Building a new application form for use in human research

Consultation on the structure and content of the form

May 2014
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PURPOSE OF CONSULTATION

NHMRC is developing a human research application form that is intended to meet the needs of all researchers who wish to conduct research involving humans, and to meet the needs of Human Research Ethics Committees (HRECs) who are required to review proposals for research in accordance with the National Statement on Ethical Conduct in Human Research (2007) (National Statement). While it is intended that, when completed, the form will replace the existing National Ethics Application Form (NEAF), it may also be used for other aspects of human research applications such as collecting information required for jurisdictional or institutional research governance processes.

As part of the development process, 2 consultations are being undertaken concurrently. These are:

1. Consultation on the structure and content of the form (This consultation)
2. Consultation on the design and implementation of the IT solution and the need for interoperability with stakeholders’ information systems (Separate consultation)

The purpose of this consultation is intended to elicit the views of stakeholders on the proposed structure and content of a human research application form. Stakeholders identified for this consultation include HRECs, researchers, institutional governance officers and jurisdictional staff who oversee and coordinate the submission of research applications. This consultation will not seek input on the specific questions the application form should include, as this will be the subject of a separate process.

Each group of stakeholders will have different needs for the form, and this paper outlines the principles underpinning the new application form, the feasibility of its interaction and compatibility with existing information databases (e.g. AU-RED) and how the form can facilitate certain aspects of the site assessment and authorisation process (‘research governance’).

It is important to note that the information obtained through this consultation, and from the other consultation occurring concurrently, will be used during the next stage of the development process. No finalisation of any form will take place without further significant consultation and user testing.
BACKGROUND AND CONTEXT

Applications for ethical approval for human research projects currently utilise a variety of forms and formats. While the commonality between all application forms is the need to demonstrate that the proposed research is ethically acceptable and will be conducted in accordance with the requirements of the National Statement, the variation in forms and formats can be attributed to a number of factors including (i) the type of research that is being conducted and where it is being conducted; (ii) the complexity of NEAF; and (iii) the variation in information management systems used by institutions both to receive and review applications for ethical review.

As an example of how the type and location of research may contribute to variation, research involving humans that is being undertaken in a university may use a different type of application form, compared to that submitted as an application for a clinical trial by either a pharmaceutical company or by an academic clinical trial investigator. In the first instance, the form may be a university specific form, whereas the latter is more likely to be the NEAF. This is because many institutions whose ethical review processes were certified as part of the National Approach to single ethical review accept the NEAF.

In 2005, the NHMRC launched the NEAF as a model of an electronic application form that could be used for all human research. NEAF is used in conjunction with other documentation, including project descriptions,\(^1\) information and consent forms and other supporting or explanatory documents. Despite being used for applications, NEAF is not as widely used for other types of human research applications. Therefore, it is hoped that by combining an approach that focuses on consideration of and adherence to the principles of the National Statement, with an approach that will better accommodate the process requirements of all parties wishing to submit applications for human research, the use of the new application form will become more widespread.

A final consideration in the development and use of any single ethics application form relates to the IT environment in which it is used. For example, a licenced version of NEAF is hosted on Online Forms\(^2\), a website that certain Australian States use as a gateway to their jurisdictional information management system, and which tracks research applications and Site Specific Assessment forms. Though this IT approach is suitable for those parties that wish to conduct human research which requires some oversight by jurisdictions, such as clinical trial research, it may not be an optimal solution for research in an academic environment. Therefore, the usability of the application form in a variety of environments must also be considered during development.

The consultation paper is separated into aspects of the key features and subsequently the proposed sections of the new human research application form. Each aspect is followed by one or more consultation questions.

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1 The term project description is used here to refer to any document that describes a proposed research project. Alternative terms include research proposal, project proposal and project plan. A protocol is a form of project description with a defined structure and content that is commonly used for, but not limited to clinical trial research.

2 https://www.ethicsform.org/au/SignIn.aspx
1. KEY PROPOSED FEATURES FOR A STANDARD HUMAN RESEARCH APPLICATION FORM

A human research application form needs to capture information that an HREC requires in order to address ethical considerations in its review of a research proposal, and information that is required by the administrative arm of an HREC (and, potentially, the institutions in which the research is conducted) for tracking and reporting purposes. An application form should also enable the export and/or import of core information common to multiple stakeholders in the research review process, such as regulatory bodies, grant review bodies, clinical trial registries and jurisdictions in order to facilitate reporting of the number and type of research proposals submitted to institutions as well as other possible metrics. The proposed format for the application form takes account of these three complementary purposes.

1.1 Appropriate grouping of information requirements
The first proposed key feature of the application form will be the appropriate grouping of information requirements. This will help to ensure that information is grouped according to whether it is related to the investigators, the research, the participants or the outputs of the research.

