internet forums, social media and other forums not well described as physical locations.

Researchers in the social science and clinical trials areas in particular challenged the HREC’s need for this information and questioned the value it added to the ethical review process. Some HRECs felt this information was critical to determine if site presented any risks in participant profile— for example additional considerations and consultation required where Aboriginal and Torres Strait Islander Peoples may be included in recruitment. HRECs also felt that site details were important in data linkage and tissue transfer to understand the flow of information and governance arrangements to ensure its ongoing use in keeping with the original approval. HRECs also asked for recruitment numbers at Australian sites to evaluate burden of research.

Equally, HRECs familiar with the split between ethics and governance responded that site information was of most relevance to governance reviews and that HRECs only need to know the minimum details of sites to know who and where they are giving approval. There was no consistency of opinion from HREC stakeholders on the level of detail required on sites, other than that it needs to be high level and contact details are only required for the primary contacts and person responsible for the conduct of the study. With the exception of research being conducted overseas, where it is appropriate for the HREC to have more details, researchers felt that site issues were governance issues.

Alternative descriptors for “site” include requesting details of locations where the research will be undertaken and what facilities will be used. The details provided may be specific to physical location or provide the parameters for inclusion rather than individual names and addresses, e.g. primary schools within 100km of the capital city, businesses, homes, community health facilities. This provides the capability for the application to deal with a large number of sites or locations.

The breadth of oversight of the governing organisation may also define the term ‘site’. As with PHOs there may be multiple locations under the auspices of the same organisation. The form needs to provide space and flexibility to describe the locations, facilities, spaces and places involved in the proposal.

HRECs wish to know what physical locations they are asked to provide approval for as well as a summary of the approval, rejection or withdrawal of the project from other HRECs. This information may be entered sequentially for each location but may be provided to the HREC as a summary table:

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Location</th>
<th>Lead Investigator</th>
</tr>
</thead>
</table>

What site/locations/facilities is THIS HREC approving the project for:
Has this been reviewed by a HREC previously?

☐ Yes  ☐ No

Other sites/Approving HREC including specialist HRECs

<table>
<thead>
<tr>
<th>Site/Purpose</th>
<th>Approving HREC</th>
<th>Status (drop down box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data linkage with National Death Index</td>
<td>Australian Institute of Health and Welfare</td>
<td>In progress</td>
</tr>
</tbody>
</table>

Sponsor and Funder Details
Stakeholders felt that these details needed to be separated, along with a clear definition of roles and requirements of funders and sponsors of studies. HRECs wanted to know:
1 – who is/are the funder(s) and where are the funds or other resources coming from?
2 – who is/are the sponsor(s) with responsibility for the running of the study?

Start Date and Duration
There was disagreement on the value of start dates in HREC application forms. HRECs generally requested that information on start dates be included in the application, with the functionality that they cannot be set for a date before the next HREC meeting. There was a view amongst HREC members that this information served as a check for projects that started without HREC approval. On further questioning the effectiveness of the information as a way of preventing research commencing without approval was inconclusive. The purpose and value of start dates was unclear from the consultation, and consideration should be given to the value of its inclusion.

The Northern Territory felt that start date was important due to the number of external researchers that wish to conduct research in the territory. Start dates and timeframes can be heavily affected by weather conditions or community requirements (e.g., the town has culturally significant events to attend and few people are available) that an interstate researcher may not reasonably be aware of.

HREC administrators reported that duration was more valuable than start date with an increasing number of institutions providing approval for the duration of the project, subject to annual reporting rather than fixed timeframes. This reduced the workload of administrative amendments seeking extensions.

Prior Scientific Review
Both HRECs and researchers consistently sought clarification of what constitutes prior scientific review of a research proposal and what evidence should be provided. A Faculty, as part of the candidacy process, reviews student projects but HRECs do not always consider this to be prior scientific review or peer review, even though significant changes may be made to methodology as a result of this feedback. The definition of peer review requires clarification – can it be an internal mechanism or must it always be external peer review?

NHMRC may wish to consider including examples of acceptable prior scientific review as pop-up help when completing this question. Examples of acceptable prior scientific review include review as part of Category 1 funding, review and approval by the FDA or an equivalent international regulatory agency.
4. Do you support the principle of information sharing between the new form and other forms/platforms? If not, why not?

Strong support was shown for this option with no recorded objections. Further details would be required on how the information would be transferred and the security protocols around this. A small number of stakeholders expressed doubt about how achievable this objective is but lauded the initiative while others had some privacy concerns and requested that data sharing be opt in.

Other organisations were identified that should be included for application data sharing or allowing forms to be completed as part of HREC. These include AIHW, cancer councils and agencies that hold large data collections for data linkage. Information sharing between NHMRC and ARC of information already entered into grant funding platforms was also desired.

6.2.3 Section 2 - Project description and Categorisation of Research

5. Is the categorisation of research function in the right location in the proposed form?

There was general agreement that any filtering functions to generate questions or forms should happen as early in the processes as possible. The application could capture this information at the beginning of Section 1 as it sets up the template for completion. This is the approach taken in IRAS where guidance is provided in the side bar on progressing through the questions and forms. Another option is to filter through the form – the tree and branch option that is currently in NEAF. Stakeholders supported moving the filtering questions to generate the ethically distinct questions relevant to the application to the beginning of Section 1.

6. Are the research categories listed in the consultation paper the best descriptors to facilitate generation of ethically distinct questions based on method or activity type? If not, what alternative categories could be proposed?

The proposed categories listed in section 2 of the consultation paper were not supported. The limitations of these groupings were reached very early with extensive discussion on the dominance of medical research and the poor definition between the categories. For example, what is the difference between non-interventional clinical research and health research? Would the questions asked of these activities differ substantially? There is also overlap between the social sciences and clinical research, such as where would research by psychologists fall? Or how do you categorise research by architects and social scientists that examines the impact of the built environment on the provision of health services? It was unclear how emerging methods such as action research, participatory research, ethnography or other descriptive methods would be categorised. Stakeholders who worked in better-defined areas, such as clinical trials of unapproved drugs, were more supportive of general categories as there was less ambiguity as to where their work fitted.

Stakeholders, particularly those working with qualitative methods and in the humanities and social sciences, questioned the value behind categorisation of research. There are often differences in how investigators self identify their research area and how HRECs categorise it but, ultimately, is the category important? If the intention of categorisation were to forward populate the relevant questions, then it would be more meaningful to collect information on what is happening in the study. Many stakeholders felt that categorisation should not just link to question generation but to the risk assessment, and should be designed with this in mind.

The preferred approach to categorisation was a series of principle-based leading questions that would generate the relevant associated questions. HRECs overwhelmingly were of the view that describing what researchers were doing was far more important than shoehorning activity into a particular category. Some attendees preferred to categorise by method or discipline but it was identified that not all methods have specific ethical considerations (e.g. interviews and focus groups), and this approach is limited where multiple methods are used or in multidisciplinary research where a single discipline is not an appropriate descriptor.
Specific categories that were suggested to generate ethically distinct questions:

- The conduct of research overseas.
- Drugs or devices either within approved indication, outside of approved indication or unapproved.
- Unapproved or unvalidated laboratory tests (now require CTN form).
- Randomisation.
- Intervention – may be educational, psychological, procedural or any variation from standard practice in a given context.
- Participatory or action research.
- Emergent design – form design does not capture the agile nature of emerging research design, these include a lot of amendments and must be dealt with quickly. Researcher may need to be asked to flag critical time points in the study where amendments will occur to clarify the next phase of the research.
- Use of deceptive methods, covert methods or non-disclosure of the true nature of research to participants.
- Collection and use of human tissue.
- Genetic research.
- Use of ionising radiation.
- Obtaining or not obtaining consent.
- Observational methods.
- Storing and linking data.

The questioning logic should focus on the activity, process and participants. However this may lead to broad categorisation for administrative and reporting purposes. For example, institutions with NHMRC Certified HREC will be interested in reporting for the categories of research for which they are certified. The consultation paper and some stakeholders suggested using the ABS Field of Research Codes to categorise research. However in reality these codes denote research fields and will be difficult to group together to forward populate ethically distinct questions. The value of the FOR codes in categorising research could not be defined other than for reporting purposes.

Qualifying questions

The principle-lead questions will need pop-up help that provides examples across a range of research activities and definition of what does – is it an unapproved therapeutic good, what is meant by standard care etc. The objective is to bring into the form the relevant questions rather than provide a series of yes/no answers. The form logic should seek text on the description of what is happening as early as possible.

Example:

Does this study use drugs or devices?
☑ Yes ☐ No

Are you using a drug or device outside of its approved indication ➔ Questions on unapproved drugs and devices and pre populate CTN Form

Are you conducting interviews or focus groups? (pop-up list examples for guidance)
☑ Yes ☐ No

Bring into form questions on recruitment strategy, privacy and confidentiality, reminder to attach survey tools or focus group questions.
Will you be collecting or using human tissue as part of the study, excluding routine blood tests?

