

IN THE MATTER OF THE HEALTH
AND DISABILITY SERVICES ACT 1993

AND

IN THE MATTER OF A MINISTERIAL
INQUIRY INTO THE
UNDER-REPORTING OF CERVICAL
SMEAR ABNORMALITIES IN THE
GISBORNE REGION.

**SUBMISSION ON BEHALF OF TAIRAWHITI REGIONAL
ETHICS COMMITTEE**

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MAY IT PLEASE THE INQUIRY PANEL:

1.0 Introduction

1.1 The submissions filed on behalf of Regional Ethics Committees (RECs) have canvassed (inter alia)

?? The origins of the RECs.

?? The National Standard promulgated and applicable to them.

?? Objectives of RECs and their operation.

?? Audit versus research.

?? Specific response to particular evidence given by Professor Skegg.

?? The allegation that the purposes for which RECs were set up have been overlooked.

?? The allegation that the system of ethical review is functioning badly.

1.2 Tairawhiti Regional Ethics Committee (TREC) does not wish to cover ground already adequately covered in the submissions referred to in Paragraph 1 above, but will concentrate its submissions on:-

?? The particular application made to TREC by lead investigator Ann Richardson and others in April 2000.

?? TREC and its mode of operation.

?? Clarification of the differences between the application of April 2000 and the exercise of the Ss 4C and 4D powers

under the Commissions of Inquiry Act.

2.0 April Application to TREC

- 2.1 At some point in the earlier part of this Inquiry, it was decided that it would be helpful to the Panel to have research data available to it, such data to have been collected and analysed prior to the resumed sitting of the Inquiry in July 2000.
- 2.2 On 23 April 2000 TREC received an application for ethical approval of a research project (dated 17 April 2000).
- 2.3 This application proposed research – “an investigation of the cervical screening histories of women diagnosed with invasive cervical cancer in Tairawhiti from 1990-1999” (page 1 of application).
- 2.4 At the time of application the number of cases to research was 42.
- 2.5 The application as presented was really in two stages:-
 - (a) Obtain information from the National Cervical Screening Register.
 - (b) Obtain information from personal medical records of the subject women. The application at page 5 states “Smear takers and laboratories in Tairawhiti will also be asked to provide information about previous cervical smears taken for these women.” This takes the research beyond the ambit of an audit.
- 2.6 TREC established a Fast-Track Committee to deal with the application.

2.7 On 28 April 2000 TREC provisionally approved the research project, as formally set out in their letter of 12 May 2000.

“Whilst the committee has no doubts as to the value of the proposed research, they are united in their opinion that consents are needed in relation to two aspects of the study:-

1. Consent to access the required information through the National Cervical Screening Register, and
2. Informed written consent from the women involved to access their personal medical records.

We have approached the Minister of Health in regard to access to the Register, but even if this aspect is cleared, it will still be necessary for patient consent to be obtained, particularly in view of the fact that one woman involved has previously declined access. We will contact you as soon as possible once the Minister has replied.”

The application was not declined.

2.8 On 28 April 2000 TREC advised of the approval for the research project (as above) in paragraph 2.7.

2.9 On 3 May 2000 TREC’s Fast-Track Committee met with two of the researchers.

2.10 TREC was already of the belief that Patient 1 had declined access to her medical records, when asked for such consent while giving evidence to the Inquiry in April 2000. (TREC is **now** aware that the initial refusal was withdrawn the following day). This belief in the refusal is confirmed in TREC’s letter of 30 June 2000 to Mr

Hindle.

2.11 TREC were supportive of the research, as evidenced by their prompt dealings with the application, and the consent given within less than one week of receipt of the application.

2.12 TREC met again on 5 May 2000, and on 12 May 2000. The result of these meetings was to confirm TREC's earlier decision to approve the research project, subject to consents being obtained for:-

(a) Access to the required information through the National Cervical Screening Register.

(b) Access to the women's personal medical records.

2.13 Further, TREC asked to see and approve the formats of:-

(a) The written information sheet.

(b) The written consent form.

No such draft documents were ever tendered by the research applicants for consideration.

2.14 TREC had been told that the research project was

“...the single most important investigation into the apparent under-reporting of abnormalities in cervical smears in Tairawhiti...” (see p3 research application 17 April 2000).

2.15 A position taken by many at the Inquiry was that this proposed research was necessary to enable the Panel to answer the first term of reference for the Inquiry.

