Submission to the Victorian Law Reform Commission
Review of the Guardianship & Administration Act 1986

from the Alfred Hospital Ethics Committee and General Ethical Issues Sub-Committee

The **Terms of Reference for this enquiry** include considering "the appropriateness of the current requirements for and criteria pertaining to, the treatment of a represented person under the Act, including a consideration of the existing provisions dealing with medical research, non-medical research, ...[and] the appropriateness of the existing 'person responsible' model in the Part 4 of the Act ...". We note, however, that there are no specific questions about medical and non-medical research in the Information Paper, and that non-medical research is not currently covered by the Act.

The Alfred Hospital Ethics Committee and researchers at Alfred Health have been putting into practice the Guardianship and Administration Act's provisions for medical research since 1999. The 2006 amendments have made the process for enrolling people with impaired decision-making ability in research less cumbersome by doing away with unnecessary double handling between the HREC and VCAT, and by providing a consent process which is relatively easy for researchers to follow and implement in most research involving experimental interventions.

Broadly speaking, the 2006 research provisions accord with the general ethical principles that this HREC follows when considering research involving adults with impaired decision-making ability, namely:

- Research without participant/proxy consent can only be done where there is no possibility of undertaking the research with consenting participants.
- The more 'significant' (or high risk) the intervention, the greater the likelihood or degree of potential benefit there needs to be for the participant if the HREC is to waive the requirement for participant/proxy consent.
- Transparency is important and researchers should have processes in place to inform people (e.g. the public, families, etc) of the research before and/or after the event.

At this institution, the research participants to which the Act is relevant fall into two main groups: those with temporary and/or sudden impairment (e.g. unconscious or severely injured patients) and those with longer term impairments (e.g. dementia, intellectual disability, some psychiatric conditions). Most of the difficulties that this HREC has encountered when putting the Act into practice relate to the first group. More specifically, the difficulties are most commonly around a mismatch between the urgency to commence a medical research procedure, the fraught nature of the situation, the (often) low risk level of the medical research procedure/s, and the requirements of the Act.

This submission highlights the key issues that have arisen for this HREC since the 2006 Further Amendment, and offers some suggestions for further consideration.

A. Extent of HREC authority to interpret the legislation

1. HREC authority vs researcher responsibility

Approval of research by a properly constituted HREC is a fundamental requirement of the Act. Research must be carried out in accordance with HREC approval, and HRECs have the authority under the Act to set conditions of approval [Section 42Q (3)]. However, there has been some uncertainty, both within the HREC and amongst researchers, about the extent of the HREC's authority to interpret the Act. For example:

- To determine what is, and isn't, a 'medical research procedure'.

- To permit/request alternative approaches when those in the 4 Step process are not appropriate or achievable, particularly with regard to obtaining consent from/informing the person responsible.
- To make judgments about 'what is reasonable in the circumstances'.
- To determine the kinds of research that can be done under procedural authorization.

Contributing to this uncertainty, in the case of procedural authorization, is the fact that the researcher/registered practitioner is required to certify in writing (via the Section 42T certificate) that various criteria have been met. This can cause considerable anxiety for researchers when the HREC's requirements and/or interpretation of the Act do not coincide with what the researchers believe is required of them. It is after all the researcher, not the HREC, who is subject to sanctions.

> **Suggestion:** It would reinforce the authority of HREC decisions, and provide reassurance to researchers, if Section 42Z 'Protection of registered practitioner' included a clause about protection of a registered practitioner who carries out a medical research procedure *in accordance with the relevant HREC approval.*

2. Duplication of responsibilities in Section 42T certificate

Section 42T (2)(f)(i) & (g) (and also Sections 6 and 7 of the Section 42T certificate) seem to require researchers to 'duplicate', or independently make, broader judgments about the purpose of the research and the validity of the hypothesis which would already have been made by the HREC. While it is appropriate for the registered practitioner to make an individual assessment of suitability for each participant, there is an element of parallel decision-making in Section 42T, which may be contributing to the uncertainty about HREC and researcher roles, responsibilities and authority.

> **Suggestion:** Consideration could be given to more clearly differentiating between matters that are addressed in the HREC review and approval process, and matters that relate to individual assessments of participant suitability. The statement in Section 5 regarding HREC approval may suffice, as this implicitly includes the points in 6 and 7. Section 6(ii) also basically duplicates the assessment already made in 3(c & d).

B. Definition of 'medical research procedure'

The definition of 'medical research procedure' relies as much (if not more) on identifying what is *not* a MRP as what *is a* MRP. Some basic principles would assist in making this determination; for example, is a MRP limited to physical interventions? Is it about physical and/or psychological risk level? Is it about physical and/or psychological impact, intrusion or 'interference'? Is it intended for procedures that are experimental (i.e. not standard of care)? Is it about a research intention or 'using' a person as a means to an end?