☐ Yes ☐ No

Bring into form questions on human tissue

Issues for discussion:

- Clarify the purpose of categorising research activity and any links with risk assessment based on category selection. The relationship between category of research and risk may be based on what is being proposed, particular participant groups or the combination of both.

- Further mapping is suggested prior to the technical build to understand what ethically distinct questions are relevant to the broad range of qualitative methods. Noting many of these may be captured by the core ethical questions requesting descriptions of methods and participants.

7. What is the best way to deal with research projects that include multiple research methods within the same study (e.g. clinical trial with genetic sub-study and with a quality of life survey). How can this information be captured? [Note: the major options are ‘auto-population’ of duplicate questions in secondary research categories or automatic deletion of those questions in secondary research categories].

The principal lead questioning (“are you/will you”) outlined in question 6 is intended to tease out research activities or methods that have additional ethical considerations. Building on this approach it would be possible to select any options that apply.

From a user interface perspective this could be a series of tick-boxes. An even simpler option could be to have an [option] button that links to a list where applicants can continue to add options as required. E.g. Add/edit methods or procedures - Click a box [option] or [edit]

This would enable a comprehensive list of options without cluttering up the screen. Applicants would only choose the multiple methods relevant to their proposal.

There is a risk that tick-boxes or functionality to add multiple options may lead to duplication of questions if multiple methods used. Mapping of options and questions would be required to determine where a question might apply to multiple methods.

One option for managing potential duplication is to duplicate a previous answer and prompt the applicant to review if this answer still applies. An alternative may be to auto-populate boxes with methods and ask how (x) applies to those methods. To further remind applicants to address ethical issues across all of their proposed methods an option may be to populate headings in the response box for each specific area. The headings could be deleted but serve as a prompt for what the application needs to address. For example:

Describe the process for recruitment in this study:

Indicate if the process of recruitment or the participant groups is different for the indicated categories (delete if not applicable)

(auto-populates to remind applicants to address the question for each method or participant group if applicable, note that the consent process may apply to a single cohort/participant group and be described as a single process for all research methods)

Participants involved in the use of drugs or devices?

Participants involved in interviews and focus groups

Participants involved in the collection or use of human tissue
If method categories are required, these could be sorted into quantitative and qualitative methods with comprehensive lists in the system backend from which options can be added. For example, ECU uses a method-based approach to categorising research. Further options could be included to select ethical issues associated with participant groups (e.g., “tell us about your participants”). Any categorisation processes must include an “other” options and advice provided on how this list links with the questions the applicant is asked to complete.

Figure 2 - ECU Application form

 rehabilitate

Figure 2 - ECU Application form

Note that more than one classification may be necessary e.g., for different stages of the project.

TIP: At least one Classification must be selected for the project

Description

- Observation only
  - eg. observation of students in a classroom
- Data/information/samples to be collected anonymously
  - Researcher will NEVER know the identity of the participant eg. anonymous questionnaire
- Creative arts research project
  - eg. participants will be involved in creating a new work of art
- Collection/creation of works of art for an exhibition
- Oral history or biographical research project
- Qualitative methodology
  - eg. focus group, semi-structured interview, action research
- Evaluation research only
  - Researchers will only conduct the evaluation of an existing program
- Comparison or evaluation of existing methods or techniques
  - eg. comparison of different training methods
- Educational research project involving tasks that are the same or similar to those usually completed by students in a standard education setting
- Research to be conducted in the researcher’s workplace
- Administration of standardized psychological tests
- Epidemiological studies
  - Projects involving population based research which may include data linkage
- Use of identifiable or potentially identifiable personal information about individuals WITHOUT their consent
- Psychiatric or clinical psychology research
- Research project involving physiological investigations
- Testing of biomedical devices
- Human tissue samples, including blood, tissues, sputum, urine
- Human genetic research
- Ionising radiation
- Clinical research NOT under CTN/CTX scheme
- Clinical trial of a drug or device under CTN/CTX scheme
- Research involving assisted reproductive technology or the use of embryos and/or gametes
- Surgical procedures
- Other - please explain briefly below

8. Is the approach taken to risk assessment of research (for the purpose of identifying low risk research at an early stage in the application process) the best approach? If not, what is a better approach?

The proposal of the risk assessment as outlined in the consultation paper was not clearly understood by stakeholders and appeared to conflict with the concept of a single form. The concept of risk assessment was generally well received but there was no clear understanding on the purpose of the risk assessment. When meeting attendees were further questioned on how the information from risk assessments were used, the responses were often not clear, however some administrators and HREC members held strong in their view that they were required. Other HRECs did not wish to see a risk assessment as it was deemed to be for administrative purposes. Checklist risk assessments appeared to be more common in Universities and in PHOs and this is reportedly due to the high volume of low risk research. One institute reported that approximately 2/3 of their HREC reviews were of low risk research.

Given that a role of the HREC review is to ensure participant safety, it was argued by some that the entire HREC review process was a risk assessment, and therefore what value does an additional checklist add? Application forms generally include questions on the risk to participants and how these risks might be reduced, managed or mitigated. HREC members wanted researchers to think about and explain the
physical, financial, social, psychological or legal risks that their proposal may cause participants. Then articulate this understanding of risks and how they might be managed in the application form.

Is the purpose of the checklist to forward populate into the form questions specific for participants or to indicate which studies are eligible for a low risk review pathway? The population of questions may be better managed through the filtering process outlined in Question 6 or in Section 3 – Participants.

The risk of a study may be considered from the risk introduced by methodology, by participants or by the combination of methods and participants. The challenge with assessing risks is how the many areas of grey are managed. Risk is introduced by what you are asking participants to do. Therefore there is significant overlap between risk assessment and ethical considerations of participants.

The concept of low risk research was not one that was commonly understood nor was there agreement on what constitutes low risk. The National Statement outlines the processes for reviewing research that is no more than low risk and describes low risk as “no more than discomfort and negligible risk and foreseeable risk as no more than inconvenience”. HRECs have different approaches to the application of low risk. Even where there is no risk of inconvenience or discomfort, some HRECs held the policy that no research involving Aboriginal and Torres Strait Islander peoples could be low risk. In the paediatric area there was similar variation – one HREC reported that they did not have a low risk review pathway as all research involving children and young people was high risk, whereas another advised they were comfortable that children could be involved in low risk research based on the idea that the determination of risk is grounded in what was asked rather than the age of the participants. Researchers require the opportunity to explain why their research is low risk, even if the participant group is perceived as vulnerable. Researchers were concerned that reliance on tick-box risk assessments will not take into consideration the context. For example:

- A study is looking at the detection of phishing emails. Participants were put into two groups, both completing the same exercise. One that was told the true purpose of the exercise was to see how accurately they could detect phishing or scam emails, the other group was told the exercise was looking at efficiency in sorting email. The methodology involved concealment, however the risk to the participant was considered to be low. However the methodology required a full HREC review as it is screened out of low risk pathways.

- A study is looking at the analysis of data from VO2 max testing for elite athletes, a common test run against a standard protocol with no intervention or deviation from standard practice. Due to the participant group, young people under the age of 18 were likely to be involved, and the standard protocols involve blood sampling to establish blood lactate level. A risk-based checklist is likely to identify this as being higher-than-low-risk research due to the blood sampling and the incidental recruitment of young people. There were varying opinions in the meeting as to the level of risk presented even though the object of analysis was the output of data rather than the procedure. The research team considered it low risk as there was no variation to standard practice.

Attendees at the consultation meetings were asked their opinion on who was best placed to assess risk – the researcher or the HREC. HRECs and Ethics Officers consistently felt that this was the role of the HREC and researchers should not be the ones to indicate if their research is low risk, while researchers reported that they should be given the opportunity to justify why their work is low risk. In the same conversation, HRECs reported that mostly researchers made the correct choice when selecting a review pathway as few proposals were reclassified from low to high risk. Different organisations also have different risk appetite as highlighted by the different approaches to low risk review in paediatric research. It will be difficult for a risk assessment to respond to variation. What the assessment considers high risk – e.g. targeted or incidental recruitment of young people, may be considered universally high risk. This has the potential to create additional work for the researcher and significant frustration from stakeholders that the risk assessment does not reflect experience or practice. One attendee commented:

“The form simply provides the opportunity to describe risk; it is up the HREC to weigh up the ratio of risk to benefit. Forms should not make decisions, people do.”

Other stakeholders from all categories were of the view that if a proposal is low risk the form will be short and will not require extensive detail, making the risk assessment redundant. In was commonly agreed

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18 National Statement (2007) p 16
that the role of the researcher is to think about the issues and communicate what they are doing via the application form. The form needs to provide the opportunity to explain higher risk or why risk is or is not relevant. The role of the HREC is to consider the risk in the context of what the researcher is proposing to do. Although there were varying views as to the need for a low risk form, the majority of meeting attendees and online consultation respondents favoured a single, dynamic form with the logic that simple proposals will have simple forms.