The proposed groupings within the new application are as follows:

- **Section One** – Core information, including information on investigators, institutions and research sponsor/s
- **Section Two** (to which a project description would be attached) – Categorisation of research, research category-specific questions, and low-risk research assessment tool and pathway
- **Section Three** – Information on participants
- **Section Four** (potential only) – Data, Privacy and Publication and dissemination of research results

These sections are designed to provide information on the core ethical questions that an HREC must consider.

The inclusion of a fourth section to include all questions related to data and privacy and also, potentially, questions related to publication and dissemination of research results, is an optional feature of the proposed structure for the new form.

In addition to the above, some consideration will be given to the need for a complementary module to collect information that may be useful to institutions or jurisdictions for their own research governance processes.

1.2 Mandatory attachment of a Project Description
As a mechanism to minimise the possible redundancy of information provided in different parts of the form, the use of a project description as an attachment to the form is being proposed. A project description is an essential component to ensure consideration of ethical concepts and research merit for all research projects. Therefore, the project description will be used to articulate the details of the research and provide context and information for HRECs and other decision makers in the process.
1.3 Consideration of Low Risk Research
One criticism of previous ethics application forms has been their inability to appropriately consider low risk research (as defined under the National Statement). For example, NEAF necessitates provision of extensive information for all research, where some of this information may not have been necessary for a review body to come to a decision that the research was indeed low risk. Therefore, a core feature of the proposed new form will be the inclusion of a risk assessment tool that is designed for use by researchers to identify if they consider their proposed research project as low risk. Applicants will be led through a short set of questions regarding criteria particular to the category of research that they have selected. If the criteria are satisfied, the applicant would then be directed down an alternative ‘low risk pathway’ embedded in the new form, avoiding the full set of questions required for greater than low risk research.

GENERAL CONSULTATION QUESTIONS

1. Are the proposed key features of the new form appropriate? If not, what alternative or additional features would you suggest structure?
2. Do you support using the new form to encompass low risk research? If not, why not?
2. PROPOSED STRUCTURE AND CONTENT OF THE NEW FORM

2.1 Introduction to the form

The introduction to the new application form would detail:

- The logic of the form
- The scope of each section
- How the form will import and export data, interact with other forms, permit compliance reporting (e.g. regarding requirements of privacy legislation) and facilitate meeting jurisdictional requirements
- The mandated attachment of a project description to the application
- The availability of guidance and templates for the development of an acceptable project description
- The form’s approach to information relating to research data and privacy considerations
- The form’s approach to assessment of the risk of proposed research, including the availability of an alternative pathway within the form for low risk research proposals

INTRODUCTION- CONSULTATION QUESTION

1. Is there any other information that should be provided in the introduction?

2.2 SECTION 1 – Core information

It is anticipated that most or all of this information will be exportable or importable to other forms or IT platforms and, potentially, that it will auto-populate fields in those forms/platforms or be populated by them during the process of completing the form. Applicants would maintain control over who their data is shared with, although the sharing of data may be a prerequisite for commencement of the research. Currently, the potential recipients and sources of this planned information exchange may include:

- The Australian New Zealand Clinical Trials Registry (ANZCTR)- for the registration of clinical trials;
- The Australian Research Ethics database (AU-RED) (currently used by some jurisdictions to collect information on ethics application for the conduct of clinical trials in public hospitals);
- The Therapeutic Goods Administration (TGA)- specifically, with respect to the provision of information required for completion of the Clinical Trials Notification (CTN) form;
- Template jurisdictional site assessment forms; and
- Institutional databases and research management systems

and, with the respect to imported data:

- ORCID.

Section 1 fields will address:

- Project title
- The Australian New Zealand Standard Research Categories field (a drop down list)
- Selection of an ethics committee (a drop down list)
- Investigators (Coordinating Principal Investigator and other investigators)
• Projected roles of investigators
• Qualifications, experience and training of investigators
• Declaration of any potential conflicts of interest of investigators
• Institutions involved in the research
• Entities sponsoring or supporting the research (related to the three potentially separate roles of financial or in-kind support, legal responsibility and regulatory compliance, and overall project coordination)
• Prior scientific or peer review

SECTION 1 CONSULTATION QUESTIONS

3. Is there other core information that should be included?
4. Do you support the principle of information sharing between the new form and other forms/platforms? If not, why not?

2.3 SECTION 2 – Project description and categorisation of research

The primary functions of this section will be to:

i. categorise the proposed research project for the purposes of ethical review; and

ii. facilitate assessment of the risk level of the project that may lead to a low risk pathway.

iii. link the application form to a separate Project Description that will contain information that does not require repetition in the form itself.

