Review of the National Statement on Ethical Conduct in Research Involving Humans

First consultation draft

Response from the joint working party of the Australian Association of Academic General Practice (AAAGP)

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The AAAGP has been in existence for almost 20 years as an association of people who are undertaking research that will add to the body of knowledge of the discipline of general practice - or are teaching from and thereby refining and propagating this body of knowledge. There are more than 170 members across all departments of general practice and colleges, and from many divisions and other general practice organisations. It strives to be at the forefront of health research and medical education in the Australian community. This body represents this membership in general and specifically the University Departments of General Practice where the majority of senior researchers are based.

Background

The joint working party was initiated by the AAAGP in response to member concerns regarding difficulties encountered by general practice and primary care researchers in conducting research in the environment created by both the NHMRC National Statement on Ethical Conduct in Research Involving Humans, and its interpretation by NHMRC constituted Human Research Ethics Committees, and by the private sector provisions of the Privacy Act.

Particular concerns were raised regarding:

- the obtaining and recording of patient consent in research where no risk to patient health or welfare was involved;
- the impact of the Privacy Act on the conduct of research and on the determinations of HRECs;
- the difficulty in distinguishing between health research and quality assurance activities and the need to ensure that QA activities are also conducted in an ethical manner;
- access to appropriately skilled HRECs in a timely and affordable manner;
- the need for approval by multiple HRECs for multi-centre research;
- indemnity cover for non institutional researchers and participating GPs.

Subsequent to the formation of the working party additional issues regarding the skills of general practice and primary care researchers in the wider areas of research governance was raised and it was resolved that the working party should also address the area of research governance training. This involves the development of a manual for general practice (GP) and primary health care (PHC) researchers and the development of distance learning programs to facilitate improvement in researcher skills. A proposal has been put to the Australian Government Department of Health and Ageing for financial support for these additional activities.

Issues related to the discussion draft

Comments are structured in the order in which they occur in the discussion draft and are identified by the headings and subheading in that document.

Overall comments

This document clarifies some of the areas of difficulty with the previous Statement and is presented in a more useable format and sequence. No background is provided setting out what the authors hoped to achieve with the alterations and the problems they were trying to address.

The document lays down mainly general principles which, while sometimes allowing a high level of flexibility for HRECs to consider individual ethics application, will allow a considerable level of variance between committees in the decisions they make. High levels of variance can lead to HREC "shopping" to obtain a favourable determination. Considerable HREC variance has been noted by GP and PHC researchers in the consultation process leading to this submission. It has been noted in the United States that the introduction of national and regional specialised ethics committee has had poor patronage due to researchers favouring institutional committee who are "the devil you know". This difficulty may be addressed by more explicit rules for HRECs that make the determinations more predictable for researchers. This is particularly important if we are to move towards cross recognition of HREC determinations by multiple institutions and researchers. The development of more explicit guidelines for various kinds of research may assist in this regard. While some kinds of research (eg clinical drug trials) get special mention, areas of particular concern to GP and PHC researchers such as health services, educational and observational research are not explicitly addressed. A better balance is needed between implicit and explicit advice to HRECs.

There is a confusion of terms in describing some forms of research. Terms such as epidemiology, health services research and public health research are used with a notable lack of discrimination. A glossary of terms (for example from Last. A Dictionary of Epidemiology) may be useful in clarifying these issues.

Detailed comments

1.1: Justice

1.1.8 (a): In contrast to the stated principle, there are not fair opportunities for participation in research in the non-institutional primary care sector. This issue needs to be actively addressed.

1.2: Consent

1.2.2: This principle is in accord with the general provisions of the Privacy Act that there should be a shared understanding between researchers and participants in research. This principle should apply whether or not consent for participation is required by the nature of the research. For example it is appropriate for patients to be informed that their de-identified data is to be used for health services research or other statistical purposes and allowed to opt out even though HREC requirements may not render formal consent necessary. Some HRECs have interpreted the previous rules as

meaning that if consent is sought, even if not technically required, then consent must be "opt in" and formally recorded in writing. This point must be clarified but does not appear in this document.

1.2.6: This clause is a major sticking point in primary care and general practice research. Much of this research is observational and carries no patient risk. In these cases the bureaucratic burden imposed by this clause to establish "each participant's voluntary participation" is grossly counter-productive to cost-effective performance of much research in clinical practice. For example the collection of data about consultations without interventions and where the de-identified but potentially identifiable data is held by organisations operating under institutional supervision, should be permitted on the basis of appropriate patient information, verbal consent and acceptance that the clinician's collection of the data is "conduct implying consent". Much general practice health services and audit research is carried out under these circumstances and this needs to be supported by the guidelines. Similarly research on patient educational interventions carried out on large patient samples suffers from these burdens. There appears in the guidelines no gradation between waiving the requirement for consent and requiring opt in and recorded consent. Greater flexibility is required to allow consent processes more appropriate to the nature of the research and patient risk. These options should be set out in sections relating to specific forms of research. It may be useful to develop a series of case scenarios as examples for HRECs.