Suggested approaches to Risk Assessment

1. Use the National Statement to filter initially by what is known to be high-risk research.
2. Checklist that lists areas believed to introduce risk (factors associated with method or participants) and if you tick particular boxes you opt out of the low risk review pathway. There are challenges with this approach as the checklist makes assumptions that some participant groups are universally vulnerable.
3. Auto calculation formula based on checked answers as used by Bond University and University of Sydney. These automatically triage the review pathway without input from the researcher.
4. Single form that has a question at the end where the application is asked if they believe their research presents low or negligible risk to participants and to justify. To aid the administrative process, this question could appear on the first page of the submitted form to allow easy allocation to the correct review pathway. Asking this question at the end was considered important to prevent the introduction of bias or presumptive thinking.
5. The RMIT approach to risk assessment has three filter components:
   a. Topic of research
   b. Cohorts/participants
   c. Methodology
   A comprehensive risk assessment would need to link in to the filtering mechanisms described in Section 1 – Core Information.
6. The alternative and equally well-supported approach was that every researcher addresses risk in the HREC application and a risk assessment is redundant if supported by suggestion (3) above, which provides administrative guidance.

Issues for discussion:

- What is the purpose of the risk assessment and what value does it add to the ethical review process?
  
  o To determine which form (low risk or greater than low risk)
  
  o To aid the administrative process of determining which committee provides review (full HREC or expedited process)
  
  o As a guide to the proposed level of review of the application

- Stakeholders were interested in a form that auto-calculated the risk and provided a score/referral to a low risk review pathway. The requirement for this approach is dependant on the purpose of the risk assessment.

- The consultation identified potential overlap between risk assessment and the role of the HREC, which is to consider risk to participants. Is this an area of duplication?

- That the risks or disadvantages of using a risk assessment should be considered before it is included in the form. See further comments on participants and perspectives on vulnerability in Section 3.

9. It is being proposed that all applicants will have to complete a preliminary risk assessment, as this can provide valuable input to the HREC. Do you agree with this approach? If not can you suggest a more suitable approach?

Most attendees agreed that risk assessment was desirable. However the nature of the conversation made it unclear if they were referring to the preliminary risk assessment outlined in the consultation paper or the evaluation of risk and benefit undertaken by the HREC. Many of the comments were focused on the latter.
There was general agreement that an applicant should be able to bypass preliminary risk assessments if they know their research is not low risk and requires full HREC review. For example, clinical trials of unapproved therapeutic goods or research where participants are unable to consent for themselves. The risk assessment was felt to be unnecessary where what was being proposed was clearly higher risk.

As discussed above with question 8, researchers were concerned about studies that are low risk but often forced to undergo full HREC review due to incidental recruitment. Qualifying questions need to be asked to flesh risk out further rather than defaulting certain categories out of the low risk review process. The opportunity to explain the context is critical.

A number of meeting attendees, including researchers and HREC members, raised objections with the consultation paper’s focus on risk with insufficient attention to the other principles of ethical conduct – justice, beneficence, research integrity and merit. Some attendees were perplexed as to why risk identification and management was such high priority in the development of HRAF with no consideration given to impact of research – both positive and negative. The discussion during the consultation meetings on the relationship between risk and vulnerability lead to a view that risk should not be determined solely by participant vulnerability, as is the case in NEAF but rather focus on what will happen to the participant as part of the study and how this may introduce or exacerbate vulnerability. This leads to a focus on methodology as the filtering mechanism for risk – if such an assessment is required.

**Issues for discussion:**
- There is need to clarify what the purpose of the risk assessment is before considering the scope of its application and the best method of risk assessment.

10. Is ‘Project Description’ (recognising that ‘protocol’ is a term with specific application to clinical trial research) the best way to describe the proposed attachment?

There was no consensus on the terminology for proposed attachments. Options that were broadly supported include:
- Research Plan
- Research Proposal
- Project Plan

Project Description was identified as the commonly used term for some researchers in the arts, humanities and social sciences but overall received a lukewarm reaction. One social scientist commented on the use of project description:

“I don’t like this term, we can come up with something better, I do phenomenological research but still have a protocol. It’s not just for clinical trials, it is the blueprint for how you are going to conduct your research and all researchers should be encouraged to clearly outline the details of their research.”

When asked what came to mind with the term “project description” quite a few meeting attendees interpreted this as a brief summary, similar to the lay summary at the beginning of the application. Regardless of the term used, the document must be comprehensible to all members of the HREC and include the information that scientific or review committees would need to consider. There was support that the document must be something that can be peer reviewed.

Most stakeholders were not too concerned about the terminology of the attachment, as long as it was clearly articulated what needed to be included and the project description could be as short or as long as the description of the what, how and why of the proposal demanded.

**Issues for discussion:**
- What is the purpose of the project description? Is it the ‘recipe’ to enable the running of the study or as an outline for review by the HREC?
- Is the document a technical document or written in lay language? With the potential for the document to be used for multiple purposes, writing for a single audience may be challenging
11. Would templates for a Project Description for broad categories of research be useful in supporting a new application form? These documents would be uploaded as part of the new application form.

All stakeholders requested templates for project descriptions and felt that these would be very valuable if supported by detailed guidance on the sorts of information that might be included under each heading.

Desired features of the templates should include:

- The ability to include images and diagrams.
- Different templates or wording options that cover different research types, perhaps with the option to “build a template” depending on the proposed methods or procedures.
- The templates should be detailed and provide guidance – this was raised in each meeting and viewed as critical.
- Detailed headings and subheadings.
- No minimum or maximum character limits.
- The ability to delete headings if not applicable or to add subheadings to improve information flow.

Generic headings may include:

- Research question or description of research including objectives.
- Background or rationale (including literature review).
- Proposed methodology.
- Data collection methods: What tools are you using? Have they been validated?
- Proposed data sources.
- Recruitment methods including identifying participants, consent processes, inclusion and exclusion criteria (if appropriate). These may need to be detailed for each phase, method or cohort.
- Methods of analysis, including statistical analysis if appropriate.
- Justification on how recruitment numbers are determined and how this achieved the research objectives. Or sample size/power calculation if appropriate.

Cross referencing between the project description and the HRAF

The majority of HREC members were comfortable with cross referencing, however it must be accurate and detailed enough to locate the relevant section. An alternative is to require an index that indicates where in the project description details on questions in the form are located. HRECs wished to avoid “see protocol” responses in the HRAF. There are some practical considerations for this implementation such as establishing conventions and standards for cross-referencing. The physical process of review also needs to be considered as HREC members use a mix of electronic and paper review.

Clinical Trial Protocols

Sponsors of clinical trials are committed to processes that reduce duplication and therefore raised concerns with the proposed project description. The sponsor perspective was unanimous that they wished to submit the clinical protocol or synopsis rather than cut and paste into a project description template. It was argued that cutting and pasting can introduce bias as well as transcription errors. The full clinical protocol provides the HREC the opportunity to review the same documents that sponsors and researchers work from.

HRECs had mixed responses to this suggestion. A significant number already use the clinical protocol for HREC review and were of the view that source documents should be reviewed by the HREC. Other HREC members were reluctant to commit to reviewing entire clinical protocols and raised concerns about how lay members might make sense of this technical information. Some HRECs were resistant to the suggestion that they “piece together” what the researcher is proposing and its ethical implications through the protocol alone.
All HRECs noted that there was information that was ethically relevant to the review that was not outlined in clinical protocols and queried how this might be captured in the HRAF. A suggested option was a question sequence that asks if a clinical protocol is attached and if yes, a series of additional questions are populated. These questions may include:

- Australian recruitment strategies including how potential participants are identified.
- Detailed consent processes, including who will be seeking consent.
- What procedures will be taking places at the sites this HREC is providing approval for. A journey map of what happens where may be useful
- What sites are involved in sub-studies outlined in the protocol (if applicable)?
- Any incentives or payments offered to participants.
- Any specific cultural considerations

**Biobanking Requirements**

HRECs wished to know specific information if human tissue was to be collected and stored for future use in a biobank. Where biobanks are being established or accessed as part of a proposal the following template headings may need to be addressed:

- Purpose of biobank.
- Parameters for inclusion.
- Process for accessing tissue.
- Funding arrangements.
- Disposal or transfer or samples.
- Governance and custodianship arrangements of the bank or collection.
- Identification status of the tissue and process for linkage with other data such as medical records.
- Consent provisions including unspecified, extended consent and the process for re-consent (or not) if tissue is from an individual under 18 at the time of collection.

**Project description as an attachment or embedded within the form**

Stakeholders had mixed view on whether the project description should be an attachment or if the template headings should be populated in the form. There was no consensus one way or the other with both options having their pros and cons. The preferred approach may be dependant on other decisions regarding the purpose of the position description and how amendments of HRAF will be managed.

If the project description is mandatory, some stakeholders felt it was better embedded in the form to mitigate the risk of the attachment not being submitted. This approach allows the project description to utilise other form functionalities such as pop-up or hover help. If changes are made to the project description then this may result in duplication, as changes may need to be made in HRAF and operational project documents.

