



OFFICE OF THE
PUBLIC ADVOCATE

**Interaction of *Health Records Act (HRA)* and
Guardianship & Administration Act (GAA) Part 4A
Div 6**

Office of the Public Advocate
Ph: 9603 9500
OPA Website: www.publicadvocate.vic.gov.au

Interaction of *Health Records Act (HRA)* and *Guardianship & Administration Act (GAA)* Part 4A Div 6

Both these Acts apply to medical research projects undertaken in relation to adults who are incapable of giving consent.

1. Human Research Ethics Committee (HREC) approval process

1. The HREC must consider whether research may be undertaken on participants who lack the capacity to consent at the time that the procedure is to be carried out. It does not matter whether it may only be a few of the participants. The HREC should consider whether it is possible that such people may be involved.
2. The HREC must consider what type of research procedures may be involved – i.e. will it fall within the definition of ‘medical research procedure’ (MRP) in the *Guardianship and Administration Act 1986 (GAA)* – is there a procedure, and if so, is it to be carried out for the purposes of medical research?

If the procedure does not fall within the definition, GAA provisions relating to medical research procedures will not apply but the *Health Records Act 2001 (HRA)* will still apply to information collected/used/disclosed.

3. If the procedure does fall within the definition of MRP under the GAA, and may involve participants who are unable to consent to the MRP, the relevant steps set out in Part 4 Division 6 of the GAA must be complied with. The first step is the responsibility of the HREC. The HREC must approve the relevant MRP, and can set down conditions by which the research project is bound [which are legally binding - see s42Q(3) of the GAA].
4. In completing the first step, the HREC must consider the basis on which patients will participate in the project. This involves an examination of how steps 3 & 4 under Division 6 of the GAA and section 42A of the GAA, might apply. The HREC must consider (a) whether it will approve the research on the basis that persons responsible for participants will be able to consent (s42S) or that the MRP may be performed because it is necessary in a medical emergency (section 42A), or (b) whether it will also approve the research on the understanding that procedural authorisation will be able to be relied upon if applicable to a particular patient (s42T).
 - (i) If it approves such research, it will still be necessary for the HREC to consider how the HRA will apply to the handling of the health information.
 - (ii) Where a person responsible consents to the MRP, they will also need to consent to the collection, use or disclosure for the purposes of the research of the health information that will be derived from carrying out the MRP¹. These two consents

¹ The person responsible is authorised to give this consent under section 85(1) of the HRA.

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should be obtained at the same time wherever possible, as they are obviously related to each other. The HREC should consider what information needs to be provided to the person responsible to enable the PR to give consent.

- (iii) Where procedural authorisation could be applied to the MRP, the HREC will need to determine whether the collection, use or disclosure of the information so derived for the purposes of the research project is permitted under the HRA. This requires consideration of the HSC guidelines on research². Many of the considerations relevant to approving the research will also be relevant to applying these guidelines.
- (iv) Where the procedure is performed because it is necessary in a medical emergency (as defined in s42A of the GAA) *as an MRP*, the HREC will need to determine whether the collection, use or disclosure of information so derived for the purposes of the research project is permitted under the HRA. This requires consideration of the HSC guidelines on research.

NOTE 1: GAA provisions provide protection for patients *and* for practitioners. A practitioner who complies with the GAA may be protected from liability associated with carrying out an MRP, but still not able to use the data collected if they have not complied with the HRA requirements.

NOTE 2: The Ethics Committee application by the researcher must contain enough information on all of these matters to allow the HREC to make appropriate decisions and set conditions.

NOTE 3: Different provisions of the HRA apply to the collection, use and disclosure of information for the purpose of a research project, depending upon the circumstances. These provisions are outlined in the appendix. This is a consequence of the fact that an MRP can be performed in a variety of situations. In some cases the information derived from performing the MRP will have no relevance to the treatment of, or the provision of health services to, the patient. In others, it may be highly relevant, and may even be considered to be the primary purpose for which the information is initially collected (ie from the patient). For instance, at paragraph 3.3.14 of the National Statement on Ethical Conduct in Human Research, the NHMRC acknowledges that there may be an intended therapeutic benefit for the patient who participates in a clinical trial. Each case will necessarily turn on its own facts.