1.2.11: This clause similarly causes problems with medium to large scale observational and health services research. Extended and unspecified consent is frequent in large scale survey data collection where data may be analysed to answer questions not predictable when the data were collected. These valuable data resources must not be disabled by unnecessary constraints when they do not involve patient risk. The law has now clearly enunciated that written consent is no guarantee of informed consent. The emphasis here must be on informed consent rather than written consent. The Privacy Act, and its interpretation by the Privacy Commissioner, has a strong emphasis on information sharing and shared understanding and no emphasis on written consent. This clause in its present form does not allow any leeway for interpretation by HRECs and no guidance regarding exceptions to these rules.

Overall the consent clauses in this revised statement do not address the problems encountered in primary and health services research inherent in the last national statement.

Section 2.3

Data in health databases are a major research resource for public health and health services research and for health policy development. These data are frequently used to answer research questions which were not envisaged when the data was collected. Extended and un-specified consent is frequently obtained to address the need for future research. (see previous comments)

As much of the data held in health databases is potentially identifiable and can frequently be linked to other data, an important issue is the regulation of the database custodians. Research organisations bound by NHMRC guidelines holding HREC

approved databases with ethically approved collection methods, and statutory authorities operating under legislative or regulatory constraints (such as the Australian Bureau of Statistics and the Australian Institute of Health and Welfare) could be reasonably trusted with identifiable and potentially identifiable data. The same cannot be said of organisations not required to play by "NHMRC rules" or under statutory constraint. It is important for the NHMRC to state clearly that all health research conducted in Australia, whether in the institutional, public or private arena should abide by the same set of rules and be subject to the same HREC oversight and have equal access to oversight and support. Primary care researchers in the private sector have poor access to appropriate HREC services at present.

2.3.1: This clause is grossly simplistic. The difficulties of defining de-identified data has been of major concern to the Federal Privacy Commissioner and is not resolved. The Clinical Colleges Working Party on Privacy Legislation suggested that much so-called de-identified data was in fact potentially identifiable. Line or "unit record" data of a single patient is potentially re-identifiable even when "normal" identifiers such as name address and date of birth are removed. Aggregated data (not defined in this clause) with minimum cell sizes as suggested by the Australian Bureau of Statistics is probably the only properly de-identified data. Such de-identification frequently renders the data useless for future research. Definitions of potentially identifiable data and aggregated data need to be added to this clause and, as the borders are in fact quite grey, the statement that they are mutually exclusive should be removed.

2.3.8: As stated above the questions which might arise in the future are essentially unknowable. Open consent should generally be considered the norm provided that privacy and patient safety are not compromised.

2.3.9: The emphasis that information and consent should be in writing is again inappropriate for database data collection in most cases. The need for written consent in some cases should be acknowledged but should be the exception rather than the norm. The rules that apply to consent to data collection for databases should be the same as those that apply to other research and should depend on HREC assessment of patient risk, privacy protection, public good and the facilitation of cost-effective research. The need to limit the information and consent recording burden on clinicians and patients should be a significant factor in HREC determinations and should be clearly stated.

Section 2.4

As stated earlier, there is confusion in this section regarding the differences between public health research, epidemiological research and health services research. These are different forms of research frequently using very different quantitative and qualitative methodologies. While epidemiological research MIGHT be considered a sub set of public health research, health services research is not related. It would be useful to HRECs, we consider, to separate these three forms of research into separate sections.

2.4.5(c): Open consent to future use should be explicitly allowed for in this clause.

2.4.10: Verbal/unrecorded and opt out consent should be explicitly allowed in this kind of research.

Section 4
A statement needs to be added to the preamble that all research involving humans conducted in Australia needs to be reviewed and approved by an HREC following the guidelines in this Statement. Research should be reviewed regardless of its location, institutional base and whether it is in the public or private sector, or in an Australian or State Government jurisdiction.

Mechanisms need to be established to facilitate the access of researchers in the non institutional and private sectors to HREC review of their research. Institutions support their HRECs from research infrastructure funds and may only charge commercial researchers such as pharmaceutical companies, providing Institutional researchers with a free review service. Community based primary care and general practice researchers generally only have access to HRECs on a user pays basis and, as their research is frequently small scale and poorly funded, the HREC costs may be a major disincentive to ethics review. The RACGP HREC is one of the few available to GP and OHC researchers and has to operate on a user pays basis. To encourage primary care research, alternative funding models need to be explored to support research infrastructure and good research governance in the community sector. Research infrastructure in the primary care sector should include adequate resources for training in research governance including the areas in the Joint NHMRC/AVCC Statement and Guidelines on Research Practice.