If the project description is an attachment, this enables the document to act as the working roadmap for the study. It can be amended and kept current, taking advantage of functionalities such as track changes when submitting amendments to the HREC. An attachment also allows modification for local issues such as recruitment and consent strategies, or where the project description needs to be submitted to multiple HRECs.

**Issues for Discussion**

- Should the position description be an attachment or embedded in the form? The pros and cons of each option should be considered in the technical build. This is an area where building and testing a proof of concept model may help in deciding the best option and understanding any potential flow on effects.
- Should sponsors and investigators be permitted to submit clinical trial protocols or will submission be required in the agreed template format?

12. What other information might need to be captured in Section 2?
On review of the consultation comments there is increasing overlap and dependencies between sections 2 and 3. Consideration should be given to combining them to one section which includes the additional information relating to the ethical issues raised by the methodology and participants.

### 6.2.4 Section 3 – Participants

13. What other information might need to be captured in this Section?

Meeting attendees felt that the information captured in this section was mostly adequate, although some felt it was redundant if all the information is captured in the project description – if information on participants is missing from the project description then it is incomplete. A few areas were identified that could be better addressed in the HRAF.

**Relationship between participants and risk**

There was significant discussion on vulnerability and section 4 of the National Statement – Ethical Consideration Specific to Participants. Researchers raised concerns of the approach of HRECs to treat any group outlined in this chapter as vulnerable regardless of the context of the research.

Researchers were strongly of the view that a project should have the option to be able to be categorised as low risk if it is being conducted in the domain of Indigenous health research. At present once that category is checked, a full ethics application is automatically required rather than outlining the specific requirements of consultation. NT HRECs were also of the view that all activity in the NT required full review due to the high incidental recruitment of Indigenous peoples.

Other researchers in the management, business and finance disciplines noted that risk was not on the radar of their faculties and as researchers they were unclear where the risk lies. It was considered helpful for HRAF to have examples of risk to privacy, reputation, social or economic status that may be introduced.

As previously discussed, risk to participants was suggested as a filtering mechanism for risk. This approach is currently used in NEAF much to the frustration of researchers. HRECs often proposed that if the proposal involved any participant groups outlined in section 4 of the National Statement then this defaults to a full HREC pathway. Researchers felt this was too simplistic and failed to address that every individual has the potential to be vulnerable. The consideration should be what vulnerability does your research proposal introduce? For example, there may be a dependant relationship that has no bearing on the research proposed (e.g. between a clinician and the patient but not with the interviewer who is asking an inpatient about their experience of recovery from illness). It is essential that there is opportunity to explain why assumed vulnerability might not be relevant. The difference between the likelihood of the risk eventuating was also considered important by researchers and that the form needs to reflect likelihood and impact, perhaps via a risk matrix or heat map. Researchers felt that the current NEAF seeks a list of every potential risk, but in reality highly remote risks are not resource effective to mitigate.

Researchers and HREC members felt that the current version of the National Statement section on Ethical Considerations Specific to Participants was not as contemporary as it could be. The definition of a dependant or unequal relationship was thought to be particularly broad and did not take into account the perceptions of dependence from all parties. For example, many cancer patients would not agree that they are in an unequal or dependant relationship for they are highly educated on their disease, and see their clinicians as partners in the management of their treatment. Researchers also objected to the often-implied relationship between capacity and mental illness in the application of chapter 4.5 of the National Statement. The prevailing view is that the form should depart from any language on vulnerability or specific participants. An option may be to include a list of specific participants that can be added, or simply asking if there are any specific ethical considerations to be considered for the recruited participants. The National Statement currently does not list culturally and linguistically diverse communities (CALD), serving members of the Defence Force and older people who may also have additional ethical considerations that are not currently captured. The ‘checklist’ approach of NEAF to specific participants was felt to focus too much on risk to these groups, without the context of the proposal and with little consideration of changing perspectives on vulnerability. It also fails to deal with
considerations of justice and beneficence. Again, the approach to participants appears to be dominated by risk management.

Researchers and HREC members were both satisfied that the following questions should be included in this section:

- What are the risks to participants in your proposal?
- What are your strategies for managing these?
- What particular aspects of these participant groups may make them vulnerable?
- What are the vulnerabilities your study may introduce to participants?
- What is the benefit of the research?

Researchers also requested HRAF provide common examples on how this risk or ethical issues specific to participants might be managed. For example, in a study where a lecturer was asking for students to complete surveys, this might be managed by having research assistants distribute surveys, or what are examples of coercion and how to manage them?

Probasble recruitment of specific participants

HRECs and researchers alike reported that the table in the current NEAF raised issues with the term ‘probable coincidental recruitment’ with reports of HRECs extending this to “possible” inclusion. For most studies this would require a “yes” response, even though the inclusion is not always relevant. Researchers poorly understood the purpose or intention of these questions on probable coincidental recruitment and how the HREC used this information.

Probable recruitment of specific participants

<table>
<thead>
<tr>
<th>a) Primary intent of research</th>
<th>b) Probable coincidental recruitment</th>
<th>c) Design specifically excludes</th>
</tr>
</thead>
<tbody>
<tr>
<td>People whose primary language is other than English (LOTE)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Women who are pregnant and the human fetus</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Children and/or young people (i.e., &lt;18 years)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>People in existing dependent or unequal relationships</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>People highly dependent on medical care</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>People with a cognitive impairment, an intellectual disability or a mental illness</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>People who may be involved in illegal activity</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>None apply</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Figure 3 National Ethics Application Form

The questions that unfold from probable coincidental inclusion may not be relevant. For example, if you were researching shopper behaviour in supermarkets you would need to indicate “yes” to many categories in the table above, despite the broad inclusion criteria of ‘people in supermarkets at 11pm’. Therefore it was unclear what purpose this table added to identifying ethical issues for specific participants given it is not exhaustive and the questions can lack relevance. The preferred approach was to focus on targeted recruitment, justification of inclusion or specific exclusion of particular participants and examples of where probable inclusion may require additional ethical consideration. If a table format is to be used then a ‘not applicable’ option should be included along with explanation of the difference between the primary interest of research (clear inclusion) and exclusion. Participants may not be the primary targets but this is not the same as being excluded. HRECs and researchers preferred the term “targeted recruitment” to “primary intent of research”.

Addressing cultural awareness and competency

Related to the conversation on participants and risk, researchers and HRECs both sought the opportunity to include more detail, if required, on specific cultural considerations. The NT presented an attachment to their form of additional questions, ‘respect indigenous culture’, (section D in NT form) where Aboriginal and Torres Strait Islander participants are included. This was the preferred approach as opposed to linking with vulnerability.
The language of the HRAF needs to reflect cultural awareness and competency and provide the opportunity for the researcher to consider the cultural issues rather than the current NEAF tick box process.

The level of detail or focus on Aboriginal and Torres Strait Islander participants specifically rather than cultural awareness more broadly was a vexed issue between HRECs and researchers. Other CALD groups also have culturally appropriate requirements for undertaking research in their communities, but this is currently not well captured. Cultural considerations could also be captured in site assessments where a particular location has different requirements.

Recruitment
Attendees suggested the following should be sought regarding recruitment, however there were varying opinions on whether it should be included in the form or in the Project Description:
- Description of the recruitment process.
- Is it opt-in/opt-out – with links to the national statement and examples on how to manage opt out recruitment and consent processes.
- How will potential participants be identified? Including examples of social media and forums.
- What tools or media will be used to invite people to participate?
- Guidance on inclusive recruitment strategies rather than the approach of “it is easier to exclude particular participant groups”.

Consent
Stakeholders supported the inclusion of consent in this section but sought clarification of any potential duplication with the project description. HRECs wished to see more evaluative and narrative questions on consent with a move away from tick-box options. It was agreed that not all questions on consent apply to all research and there may be an option to further filter questions based on if waivers for consent are sought. The question logic may be:

Will consent to participate in the study be sought from the participants
☐ Yes ☐ No

A description of the consent processes including how will consent be obtained and by who. Include guidance on the different methods of consent such as written, verbal or implied consent and where these methods may be best utilised.

Details on how to withdraw from the study.

Will consent to participate in this study be sought from the participants
☐ Yes ☐ No

Outline consent previously obtained that applies to this study
Is this a secondary use of information?
Or
☐ Is participant unable to give consent ➔ why not? Describe how consent will be obtained on behalf of the participant?
☐ Parental consent
☐ Guardianship Tribunal/ Person Responsible/ Next of Kin – links to jurisdictional specific requirements
Will consent be sought from the participant when they are able to do so?
What is the process should the participant wish to withdraw from the study?

Is a waiver of consent sought?
The question logic on consent needs to accommodate both yes and no answers to “will consent be sought”. Some studies, particularly those involving those highly dependant on medical care will include both participants who can give consent and those that cannot. This ‘delayed consent’ (where consent should be sought at the earliest opportunity from the participant) must be distinguished from proposals where a waiver of consent is sought from the HREC under the provisions in the National Statement or under privacy law. Where consent is not being sought, no questions on the consent process should be populated, unless both yes and no options are selected.