Importantly, *the substantive requirements of the HRA are the same* - the question will be whether the consent of the person responsible (or patient) has been obtained, or whether the requirements regarding research that apply where it is not practicable to

² HPP 1.1(b) and HPP 2.2(c) allow the collection, use or disclosure of health information which is authorised, expressly or impliedly, under another law. It is arguable this means that section 42T of the GAA may, by implication, authorise the collection of information where the procedure was carried out as an MRP, or the use or disclosure of the information for that purpose (as applicable). However, to be certain about compliance with the HRA, it is recommended that researchers comply with HPP 1.1(e) or HPP 2.2(g) (as applicable). In either case, this involves applying the same criteria (including the Health Services Commissioner's guidelines on research.) Refer to discussion below.

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obtain such consent (including the HSC guidelines on research) have been complied with. *These are essentially the same regardless of the question of characterisation of primary and secondary purpose. This is because the provisions that apply to collection and use for primary purpose, or for a "secondary purpose" are consistent.*

HPP 1 and HPP 2.1 of the HRA collectively apply to the collection, use and disclosure of health information for a *primary purpose*. HPP 2.2 applies to the use or disclosure of health information for a *secondary purpose* (and HPP 1.1 will also be relevant in this situation if there is a researcher collecting it from the "disclosing organisation" for the purposes of the research).

The significance of understanding what is a primary and secondary purpose for the purposes of the HRA (as with all privacy legislation) is to be able to understand *how* the relevant privacy principles apply.

To identify which provisions of the HRA apply, the first question to be resolved is "what is the primary purpose for which the information derived from performing the procedure is collected?" In some situations, the primary purpose will be for the purposes of the research project. This is likely to be the case where the procedure has no intended therapeutic benefit, or where the results of the procedure *are not relevant* to the treatment of the patient. In others, the primary purpose of collecting the information will be to inform the treatment of the patient.

Another relevant factor may be *who* is collecting the information, as different organisations may have different purposes. A hospital may collect the information (from the patient) primarily for treatment, with its secondary purpose for the collection being the research. However, the third party researcher who is to use this information will be engaged in a separate act of collection- *from the hospital* - for the purposes of their research- so *their* primary purpose for this act of collection is research.

If a HREC is applying the HSC guidelines on research, and considering whether to approve the handling of information derived from a MRP for the research project on the basis that it is impracticable to obtain the relevant consents, but considers that there is some uncertainty as to whether it should apply HPP 1.1(e) or HPP 2.2(g), it is suggested that if it is satisfied that the criteria are met that it approve the collection, use and disclosure as set out in the application under both provisions, for the avoidance of doubt.

2. Medical research procedures on individual patients

Once HREC approval is granted, any enrolment of individuals in the project must be in accordance with conditions set down by the HREC.

In relation to the procedure ...

Conduct of an MRP on individuals must be in accordance with the relevant steps in the GAA.

NOTE 4: The HREC should have already considered the broad circumstances when s42A (emergency treatment) or s42T (procedural authorisation) may be used. The

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obligation on the practitioner is limited to considering whether those circumstances apply in the case of each particular participant, and then following the steps in the GAA.

In relation to the collection / use of information ...

The information privacy implications associated with the research project have already been assessed by the HREC to ensure compliance with the HRA. Where the MRP is being performed on a particular individual, the researcher/disclosing organisation must be satisfied that the relevant research project has been approved by the HREC, and that the other requirements of the HRA are met *in the case of the particular patient*.

That is-

(a) has the patient (if capable) or the person responsible (who consented to the MRP) consented to the collection, use (or disclosure, if relevant) of the health information for the purposes of the research project?;

(b) if the answer to this is no:

- (i) is the collection, use or disclosure necessary for research, or the compilation or analysis of statistics, in the public interest?