Non-intrusive examinations are excluded as MRPs and some kinds of examinations are specifically mentioned. However, these may be more intrusive to some categories of participants than others (e.g. an ear examination may cause considerable agitation for someone with dementia). On the other hand, other examinations that probably *would* be considered a MRP might have no impact on the patient at all (e.g. taking a small additional quantity of blood for research-related tests at the same time blood is taken for a clinical purpose).

Certain kinds of research involve 'grey areas', where it is unclear whether the research activity would be classified as a procedure; for example, psychological/psychiatric research involving neuropsychological testing where a participant is required to carry out certain tasks for the research. Such research may be more than observational, but does not involve an intervention or therapy.

How an activity is categorised is significant. If an activity is deemed a MRP, the 4 step process must be complied with and this may not be appropriate for some research. If an activity is deemed *not* to be a MPR, the practitioner does not have the reassurance of legal protection (against assault/battery or medical negligence) afforded by the Act.

C. Person Responsible (PR)

1. Identifying the PR – adherence to the hierarchy

The G&A Act has (in section 37) a very specific hierarchy for determining who is the 'person responsible'; however, this is qualified (in the definition of person responsible) as "the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision". This HREC accepts that the thoroughness with which the PR hierarchy can be explored by those undertaking the research will depend on the situation in which the consent process needs to occur. For example, if there is limited time before the MRP has to be undertaken, exhaustive attempts to identify and locate the first applicable person in the hierarchy would not be considered appropriate as this could compromise patient safety and/or the validity of the research.

This HREC requires that:

- the steps that will be taken to identify the person responsible are detailed in the ethics application and that these are appropriate to the circumstances;
- researchers responsible for recruiting/consenting have the experience and training to make decisions that are appropriate to the circumstances;
- for each participant enrolled via PR consent, there will be proper documentation of the consent process (including how the PR was ascertained) in the research records;
- research involving person responsible consent is a priority for random audits by the Ethics Office.

This point is made because there is a lack of understanding, or confusion, within the research community about how closely the hierarchy must be adhered to. We are aware of at least one research project where participants with impaired decision-making capacity were specifically removed from the protocol because of the difficulties anticipated by the researchers in working out who the person responsible would be; and we suspect that a number of studies have from the outset only included participants capable of consenting for the same reason. This is particularly an issue of concern in aged care research.

2. Contacting the PR before Procedural Authorisation

This Ethics Committee has had some concerns that researchers might inappropriately approach family for consent because of 'the rules'. The consent conversation is time-consuming and needs to be done at the appropriate time.

In some research situations, attempts to contact the person responsible before commencing the procedure may be logistically impossible or ethically problematic. If the research is time-critical, delays in commencing the procedure may adversely impact on scientific validity or (if the letter of the law was followed) the safety of participants. In some circumstances, contact attempts for a low risk/minor procedure – although in theory possible – might be inappropriate. For example, if the medical research procedure needs to be undertaken very late at night it may not be reasonable to contact the person responsible to seek consent given the substantial inconvenience and potential distress this may cause. In acute situations, even if the person responsible was present, their distress and distraction may make it inappropriate to approach them *at that time* about a minor matter that is peripheral to the patient's immediate needs.

In the past, researchers and the Ethics Committee have resorted to Section 42A (medical emergency) of the Act to 'cover' situations where PR consent cannot be attempted before commencing the MRP. However, more recently, the Ethics Committee has decided that the criteria in Section 42T are sufficiently flexible to allow for minimal, or no, contact attempts to be made in certain clearly proscribed circumstances. [This is discussed further in Part E below.]

3. Differentiating between *informing* the PR and *seeking consent from* the PR

It is unclear what S42T, subsection 4, requires. (4a) seems to require that the PR or patient be informed of the patient's *inclusion in the research project* (i.e. irrespective of whether or not the MRP still continues); (4b) speaks of the option to refuse consent for the procedure to continue and to withdraw the patient, which suggests that subsection 4 is intended for situations where the MRP is ongoing.

> **Suggestion:** If the intention is to mandate that the relevant person is informed of a patient's research participation (even if the MRP/participation is over), then this could be more clearly expressed in the Act and in the S42T certificate, and (4b) should begin with the qualifier "(If applicable"). If such a mandate is not the intention, it would be clearer if (4a) and (4b) were combined into one point.

4. Informing the PR after Procedural Authorisation

While this Ethics Committee would generally require researchers to inform the relevant person of a patient's inclusion in a research project, in rare cases it may be ethically problematic to make ongoing attempts to inform the PR *after* the MRP/PA. For example, in research involving acute trauma patients many participants will die before the PR can be informed. Where the MRP is very minor/low risk, the potential for causing distress to family could outweigh any benefit that 'transparency' might achieve. This is a decision most appropriately made by an ethics committee on a project by project basis.