The consent process for research involving children and young people may vary markedly depending on the study. The HRAF needs to provide the space for the applicant to describe the consent process, as it may be two tiered depending on the age of the child or young person involved.

There is the potential for duplication in questioning where a waiver of consent is sought as Federal and some jurisdictional privacy laws also cover this process. Stakeholders supported aspects of privacy related to participants and consent to be included in section 3, with links to section 4 as appropriate. However it is imperative that there is no duplication of questioning between the two sections.

**Consent for Biobanking, Genetic Research and Databanks**

Consent in bio banking or tissue banking generally has two components that would generate ethically specific questions:

1. Consent to place the tissue in the bank
2. Use of the tissue in the bank

The specificity of consent can vary from single projects (which are not usually biobanks), to specific research areas such as cancer, or specific populations such as children and defined ethnic groups. Clinical registry forms and the WA biobanking guidelines were highlighted as examples that could inform the question logic of this section. Careful mapping is required to see where these specific questions fit as there is overlap between section 3 – participants and section 4 – privacy due to the specific nature of this information and what it might reveal about individuals and their families. Stakeholder supported state-specific human tissue questions being populated in this section.

Filtering questions could be used to draw into HRAF relevant questions to biobanks and databanks:

- Are you collecting or storing human tissue for future research purposes?
- Do you wish to access human tissue in a biobank?
- Do you wish to establish a data bank?
- Do you wish to access or link information in a databank, database or registry?

On establishing biobanks, HRECs require narrative on:

- What consent will be obtained, what limitations are there to this consent?
- Will participants be approached for consent in the future (or is consent unspecified)?
- What mechanisms are in place to feedback results?
- Can information or samples be withdrawn? How?

This was an area where HRECs and researchers sought further definition of terms, such as what constitutes a biobank and how does it differ from tissue collections held by individuals? What is considered human tissue and what isn’t? What is the definition of a databank?

**General Additional Consent Requirements**

- The HRAF needs to collect information on the consent process where the research is conducted overseas.
- Where deceptive or covert methods are used HRAF needs to capture the debrief process and the process of re-consent if the participant is still happy to be involved once the nature of the research is known.
- Advice on consent requirements in observational research in public spaces.
- How will individual results be fed back to participants (if required)? Who will do this?
Issues for discussion:

- What information on participants belongs in section 3 and what should be included in the project description? This needs to be clearly outlined for areas such as inclusion/exclusion criteria, recruitment and consent. A solution may be to have procedural matters in the Project Description and the discussion of the ethical issues in the HRAF.

6.2.5 SECTION 4 – Data/Privacy

14. Do you favour the inclusion of a separate section for questions related to data, privacy and publication and dissemination of research results? If not, why not?

This section received wide support for inclusion as a separate section on the condition that there was no duplication of questions or overlap with the project description. The consensus from the consultation is that issues relating to participants and consent should be included under section 3 – participants; anything else related to privacy is included in section 4. Researchers found that the legalistic approach to privacy is far too complex and confusing, particularly when combining the requirements of the National Statement, federal and jurisdictional privacy frameworks. A “which privacy stuff applies to me” section was universally considered useful. This was proposed to be another filtering process that also brings in the questions relevant to particular jurisdictions.

The question logic needs to consider the application of jurisdictional and Federal privacy law, noting that there are many consistencies between the requirements of privacy law generally and the National Statement. Many of the questions relating to “privacy” only apply when consent is not sought. If consent is to be obtained, the questions relating to waiver of consent under privacy legislation should not appear in the form.

Privacy questions relating to the collection of identifiable data can be triggered earlier in Section 1 as per the ECU example that can be reviewed in appendix 7.5(Example Privacy Filtering and Question Logic). In this example the fields are based on s95 and 95A guidelines and each field is able to be used as a query to collate information required for the NHMRC annual report.

This section should also include questions relating to how the data management and how the privacy of individuals will be protected, provisions for securing the identified or potentially identifiable data and how results will be disseminated to participants. Areas of questioning may include:

- How will you collect, manage and ensure appropriate governance over this information?
- Who will have access to what information (table format)
- Data lifecycle including disposal.
- Format of data (this may include risks to participants if photos/videos are taken and in the project description for data collection).
- Physical security of the information.
- How will data quality be ensured?
- How long will data be retained (there may be conflicts here with GCP, which requires data to be destroyed)?
- How will results be given as feedback to participants (study result rather than an individual result, the latter addressed in section 3)?
- Questions on publication.
- Risks associated with data management.

Researchers were generally of the opinion that this section had a number of “right” answers that were acceptable to HRECs, whereas HRECs wanted to see researchers undertake the “thinking process” associated with completing the application. For questions around storage and security of information researchers requested tick-boxes of known acceptable responses as they currently cut and paste responses from other applications.

For example how is information secured (tick all that apply)

- ☐ Password protected computer
• ☐Physically locked room
• ☐De-identified data held separate to look up codes
• ☐Networked drive
• ☐Cloud or third party supported storage (e.g. Google, Amazon)
• ☐Portable storage device
• ☐Other (please explain)

Data sharing and NHMRC/ARC Open Access Policy
The environment around data sharing and the availability of results and publications is placing additional demands on researchers and institutions. These issues were of particular concern to universities who sought advice from NHMRC on how compliance might be captured during the HREC review and progress reporting processes. The HRAF could also be used as a tool to ensure that participants are aware of the change in policy whereby their information may be used for other secondary purposes (subject to HREC approval). A survey respondent recommended:

“That the HRAF request information from researchers about how the data will be deidentified and with whom it may be published by and/or shared. Consent forms to participants should include statements that: i) Inform participants that their data will be deidentified before viewed by others ii) Published and/or shared with other genuine researchers. Common conditions to data access include: providing names and contacts, affiliations, and purpose of secondary research. This is referred to as ‘conditional access’ - it enables ‘gated’ data publication, which adds an additional layer of security to already-deidentified data.”

International examples of such statements in the equivalent of HRAF or consent templates include:

‘Other genuine researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form’

‘In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information’.

Issues for discussion:
• NHMRC should be aware that there is a risk of duplication of privacy questions with mixed methods, multiple participant groups and jurisdictional-specific requirements. This should be tested as part of the technical development of the form.
• Should questions on Open Access policies included as part of the HRAF?
• How will NHMRC deal with privacy and security aspects of holding application information?

6.3 Option of a Site Assessment or Research Governance Module

15. Do you favour the development of a specific module for site assessment/research governance information? Please provide reasons as to why or why this may not be the case.

This question caused a degree of confusion as to its intention, whether it is intended to have a single national site assessment module or there would be a repository of site assessment forms populated by the early selection of jurisdiction(s) and institutions as per IRAS. The concept of research governance was less familiar to universities who are more accustomed to managing institutional specific issues and policies via the HREC. Some stakeholders found the divide between ethics and governance unclear, mostly in organisations such as private hospitals or professional organisations where governance aspects were dealt with through less formal processes or by the HREC. As many researchers may be unfamiliar with governance processes, site assessments, question logic and help functions should be designed with the novice researcher in mind and to use the opportunity to help researchers think of issues they have not considered before.

19 http://www.data-archive.ac.uk/media/112638/ukdamodelconsent.pdf
20 http://ora.research.ucla.edu/OHRPP/Documents/Consent/ICF_Standards_Biomedical.pdf
Meeting attendees familiar with the health site-specific assessment processes saw significant value in having all site assessment forms in one location and auto-populating common information. A number of attendees across several jurisdictions pointed out that there should not be a need to auto-populate information in site assessment forms as there should be no overlap between the HREC application and the site assessment other than basic linkage of information such as title and chief investigator. This presents a change to the workflow of many research governance officers who may not review the HREC application in full. Under this approach the governance officer will need to review the HRAF and the site assessment and refrain from requesting changes or clarification to the HRAF aspects of the proposal.

WA deals with radiation safety at a state level and expressed interest in including this application form for completion in the HRAF portal along with the WA site assessment forms and applications/requirements for specialist HRECs. Most jurisdictions requested that working with children checks and criminal record check forms be included on the portal to be pre-filled as appropriate to allow printing and submission to the relevant body.

Stakeholders also saw the site assessment as the opportunity for researchers to explain any deviation from the approved multicentre HREC approval where required to meet local recruitment process requirements (e.g. who approaches patient, identification of potential participants).

Further consultation is required on how universities would fit into the site assessment process and to accommodate institutional specific issues such as insurance, travel, students and international research. An option may be for the HRAF portal to hold institutional specific information required by universities and to allow applicants to add universities into their forms list for completion.

The site assessment may also be used to address jurisdictional specific issues such as approval from Guardianship Tribunals, specific HRECs, community consultation and permissions associated with research activity in Indigenous communities. This information could be populated into a single module on jurisdictional-specific requirements, dependant on the jurisdictions selected early in the form.