The research categories and sub-categories to be included in the form represent those categories for which there are ethically distinct issues and questions that must be considered. The proposed five top-level categories (and sub-categories) include:

- Laboratory/basic science research (includes most genetic and genomic/proteomic research)
- Clinical research
  - Interventional clinical research (clinical trial)– drug and/or device
  - Interventional clinical research (clinical trial) – other medical
  - Interventional clinical research (clinical trial)– non-medical
  - Non-interventional clinical research
- Health research (includes population health, epidemiological, public health, health services)
- Research infrastructure (includes registries, databases and biobanks established with the intention of being used for research)

Section 2 will be designed so that after the applicant chooses the research category (or categories) that apply to the proposed project, the applicant will be led through a series of tailored questions intended to ascertain the risk level of the research project. If the responses to the risk assessment questions suggest that the project carries low risk, then the applicant will be diverted from the main body of questions onto a ‘low risk pathway’ that will be embedded in, but independent from the main form. It should be noted that even if the

3 Note: The categories of research that are included here may not correspond to categories in the ANZSRC field in Section 1. The decision to include ‘research infrastructure’ as a distinct category is necessary as it generates its own ethically distinct questions.
applicant believes their research project is low risk, an ethical review body may ultimately determine that the research project involves more than low risk to participants and require a more detailed response.

If the project is more than low risk, the applicant will follow one or more sequences of questions that address the ethically distinct issues related to the category/ies of research that they have selected. Reference can be made to relevant parts of the attached project description in answering these questions.

SECTION 2 CONSULTATION QUESTIONS

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

4. Are the research categories listed above the best descriptors to facilitate generation of ethically distinct questions? If not, what alternative categories could be proposed?

5. What is the best way to deal with research projects that include multiple research modalities (e.g. clinical trial with genetic sub-study and with a quality of life survey) that fall into more than one research category? In particular, how should the form manage any duplication in questions that would be likely to arise? [Note: the major options are ‘auto-population’ of duplicate questions in secondary research categories or automatic deletion of those questions in secondary research categories].

6. 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?

7. It is being proposed that all applicants will have to complete the 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?

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

9. What other information might need to be captured in this section?

10. 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.

2.4 SECTION 3 – Participants

Section 3 will capture information about the proposed research participants in addition to exploring the critical matters associated with participation in research such as:

- consent;
- burden, risk and benefit;
- payments and other potential incentives;
- recruitment intentions and strategies;
- dependent relationships; and
- key jurisdictional requirements, such as those related to guardianship, specific sub-populations and, potentially, privacy.
The questions in this section related to how the researcher proposes to manage any ethical issues that may arise from recruiting or excluding potential participants, or tissue or records or data associated with them. Reference can be made to relevant parts of the project description in answering questions.

**SECTION 3 CONSULTATION QUESTIONS**

11. What other information might need to be captured in this section?

2.5 **SECTION 4 – Data/Privacy**

The inclusion of a separate section for information related to the data and privacy-related aspects of a proposed research project is being considered. If included as a separate section, the questions would be designed to capture issues related to the collection, processing, storage, access, use, disclosure, return and/or destruction of any research data associated with participants in a research project. This would include any projected or likely secondary use of the data. Any privacy implications of the collection, use or disclosure of any of this information would logically also be included in this section. Questions related to information on the dissemination of research findings, via publication or directly to research participants might also be included in this section.

The argument in favour of a separate section to capture information related to the data and privacy-related aspects of a proposed research project is twofold:

i. It permits all ‘like’ questions to appear in one place, thus reducing both potential duplication and inconsistency in responses; and,

ii. It permits the questions to be asked in a logical, sequential and comprehensive manner.

The principal argument against a separate section for this information is that it artificially separates data-related aspects of a research project from questions related to the nature of the research and from questions related to the participants from whom the data are collected or with whom the data are associated. This is particularly the case for research projects in which the primary aims or activities are the collection, use etc. of data and with respect to research infrastructure.

It is noted that whichever option is chosen, the form will need to be able to facilitate exportation of the necessary information so as to enable efficient reporting under State and Commonwealth privacy regimes.

**SECTION 4 CONSULTATION QUESTIONS**

12. Do you favour the inclusion of a separate section for questions related to data and privacy and publication and dissemination of research results? If not, why not?
2.6 Option of a site-assessment/research governance module

NHMRC is interested in stakeholder’s views regarding the merits of designing the new form to include or be joined with a module to cover site assessment/research governance issues. Institutional governance officers, rather than HRECs, would review this module. Examples of matters that could be included, include funding and budgetary issues, the identification of every site (as opposed to investigator) potentially involved in the project and prior ethical review\(^4\). It is noted that the UK has included this in its Integrated Research Application System (IRAS).

If the option of developing a site assessment/research governance module were taken up, NHMRC would undertake additional consultation.

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\(^4\) The argument for prior ethical review being only a matter of site assessment/research governance is that no HREC re-review of an already ethically reviewed project should be occurring. Thus, if re-review is occurring, then the prior review has not been accepted and its content and outcome are redundant and irrelevant to the new review. If the prior ethical review is accepted as sufficient, then only site assessment, not additional ethical review, is required.