This Ethics Committee has, in the past, approved more general/indirect transparency measures such as publicity about the research in the media, within the community, and within the hospital (eg. brochures or posters in waiting rooms). It is unclear whether such measures would be consistent with the Act's (and the S42T certificate's) requirement to inform the person responsible of the patient's inclusion in the research (if indeed there is such a requirement – see comments in (3) above).

Again, clarification of the extent of HRECs' authority to interpret the Act and to stipulate conditions for the conduct of the research that do not fit the letter of the Act would be helpful.

D. Procedural Authorisation

1. Non-therapeutic research is a 'poor fit'

In Section 42T there are a number of criteria which must exist in order for procedural authorisation to be relied upon, two of which appear to limit the kinds of research that can be done without the consent of the patient/person responsible:

> 2f(i) [a practitioner may carry out a medical research procedure without the consent of the patient or person responsible if he/she believes on reasonable grounds that] "one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched" ["Therapy" is not defined.]
>
> and

2g "the practitioner believes on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment."

In the first instance, it seems that there needs to be a therapy being offered/researched.

In the second instance, it seems that there needs to be some potential benefit (as compared with standard treatment) *for the individual participating.*

Medical research projects are not always about trying out a potentially beneficial therapy. There is a great deal of research leading up to the trial of a therapy (i.e. a condition needs to be investigated before a therapy can be developed and then tested), some of which may necessarily and essentially need to involve the particular participant group that is unable to consent (either themselves or via person responsible). However, such research usually brings no benefit to the patient/participant although it may do so for others in the future.

Often this 'preliminary' research involves minor/low risk procedures, such as taking small quantities of blood or other bodily samples for testing, so that while there is no benefit to individual participants there is also no harm. If the research is time-critical, consent may not be achievable before the procedure needs to be undertaken. However, because the procedure is not necessary and does not help the patient in any way, neither does the research fit within the 'medical emergency' (S42A) provisions which would allow it to be done without consent.

Strictly speaking, the above provisions in the Act do not accommodate 'preliminary' research; however, it would be surprising if the intention was to prevent this kind of research. The Second Reading of the Further Amendment Bill of 2006 makes the point that "[p]roperly approved medical research is important both for individuals who will have an opportunity to benefit from the medical developments and for society as a whole"[1] and that "[p]eople with disabilities should not be disadvantaged simply because their disability means they cannot provide consent themselves"[2].

In comparing the wording in S42T with that in the National Statement on Ethical Conduct in Research Involving Humans 1999 (which was the relevant NHMRC guideline at the time the Further Amendment was drafted), it appears that the requirements for PA were developed for/based on clinical trials - i.e. research which investigates an intervention (or alternative treatment). For such research, if the participant cannot consent it is important/ethical that there potentially be some therapeutic benefit. It does not automatically follow that preliminary research needs to have the same degree of 'benefit' or that it should not be done, particularly when the 'non-beneficial' procedures involved are of minimal risk and non-intrusive, and are likely to contribute to the development of future therapies for that population.

Currently, if an ethics committee approves such research projects for procedural authorization, the researchers need to submit a S42T certificate each time a participant is enrolled under PA and thereby risk falsely certifying that the research is about "the effectiveness of the therapy" and offers a "reasonable possibility of benefit to the patient".

Suggestion: Consideration be given to broadening the scope of research appropriate for Procedural Authorization.

2. Individual Section 42T certificates

In some circumstances, it is clear that all participants in a project will need to be enrolled via procedural authorization because of the time-critical nature of the research. For non-

[1] Guardianship and Administration (Further Amendment) Bill, Second Reading, 16 Nov 2005, p.2191
[2] ibid

therapeutic/preliminary studies, involving a minor MRP and a large number of participants, the value of submitting individual Section 42T certificates is questionable.

> **Suggestion:** Consideration be given to providing the option of a 'group' or project-wide certificate (or covering letter) for certain kinds of research.

E. Medical Emergency (Section 42A)

In response to the 2006 changes to the GAA, a group of researchers in this institution developed a consent/enrolment model consistent with the revised Act. This process was approved by the Ethics Committee and has – until recently – been used as a model for subsequent research applications.

One aspect of the model is that a '5th step' has been added, incorporating the 'medical emergency' provisions of the GAA (Section 42A). In this 'step', the researchers can carry out the medical research procedure without consent in "emergency circumstances" if the criteria for PA cannot be met (e.g. because of time constraints)[3].