The NT highlighted a range of specific requirements that need to be addressed but acknowledge they may not be required in the HRAF for all research activity:

- How to deal with information that comes out of research (e.g. family and domestic violence, at risk behaviour for HIV).
- Where should mandatory reporting requirements be addressed? This is very prevalent in the NT and interstate researchers are unlikely to be aware of their obligations.
- Risk to relationships.
- Community engagement and partnerships.
- Have the correct permits and permissions been obtained? Is the researcher aware of what is required?

Issues for discussion:

- What opportunities are there for universities to take advantage of site-specific forms?
- What forms should be included as part of the governance module? Who should maintain them? NHMRC or jurisdictions? Should jurisdictional-specific requirements be included in their governance module rather than embedded in the HRAF form?

6.4 Concluding Comments

The consultation demonstrated wide-ranging support for the revision of the NEAF and the NHMRC’s objectives to improve the experience of submitting and reviewing HREC applications. Although the concept was universally supported, a number of issues outlined in this paper require decision or incorporation before the support for implementation can be established.

Stakeholders who attended the consultation meetings or provided responses on line indicated a high level of engagement and willingness to be involved in the testing of the draft form. NHMRC has the opportunity to leverage this engagement to undertake proof of concept testing and beta testing to establish the most
functional form structure. A number of options are presented in this paper for deliberation by NHMRC prior to referral for technical development of the form. Many of the options presented in the paper require assessment for technical feasibility, however much of this functionality exists in other forms and systems.

With high-level engagement in the health and university sector, the ongoing development of HRAF will provide the opportunity to test the barriers to implementation and the suitability of a single form for all research activity across all jurisdictions. As part of this ongoing process NHMRC may wish to consider success factors and evaluation points to ensure the form remains on track. Forms and the supporting technologies are enablers of a process – to allow researchers to communicate their proposed research activity to the reviewing HREC. Therefore the technical build should lead by these objectives rather than technology dictating the look, feel and content of the form. This is best achieved through ongoing communication within a skill based project team. The integration of content, policy and technical resources in the form building process will ensure that the technical capabilities support the functionality required by the NHMRC and the key stakeholders.
## 7 Appendices

### 7.1 Summary of the Consultation Schedule

<table>
<thead>
<tr>
<th>Location</th>
<th>Consultation Meeting</th>
<th>Number of Attendees</th>
</tr>
</thead>
</table>
| 24th July – Department of Health, 189 Royal St, East Perth, (Level G, C Block Conference Room) | 11am - Use of the HRAF in clinical trials and interventional research  
1.30pm - Use of HRAF in research that involves, databanks, human biospecimens in laboratory research  
3.30pm - Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods                                                                                                                                                    | 9                   |
| 25th June – Department of Health, 189 Royal St, East Perth, (Level 3, A Block Meeting Room 1)  | 9am - HREC Chairs, HREC members and Executive Officers  
11am - Use of the HRAF in clinical trials and interventional research  
12.30pm - Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods                                                                                                                                                                                                 | 17                  |
| 1st July – Menzies School of Health Research, CDU Red 9 Room 2.46 | 10.30am - HREC Chairs, HREC members and Executive Officers  
12pm - Use of HRAF in humanities, social science and behavioural research. Including qualitative, observational and low risk methods  
1.30pm - Use of the HRAF in clinical trials and interventional research qualitative, observational and low risk methods                                                                                                                                                                                                 | 8                   |
| 2nd July – Level 2, Large Meeting Room (LMR) 3, Department of Health, 15 Butterfield St, Herston, QLD 4006 | 10.30am - HREC Chairs, HREC members and Executive Officers  
12.30pm - Use of the HRAF in clinical trials and interventional research  
2.30pm - Use of HRAF in research that involves, databanks, human biospecimens in laboratory research  
4.00pm - Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods                                                                                                                                                                                                             | 31                  |
| 3rd July – University of Queensland - Conference Room, Ground Floor, Cumbrae-Stewart Building (72), | 10am - HREC Chairs, HREC members and Executive Officers  
11.30am - Use of HRAF in humanities, social science and behavioural research. Including qualitative, observational and low risk methods  
1.30pm - Use of the HRAF in clinical trials and interventional research  
3pm - Use of HRAF in research that involves, databanks, human biospecimens in laboratory research qualitative, observational and low risk methods                                                                                                                                                                                                 | 8                   |
| 8th July – Coordinating Office for Clinical Trial Research, 50 Lonsdale St Melbourne | 1pm, Level 14 - Use of the HRAF in clinical trials and interventional research  
3.30pm, Level 13 - HREC Chairs, HREC members and Executive Officers                                                                                                                                                                                                                                                                                                                                                         | 10                  |
| 9th July – Meeting Room 2, Function and Convention | 9.30am - HREC Chairs, HREC members and Executive Officers  
11.30am - Use of HRAF in humanities, social science and behavioural research. Including qualitative, observational and low risk methods                                                                                                                                                                                                                                                                                                  | 15                  |
<table>
<thead>
<tr>
<th>Location</th>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre - Ground Floor, The Royal Melbourne Hospital, Grattan Street, Parkville</td>
<td>2pm</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
</tr>
<tr>
<td>3.30pm</td>
<td>Use of HRAF in research that involves, databanks, human biospecimens in laboratory research</td>
<td></td>
</tr>
<tr>
<td>10th July – Meeting Room 2, Function and Convention Centre - Ground Floor, The Royal Melbourne Hospital, Grattan Street, Parkville</td>
<td>9am</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
</tr>
<tr>
<td>11am</td>
<td>Use of HRAF in research that involves, databanks, human biospecimens in laboratory research</td>
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<tr>
<td>1pm</td>
<td>Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods</td>
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<tr>
<td>3pm</td>
<td>HREC Chairs, HREC members and Executive Officers</td>
<td></td>
</tr>
<tr>
<td>11th July – University of Tasmania, Office of Research Services, 301 Sandy Bay Rd, Sandy Bay</td>
<td>10.30am</td>
<td>HREC Chairs, HREC members and Executive Officers</td>
</tr>
<tr>
<td>2pm</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
<td></td>
</tr>
<tr>
<td>14 July – Canberra Hospital, Yamba Dr, Garran Building 24, Level 1 Meeting Rm 2</td>
<td>10.30am</td>
<td>HREC Chairs, HREC members and Executive Officers</td>
</tr>
<tr>
<td>12.30pm</td>
<td>Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods</td>
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<tr>
<td>2.30pm</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
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<tr>
<td>15th July – NSW Department of Health, 73 Miller St North Sydney</td>
<td>12.00pm</td>
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<tr>
<td>2pm</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
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<tr>
<td>4pm</td>
<td>Use of HRAF in research that involves, databanks, human biospecimens in laboratory research</td>
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<tr>
<td>16th July – Macquarie University, E3A 244 Seminar Room</td>
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<td>10.30am</td>
<td>Use of HRAF in research that involves, databanks, human biospecimens in laboratory research</td>
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<td>11.30am</td>
<td>Use of HRAF in humanities, social science and behavioural research, including qualitative, observational and low risk methods</td>
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<tr>
<td>1.30pm</td>
<td>Use of the HRAF in clinical trials and interventional research</td>
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<tr>
<td>17th July, Royal Prince Alfred Hospital, Meeting Room, Level 6, Gloucester House</td>
<td>9am</td>
<td>HREC Chairs, HREC members and Executive Officers</td>
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<tr>
<td>10.30am</td>
<td>Use of HRAF in research that involves, databanks, human biospecimens in laboratory research</td>
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<td>Use of HRAF in humanities, social science and behavioural research including qualitative, observational and low risk methods</td>
<td></td>
</tr>
</tbody>
</table>

Total attendance for all sessions was 404. However some individuals attended more than one session. Number of individual attendees was approximately 350.
### 7.2 Standardised Reporting Items

**SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents**

<table>
<thead>
<tr>
<th>Section/item</th>
<th>ItemNo</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and rationale</td>
<td>6a</td>
<td>Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Explanation for choice of comparators</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Specific objectives or hypotheses</td>
</tr>
<tr>
<td>Trial design</td>
<td>8</td>
<td>Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)</td>
</tr>
<tr>
<td><strong>Methods: Participants, interventions, and outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study setting</td>
<td>9</td>
<td>Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>10</td>
<td>Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)</td>
</tr>
<tr>
<td>Interventions</td>
<td>11a</td>
<td>Interventions for each group with sufficient detail to allow replication, including how and when they will be administered</td>
</tr>
<tr>
<td>11b</td>
<td>Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)</td>
<td></td>
</tr>
<tr>
<td>11c</td>
<td>Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)</td>
<td></td>
</tr>
<tr>
<td>11d</td>
<td>Relevant concomitant care and interventions that are permitted or prohibited during the trial</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended</td>
<td></td>
</tr>
<tr>
<td><strong>Participant timeline</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)</td>
<td></td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</td>
<td></td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
<td></td>
</tr>
</tbody>
</table>

**Methods: Assignment of interventions (for controlled trials)**

| **Allocation:** | |
| **Sequence generation** 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions |
| **Allocation concealment mechanism** 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned |
| **Implementation** 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions |
| **Blinding (masking)** 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how |
| 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial |

**Methods: Data collection, management, and analysis**

<p>| <strong>Data collection methods</strong> 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol |
| 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
</tr>
<tr>
<td></td>
<td>20b</td>
<td>Methods for any additional analyses (e.g., subgroup and adjusted analyses)</td>
</tr>
<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)</td>
</tr>
<tr>
<td>Methods: Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
</tr>
<tr>
<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
</tr>
<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
</tr>
<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
</tr>
<tr>
<td>Ethics and dissemination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research ethics approval</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
</tr>
<tr>
<td></td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
</tr>
<tr>
<td>Declaration of interests</td>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
</tr>
<tr>
<td>Access to data</td>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
</tr>
<tr>
<td>Ancillary and post-trial care</td>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
</tr>
</tbody>
</table>
Dissemination policy

31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

31b Authorship eligibility guidelines and any intended use of professional writers

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials

32 Model consent form and other related documentation given to participants and authorised surrogates

Biological specimens

33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

Consolidated criteria for reporting qualitative research (COREQ: A 32 Item Checklist for interviews and focus groups

<table>
<thead>
<tr>
<th>No</th>
<th>Item</th>
<th>Guide questions(description)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: Research team and reflexivity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Personal Characteristics</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Interviewer/facilitator</td>
<td>Which author/s conducted the interview or focus group?</td>
</tr>
<tr>
<td>2.</td>
<td>Credentials</td>
<td>What were the researcher's credentials? E.g. PhD, MD</td>
</tr>
<tr>
<td>3.</td>
<td>Occupation</td>
<td>What was their occupation at the time of the study?</td>
</tr>
<tr>
<td>4.</td>
<td>Gender</td>
<td>Was the researcher male or female?</td>
</tr>
<tr>
<td>5.</td>
<td>Experience and training</td>
<td>What experience or training did the researcher have?</td>
</tr>
<tr>
<td><strong>Relationship with participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Relationship established</td>
<td>Was a relationship established prior to study commencement?</td>
</tr>
<tr>
<td>7.</td>
<td>Participant knowledge of the interviewer</td>
<td>What did the participants know about the researcher? E.g. personal goals, reasons for doing the research</td>
</tr>
<tr>
<td>8.</td>
<td>Interviewer characteristics</td>
<td>What characteristics were reported about the interviewer/facilitator? E.g. Bias, assumptions, reasons and interests in the research topic</td>
</tr>
<tr>
<td><strong>Domain 2: study design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Theoretical framework</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Methodological orientation and Theory</td>
<td>What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</td>
</tr>
<tr>
<td><strong>Participant selection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Sampling</td>
<td>How were participants selected? E.g. purposive, convenience, consecutive, snowball</td>
</tr>
<tr>
<td>11.</td>
<td>Method of approach</td>
<td>How were participants approached? E.g. face-to-face, telephone, mail, email</td>
</tr>
<tr>
<td>12.</td>
<td>Sample size</td>
<td>How many participants were in the study?</td>
</tr>
<tr>
<td></td>
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<tr>
<td>---</td>
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</tr>
<tr>
<td>13.</td>
<td>Non-participation</td>
<td>How many people refused to participate or dropped out? Reasons?</td>
</tr>
<tr>
<td>Setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Setting of data collection</td>
<td>Where was the data collected? e.g. home, clinic, workplace</td>
</tr>
<tr>
<td>15.</td>
<td>Presence of non-participants</td>
<td>Was anyone else present besides the participants and researchers?</td>
</tr>
<tr>
<td>16.</td>
<td>Description of sample</td>
<td>What are the important characteristics of the sample? e.g. demographic data, date</td>
</tr>
<tr>
<td>Data collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Interview guide</td>
<td>Were questions, prompts, guides provided by the authors? Was it pilot tested?</td>
</tr>
<tr>
<td>18.</td>
<td>Repeat interviews</td>
<td>Were repeat interviews carried out? If yes, how many?</td>
</tr>
<tr>
<td>19.</td>
<td>Audio/visual recording</td>
<td>Did the research use audio or visual recording to collect the data?</td>
</tr>
<tr>
<td>20.</td>
<td>Field notes</td>
<td>Were field notes made during and/or after the interview or focus group?</td>
</tr>
<tr>
<td>21.</td>
<td>Duration</td>
<td>What was the duration of the interviews or focus group?</td>
</tr>
<tr>
<td>22.</td>
<td>Data saturation</td>
<td>Was data saturation discussed?</td>
</tr>
<tr>
<td>23.</td>
<td>Transcripts returned</td>
<td>Were transcripts returned to participants for comment and/or correction?</td>
</tr>
<tr>
<td></td>
<td>Domain 3: analysis and findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data analysis</td>
<td></td>
</tr>
<tr>
<td>24.</td>
<td>Number of data coders</td>
<td>How many data coders coded the data?</td>
</tr>
<tr>
<td>25.</td>
<td>Description of the coding tree</td>
<td>Did authors provide a description of the coding tree?</td>
</tr>
<tr>
<td>26.</td>
<td>Derivation of themes</td>
<td>Were themes identified in advance or derived from the data?</td>
</tr>
<tr>
<td>27.</td>
<td>Software</td>
<td>What software, if applicable, was used to manage the data?</td>
</tr>
<tr>
<td>28.</td>
<td>Participant checking</td>
<td>Did participants provide feedback on the findings?</td>
</tr>
<tr>
<td>Reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.</td>
<td>Quotations presented</td>
<td>Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number</td>
</tr>
<tr>
<td>30.</td>
<td>Data and findings consistent</td>
<td>Was there consistency between the data presented and the findings?</td>
</tr>
<tr>
<td>31.</td>
<td>Clarity of major themes</td>
<td>Were major themes clearly presented in the findings?</td>
</tr>
<tr>
<td>32.</td>
<td>Clarity of minor themes</td>
<td>Is there a description of diverse cases or discussion of minor themes?</td>
</tr>
<tr>
<td>Section/Topic</td>
<td>Item No</td>
<td>Checklist item</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Title and abstract</td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
</tr>
<tr>
<td>objectives</td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
</tr>
<tr>
<td>Methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial design</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
</tr>
<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
</tr>
<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
</tr>
<tr>
<td>Randomisation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
</tr>
<tr>
<td>Allocation concealment mechanism</td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
</tr>
<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
</tr>
<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
</tr>
<tr>
<td></td>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
</tr>
<tr>
<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>13a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
<td></td>
</tr>
<tr>
<td>13b</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
<td></td>
</tr>
<tr>
<td>14a</td>
<td>Dates defining the periods of recruitment and follow-up</td>
<td></td>
</tr>
<tr>
<td>14b</td>
<td>Why the trial ended or was stopped</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
<td></td>
</tr>
<tr>
<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td></td>
</tr>
<tr>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Registration number and name of trial registry</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
<td></td>
</tr>
</tbody>
</table>

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).
7.3 Integrated Research Application System Forms, Functions and Governance

IRAS captures the information needed for the relevant approvals from the following UK review bodies:

- Social Care Research Ethics Committee
- National Information Governance Board (NIGB)
- NRES / NHS / HSC Research Ethics Committees
- NHS / HSC R&D offices
- Ministry of Justice
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Gene Therapy Advisory Committee (GTAC)
- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Ethics Committees (MREC) form was expanded to included data required by other agencies and online submission capability.

**IRAS Features**
The project structure and forms:

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21 IRAS E-Learning www.myresearchproject.co.uk accessed 19th July 2014
The Contact tab enables researchers to collate contact and qualification details about co-investigators. These details are accessible for new and approved projects, which makes adding investigators simple.

Pop up help is offered at a general level, such as “how do I login” or “how do I create a project”, as well as at a specific level providing advice on how to answer specific types of questions. “Question Specific Guidance” is available throughout the form.

A Project Filter determines what forms will be generated by IRAS for completion. The Project Filter is dynamic - when answering questions in the filter this may cause
subsequent filter questions to change. This enables IRAS to gradually refine requirements specific to the study. The filter questions determine (1) what approvals are needed, (2) what information needs to be provided to complete all the approval forms, (3) what declarations need to be signed and submitted. The required forms are listed on the left hand side of the screen under “project forms”.

- **Full Set of Project Data** - Instead of populating multiple forms for each separate review body, the Full Set of Project Data provides a single location where the project information is added and IRAS simultaneously populates all the relevant forms. Completing the Full Set of Project Data will also complete large parts of site specific forms.
- The ability to transfer your full dataset to other users to enable collaboration.
- The ability to print blank questions/forms.
- A graphic representation of what you have completed and what remains outstanding.

**The dataset navigation page will show you:**

- Which forms IRAS has activated on the left hand side.
- Which questions you need to answer in the grid on the right hand side. Active questions are shown in a white box with a link underlined, whereas inactive questions which you don’t have to complete are shown in pale blue with no active link.

In the screenshot on the right, the first active question in the Full Set of Project Data is outlined in red.

- Categorisation of research as part of the project filter, including definitions.