If the answer to this is yes, it must also be clear that-

- (ii) this purpose cannot be served by the collection, use or disclosure of information that does not identify the patient or from which the patient's identity cannot reasonably be ascertained; and
- (ii) it is impracticable for the organisation to seek the consent of the patient (or the person responsible) to the collection, use or disclosure; and
- (iii) the information is collected, used or disclosed in accordance with guidelines issued or approved by the Health Services Commissioner regarding research.

This document was issued by the Office of the Public Advocate to assist researchers after a meeting at The Alfred with researchers and members of the Ethics Committee in September 2007. The document was prepared in consultation with the Office of the Health Services Commissioner and the Department of Human Services. This document is not in substitution for legal advice which researchers may require to evaluate the compliance of their particular research project.

Colleen Pearce

Public Advocate of Victoria

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Definition of medical research procedure in the GAA

- (a) a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device; or
- (b) a procedure that is prescribed by the regulations to be a medical research procedure for the purposes of this Act—
but does not include—
 - (c) any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision); or
 - (d) observing a person's activities; or
 - (e) undertaking a survey; or
 - (f) collecting or using information, including personal information (within the meaning of the **Information Privacy Act 2000**) or health information (within the meaning of the **Health Records Act 2001**); or
 - (g) any other procedure that is prescribed by the regulations not to be a medical research procedure for the purposes of this Act;

Four steps under Part 4 Division 6 of the GAA

- (a) step 1 is to determine whether the relevant research project is approved by the relevant human research ethics committee—see section 42Q;
- (b) step 2 is to determine whether the patient is likely to recover the capacity to consent to the procedure within a reasonable time—see section 42R;
- (c) step 3 is to seek the consent of the person responsible for the patient, which only applies where allowed by section 42R—see section 42S;
- (d) step 4 is procedural authorisation, which only applies where allowed by section 42R and the person responsible cannot be ascertained or contacted—see section 42T.

Health Privacy Principle 1.1(a), (b) & (e) in Schedule 1 of the Health Records Act 2001

When health information may be collected

- 1.1 An organisation must not collect health information about an individual unless the information is necessary for one or more of its functions or activities and at least one of the following applies—
- (a) the individual has consented;
 - (b) the collection is required, authorised or permitted, whether expressly or impliedly, by or under law (other than a prescribed law);
 - ...
 - (e) if the collection is necessary for research, or the compilation or analysis of statistics, in the public interest—
 - (i) that purpose cannot be served by the collection of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained; and
 - (ii) it is impracticable for the organisation to seek the individual's consent to the collection; and
 - (iv) the information is collected in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this sub-paragraph;

Health Privacy Principle 2.1 and 2.2(b), (c) & (g) in Schedule 1 of the Health Records Act 2001

- 2.1 An organisation may use or disclose health information about an individual for the primary purpose for which the information was collected in accordance with HPP 1.1.
- 2.2 An organisation must not use or disclose health information about an individual for a purpose (the "**secondary purpose**") other than the primary purpose for which the information was collected unless at least one of the following paragraphs applies—
- ...
- (b) the individual has consented to the use or disclosure; or
- (c) the use or disclosure is required, authorised or permitted, whether expressly or impliedly, by or under law (other than a prescribed law); or
- ...
- (g) if the use or disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest—
- (i) it is impracticable for the organisation to seek the individual's consent before the use or disclosure; and
 - (ii) that purpose cannot be served by the use or disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained; and
 - (iii) the use or disclosure is in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this subparagraph; and
 - (iv) in the case of disclosure—
 - (A) the organisation reasonably believes that the recipient of the health information will not disclose the health information; and
 - (B) the disclosure will not be published in a form that identifies particular individuals or from which an individual's identity can reasonably be ascertained;

Link to HSC guidelines on research

<http://www.health.vic.gov.au/hsc/downloads/guideres.pdf>