The rationale for having this step is the concern that PA must necessarily first actively involve attempts to contact the Person Responsible to obtain consent, and this cannot be complied with in some situations (e.g. when the procedure needs to be done within a short time frame).

Prior to May 2010, the Ethics Committee also took the view that contact attempts needed to be made first. If this was not possible, the research was permitted to be done without consent under the 'medical emergency' provisions (S42A) of the GAA.

In May 2010, this position was re-considered and it was decided that in some circumstances where it is not possible or practicable to make initial contact/consent attempts, it might still be preferable for the research to be done under PA rather than the 'medical emergency' provisions. This is particularly the case where such circumstances are known and will routinely occur, and can be 'factored in' to the consent/enrolment process.

The following considerations contributed to that decision:

- The Act requires (for PA) that "steps that are *reasonable in the circumstances* have been taken" to ascertain whether there is a Person Responsible and to contact him/her. It might not be reasonable, for e.g., to contact the PR at 2am to ask for consent for a low risk or minor procedure that needs to be carried out immediately.
- The 'medical emergency' provisions are intended for situations where conventional treatment would not meet the patient's urgent medical needs. This understanding is based on a guidance document[4] available on the Department of Health website explaining the 2006 changes to the GAA. [The relevant points are quoted in the box below.] The Committee believed the S42A provisions should be preserved for this purpose.
- PA has some additional 'accountability' measures built in: the researchers must submit a Section 42T Certificate each time a patient is enrolled under PA to the Office of the Public Advocate and the Ethics Committee; and there is an obligation to inform/attempt consent from the Person Responsible or participant. Under 'medical emergency', these are not required.

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[3] In all cases where this was approved, the research involved comparing standard care with an experimental alternative, or two types of standard care, intended to save life or prevent harm or distress.

[4] Guardianship and Administration Act – the law on medical research procedures involving adult patients under a legal incapacity; July 2006; http://www.health.vic.gov.au/legislation/medicalresearch

Is there a medical emergency?[5]

22. If a registered practitioner believes on reasonable grounds that the medical research procedure is *necessary*, as a matter of *urgency*, to-
    - save a patient's life; or
    - prevent serious damage to the patient's health; or
    - prevent the patient from suffering or continuing to suffer significant pain or distress-

    then the procedure can be carried out, or supervised by, the registered practitioner (section 42A). In this situation consent is not required.

23. This provision is important because if treatment is novel and is being conducted as part of a research project, it is a medical research procedure and would need to be authorised under the "medical research procedures" provisions, rather than under the separate provisions in the Act governing medical treatment. This provision is therefore intended to ensure that if a medical research procedure meets the emergency criteria outlined above, the Act enables the procedure to be performed.

24. **However, it should be noted that before this provision will apply, the researcher must believe on reasonable grounds that the procedure is *necessary*. In the context of research, it is anticipated that this source of authority would be exercised rarely. This is because the practitioner would need to have reasonable grounds to believe that conventional available treatment would not meet the patient's urgent clinical needs.**

25. If the medical emergency criteria outlined above applies, *it is not necessary* to comply with the remaining steps in the Act (i.e. steps 2, 3 or 4) in relation to the performance of the procedure on that patient. If the medical emergency criteria do not apply, go to step 2.

It is unclear whether, or not:

- the medical emergency provisions are necessary or appropriate for most research;

- the medical emergency provisions are designed/intended for approval in advance by an ethics committee. It would seem that a clinical judgment is needed in each case that an emergency exists and that the MRP is necessary; therefore, the provisions would be applied on a case-by-case basis, and are something that the treating clinician always has the option to use (as an option for clinical care). An ethics committee has no explicit role in these decisions under 42A. Section 42T(e) would seem to support this interpretation, in that *for procedural authorization* an ethics committee has to approve the research in the knowledge that there will be situations where consent will not be possible, whereas this is not a pre-requisite for medical emergency. This suggests that 'approval in advance' to carry out a medical research procedure under the medical emergency provisions is not necessary.

The requirement in Section 42A (2) that "...in the case of a medical research procedure, section 42Q [i.e. approval by an ethics committee] [has] been complied with..." is unclear about what ethics committee approval covers. Is it the scientific/medical aspects of the ethics committee's review that are being referred to?

[5] ibid, p.4

F. Non-medical research

Non-medical research is not covered by the Act but may impact on participants' lives and well-being in significant ways. This Ethics Committee also reviews applications for social science research and has found that the National Statement provides adequate guidance on the ethical design and conduct of such research where it involves participants with impaired decision-making ability.

G. Consultation

It is noted that two, or possibly three, consultative groups have been set up to assist the VLRC in its enquiry. It is recommended that advice also be sought from people with expertise in human research ethics in a medical research context, particularly in the area of hospital and emergency settings involving unconscious/severely injured/seriously ill patients.

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