### 2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/Interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

- Other study

### Submission

IRAS has the capability to function as a single or bidirectional application process. Some agencies simply require a form be completed and submitted as a PDF, while others use IRAS for electronic submission and to provide feedback to applicants. The two submission processes are differentiated by the type of submission button, either E-Submit (electronic) or Proceed to Submission (print to PDF/hard copy).

Where a REC uses the E-submit process, this then creates an electronic link between the applicant and the review body that enables the provision of feedback. Additional feedback,
documentation and communication takes place outside of IRAS. It is not a requirement that IRAS is the only communication tool between applicant and reviewing HREC.

The Research and Development form for site governance is managed in IRAS in one of two ways. For studies that are part of the National Institute for Health Research (NIHR) portfolio, there is a coordinated system of permissions that is managed by an intermediary to ensure a speedy governance review process. IRAS is used to measure the NHIR performance indicators of time to first patient (70 days) and time and target for ongoing recruitment. Portfolio studies are mostly commercially sponsored clinical trials or participant collaborative research groups. There is no mandate to use the NHIR portfolio process and sponsors may still approach NHS trusts directly.

Non NIHR portfolio studies are submitted to the Research Ethics Committee and the site specific form as a PDF to the site Research and Development office, where a mix of hard and soft applications are accepted. No data is shared with Research and Development Offices from IRAS due to the challenge of integrating the systems of over 200 separate offices, however the Health Research Authority requires a standard site governance form that is submitted to individual sites.

Governance
IRAS is managed by the NRES on behalf of all the participating agencies. It was understood by Infonetica CEO Mark Lawson22 that NRES manages the budget for IRAS on behalf of the collaborating agencies, including the cost of system maintenance and amendment. It is further understood that there is no cost recovery from participating agencies. Agencies that approve aspects of health research or that require data relating to health research activity are encouraged to include their forms in IRAS. New agencies joining IRAS are required to use the standard data set. They are not permitted to create their own forms with a new version of similar questions. Each agency essentially has their own form in IRAS that draws data from previously answered questions wherever possible. However there are limitations to changes that can be made to forms— all new forms and changes to the full dataset require the approval of the Data Project Board.

The IRAS vendor, Infonetica, supports links between IRAS and other systems used in institutions or linking agencies that have forms in the system. The agency is able to control workflow within IRAS by controlling what fields an application cannot change when submitting or amending an application.

The challenges of IRAS
Infonetica CEO, Mark Lawson, reported that the process of gaining consensus to a standard data dictionary and definitions proved difficult and time consuming. Gaining stakeholder agreement on the small details took a very long time despite the mandate for a single ethical review. To ensure that data was only collected once and could be forward populated, there was a need for agreed questions between the agencies. The consultation process to establish agreed wording of common questions was extensive and time consuming. The functions of the NRES and many of the agencies involved in health and medical research were subsequently absorbed by the newly created Health Research Authority (HRA) which aided in the creation of a unified approvals process.

Any changes to the IRAS questions and data dictionaries requires major stakeholder consultation and internal testing. This results in long lead times for new releases of IRAS and often slow responses to changes in requirements. This is due to the integrated nature of the system and the need to test all aspects of it once a change is implemented to ensure there are no downstream effects or impacts on how the system operates. Once a system has established a two-way sharing of information, maintaining it is difficult. Changes to IRAS must

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22 Lawson, M. (2014) Meeting on the function and scope of the integrated research application system (IRAS), 19th July 2014
be tested with each agency to ensure functionality is maintained. IRAS currently maintains links to the NRES, NIHR and the MHRA. There is also the grey area where information is integrated in terms of how it is managed, who owns it and who pays for the testing and maintenance.

Infonetica report that as agencies have control over their submission processes, including the content in the “submission tab”, areas of inconsistency have started to creep in. Although the questions asked are consistent, guidance terms and definitions are not and differ between agencies.

In future integrated systems the following should be considered:

- To leave the process as is where it is agency controlled and accept inconsistencies (and subsequent confusion) or;

- To centrally control the content in the submission tabs for all agencies. This option is associated with an increase in resources and longer timeframes for updates.

Maintaining multiple forms is challenging from a programming and governance perspective. The process is made smoother through clear, agreed definitions, consistent questions and data dictionary and by clear delegation on who can change the parameters of any field within the system – e.g. contact details or guidance text can be changed by an agency but not question title or response format. Ideally the fewer functions that require developer input the better, in terms of constraining costs and ensuring that the form remains responsive.

An issue for consideration prior to the implementation of any repository of forms is how version control will be managed. Introducing new questions where researchers are halfway through an application proves problematic as IRAS will allow the researcher to complete applications on the form they commence with, which means it may be an older version at the time of submission as IRAS does not force the use of the most current form (although the current form is used when commencing an application).

One of the key differences to the Australian context is that the UK does not have the complexity of the Federation with state and territories having jurisdiction over legislation and policy development. Options for accommodating jurisdictions in an IRAS type system include allowing each jurisdiction to control their local content such as site specific forms, or forms for local agencies such as radiation protections. For consistency a final signoff by NHMRC may be helpful. An alternative is for all changes to be made centrally by the NHMRC on submission of change requests from jurisdictions. However this creates an ongoing commitment from NHMRC to the maintenance of jurisdiction specific content and processes.
7.4 Suggestions for Potential Future Development and Extension of Functionality

The following are suggestions from stakeholders regarding the possible extension of development from a form to an ethics management system. The Pharmaceutical Industry in particular saw a single system as a valuable tool for measuring performance metrics and to provide data for strategic decision-making and development of clinical trial infrastructure:

- Bi-directional dataflow with a clinical trials portal and other systems as required.
- Complete database of national research activity that is searchable by HREC staff-granted access.
- End-to-end online process including submission and post-approval processes (reporting, close out).
- National, standardised amendment form and annual/final report forms.
- Include an amendment/modification module that differs between administrative amendments and substantive protocol amendments.
- Online lodgment of amendment and annual/final report forms.
- Project identifier is a constant; can HRAF issue a national identification number?
- Ability to capture metrics: numbers of studies, types of studies, therapeutic area. This provides data to government and health departments to influence policy development.
- Use other systems – what can be leveraged off international systems.
- Look at e-tax, as a client that downloads and keeps clients locally.
- NHMRC to provide list of accepted GCP training providers.
- Why don’t we just buy or subscribe to a form that already works well?
- Need to change thinking from paper forms to the electronic environment; the UK builds in authorisation built into the system, goes electronically with all the attached documents.
- Use of the system as a collaborative tool for HREC meeting, comments made by HREC members and ability for researchers to respond.
- Use the system to improve communication between sites, auto emails and notification of HREC review/approval in multicentre studies.
- Auto population of CTRA.
- Include data collection for the Australian Bureau of Statistics Research and Development Expenditure Survey.
- Ability to host local version – with own logos, localised help etc., but standard form.
7.5 Example Privacy Filtering and Question Logic

Figure 4 ECU Research Procedures
18 Privacy Considerations

Personal Information includes names, addresses, or information/opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information/opinion. It also includes Health Information (e.g. health opinions, organ donation or genetic information) and Sensitive Information (e.g. political views, sexual preferences, criminal records).

IMPORTANT: These questions relate to the collection, use or disclosure of personal information about individuals, which is either identifiable or potentially identifiable, without their consent.

If this research project:
only involves the collection, use or disclosure of deidentified personal information; or involves the collection, use or disclosure of deidentified personal information WITH CONSENT of the individuals; this section does not need to be completed.

Researchers are strongly advised to review the relevant privacy legislation, available from the ethics website. Note that access to information held in departments or agencies not in WA may require review of further State-based legislation.

18.1 Access to Personal Information

Does the project involve the collection, use or disclosure of personal information from:

- Commonwealth departments or agencies [✓]
- WA State departments or agencies [ ]
- Other State departments or agencies [ ]
- Private sector organisations in WA [ ]
- Private sector organisations in other States [ ]

Please provide an explanation indicating the following:
- The name of the department or agency
- The information that will be sought
- The number of records to be accessed
- A general description of the records to be accessed

NOTE: If any of the departments or agencies has provided permission for access to the information, please attach a copy of the permission to the application.

Figure 5 ECU Privacy Question
18 Privacy Considerations (cont.)

18.2 Identifiable Or Potentially Identifiable Information
Why is it necessary for the information to be identifiable or potentially identifiable?
- The research project involves the linkage of data
- Scientific defects would result if deidentified information was used
- Other
  - Please Explain
    Explanation goes here if other box is ticked.

18.3 Consent
Why is it not possible to obtain consent of the individuals?
- The nature of any existing consent with respect to the collection, use or disclosure of the information
- It would be impossible or difficult to obtain consent due to the age of the records or lack of up to date contact details
- The proposed research will be minimally intrusive on the privacy and well being of the individuals involved
- This research project is an extension of, or closely related to a previously approved research project
- Other
  - Please Explain
    Explanation goes here if other box is ticked.

Figure 6 ECU Information Status and Consent