Other than the RACGP HREC, few HRECs have experience in reviewing primary care research. GP and PHC researchers may use methodologies foreign to institution based researchers and may be presented by researchers with little experience in ethics review applications. The presence of appropriate expertise in HRECs reviewing primary care research is essential, as is encouragement for novice researchers. The development and support of HREC with special expertise in specific research areas such as GP and PHC research is essential for the viability of research. Special purpose HRECs need to be recognised by Institutions as a valid alternative to their own HRECs for review of Institutional research.

4.1.1: The NHMRC and the Australian Government Department of Health and Ageing should ensure that funding support is available for HRECs in all health research sectors.

Review of minimal risk research

4.1.13/14: Much GP and PHC research is in the minimal risk category. While welcoming a process to streamline HREC consideration of minimal risk research, the process will continue to be unsatisfactory unless appropriate guidelines are developed for this class of research. A separate section in the Statement setting out more flexible guidelines for minimal risk research is needed, particularly in the areas of participant information, types of consent and the recording of consent. Unless this is done then the outcome of review will continue to hamper this type of research.

4.2 Multiple ethical review of research

The joint working party welcomes the inclusion in the Statement of guidelines to eliminate, or at least reduce the need for multiple HREC review of research projects and programs.

An issue which could be included in this section, which is discussed earlier in this submission, is the appropriate skills of the HRECs to consider the research under review. Even in situations where the research is to be based in one institution, the research may be more appropriately reviewed by an HREC with required skills, outside the institution. A more general recognition of "outside" HREC determination by institutions is required to allow Chief Investigators to obtain the best ethical advice and review of their research.

4.3 Monitoring

Specific mention needs to be made in this section of the HRECs responsibilities when the research is being undertaken outside any supervising "Institution". GP and PHC research occurs both within and outside institutions and this fact needs to be addressed in the text.

4.4 Complaints handling procedures

As with the section above on 'Monitoring' mention needs to be made of processes for complaint handling for research undertaken outside the jurisdiction of an institution.

4.5 Accountability

This section again focuses wholly on the triad of institution, HREC and researcher. In GP and PHC research the 'institution' in the sense implied in this Statement may be missing may or be an 'institution' of a different sort such as a Division of General Practice which does not have the structures and capacity of NHMRC recognised institutions. This may place an additional burden on an HREC reviewing research under these circumstances. In addition, early GP and PHC researchers may lack both research governance skills and experienced supervision. These factors need to be taken into account in the guidelines. Mechanisms need to be in place to ensure that education and training in research governance is available to new researchers to address this problem. It is notable that the US National Institutes of Health have proposed that CIs should have institution certified training in research governance to be eligible for research grants. Accountability begins with the researcher but should still have an upward chain in the absence of an 'institutional' base.

Issues not addressed in the National Statement

Quality Assurance

Although the NHMRC endorsed guidelines regarding the criteria for quality assurance requiring ethical review in 2003 the area is still fraught with difficulty for both practitioners and HRECs. As with our more general concerns that this Statement is insufficiently explicit in its advice, the QA advice suffers similar problems. It sets out a series of questions to be asked of a QA proposal but does not specify who asks the

questions and of whom. In general practice and primary health care many QA activities are developed and administered by organisations that are not in the public health sector nor governed by the ethical constraints of Universities or other similar institutions. Significant numbers are commercial organisations such as pharmaceutical companies. To suggest that such organisations should ask the questions in the Advice of themselves to determine if ethics review is required abrogates the responsibility the NHMRC has for the protection of human participants in research or related activities. QA providers may have a significant commercial interest in the provision of activities and have an unresolved conflict of interest. The Working Party on Privacy Legislation of the Committee of Presidents of Clinical Colleges suggested that all QA activities should be assessed by a third party to determine the methodological validity and the compliance with privacy and ethical principles. It was suggested that this role could be undertaken by clinical colleges who would also determine if HREC review was required. This is not intended to apply to internal practice audit but to regulate QA processes organised by third parties outside the practice or clinical unit. The RACGP undertakes such assessment as part of the process of awarding points for QA activities for its professional development program.

We suggest that as part of the review of the Statement, the 2003 QA Advice be updated to include an explicit requirement for third party review of compliance with the criteria in the Advice and that the updated Advice be incorporated in the Statement.

Medical indemnity cover for researchers

Insurance cover for misadventure in participants in research is provided by Universities, research institutions and public sector health providers such as hospitals. However in the private sector, such as private general practice, practice medical indemnity insurance only covers the indemnity of normal practice and not of practice patients involved in research. Appropriate indemnity cover is an essential consideration when assessing patient risk in research. Lack of cover is potentially a major barrier to conduct of research in the private sector. This problem needs to be addressed as part of the requirement for adequate research infrastructure for all health sectors.

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