By 24 July 2000, Professor Skegg noted in his evidence (24 July 2000 B/2300) that he no longer believed that the study he proposed was essential in order to answer the first term of reference.

- 2.16 No attempt was made to progress the research subject to the consents required by TREC to ascertain whether the perceived difficulties in obtaining consents from 42 women (or perhaps fewer if some may have by then been deceased) were in fact real.

During his evidence, Professor Skegg confirmed that no attempts were made to ascertain **actual** difficulties, but rather his perceptions were based upon past experience in other research project(s), of which the number of participants or geographical implications are simply not known to the Inquiry.

- 2.17 The National Standard for Ethics Committees (July 1996 Appendix 7) provides for either the Committee or the Applicant to obtain a second opinion. None was sought by the Applicant.

- 2.18 The Privacy Commissioner in his evidence alluded to the possibility of the Applicant applying to his office for intervention. This was not done.

- 2.19 It is wrong to suggest that TREC have impeded the research, they having promptly and properly dealt with the application in terms of the National Standard (and in particular see paragraph 5.1.1 of the same which emphasises that the safety and benefit of the individual must take precedence, and where there is not likely to be any direct benefit to the **participant** (emphasis added) then the risks to the individual ought to be heavily outweighed by the potential good to society or future individuals with relevant needs).

- 2.20 What seems clear is that the researchers felt pressed for time to complete the research for presentation to the Inquiry in late July and with this application not having been made to TREC until April 2000. The application projected three months to completion. That left an additional month to try and obtain consents.
- 2.21 What also seems clear is that the researchers regarded the obtaining of consents as a difficult (if not impossible) and time-consuming task.
- 2.22 There had been a similar (but wider-ranging) application to the Otago Ethics Committee in 1999. The application to TREC was of a narrower ambit. Whilst there was not proposed to be direct contact with the subject women (as in the Otago application), the research was to go as far as examination of personal medical records held by doctors/laboratories.
- 2.23 What also seems clear, it is submitted, is that TREC and the research applicants held differing views as to the weight to be attached to the privacy rights of the individual, and the right to give informed consent to the disclosure of information; and also the potential for reporting of the information in a way which might identify the subject women (or at least some of them). Professor Skegg referred to a “small loss of privacy”. It is noted that each individual has their own view as to the potential impact upon them of **any** loss of privacy, however small it may seem to someone not so affected.

Ronald Jones (in his addendum to his brief of evidence at paragraph 6) appears to suggest that the consent of the subject women could be assumed. It is submitted that it would have been

improper for TREC to do so.

2.24 With respect, it is not for the Inquiry to determine whether the detriment to the individual **in this case** was outweighed by the greater good.

2.25 The research applicants were unwilling to even embark upon the project unless it was on the terms they desired.

It is not reasonable to then blame TREC for properly doing its job, just because the outcome was unpalatable to the research applicants.

2.26 Avenues available for review were not pursued by the research applicants.

3.0 Research versus audit

3.1 At all times TREC viewed this application as being one for ethical approval for **research**, not **audit**.

3.1.1 The application was submitted under cover of a letter seeking for “ethical approval of a research project”.

3.1.2 It was presented on a form headed “National Application form for Ethical Approval of a Research Project”.

3.1.3 Had it been an “audit”, ethical approval is not required. Nevertheless, ethical approval was sought by the applicants.

3.1.4 The research was more than just “inhouse” audit and would involve approaches to personal medical records

through appropriate medical personnel.

- 3.2 It is submitted that the line between research and audit can be a fine one. In this case, the applicants apparently felt it prudent to seek ethical approval.
- 3.3 That they were unhappy with the outcome of such application for ethical approval is, it is submitted, unfortunate, but the research was still open to them.

4.0 TREC

- 4.1 TREC is composed in terms of paragraph 2.2 of the National Standard.
- 4.2 It operates by consensus (see National Standard). This safeguard avoids any opportunity for improper influence by one or more members.
- 4.3 It has been suggested by some that a member with legal knowledge may be essential.

It is submitted that this is not so. More importantly, TREC has recourse to legal (and indeed other advice) as necessary.

- 4.4 TREC as an REC operates by recognition of principles contained in/expounded by (inter alia) the Health Information Privacy Code 1994, the National Standard, the Treaty of Waitangi, Code of Health and Disability Services Consumers' Rights, the Council for International Organisations of Medical Science, International Ethical Guidelines for Bio-Medical Research involving Human Subjects and for Epidemiological Studies and the Helsinki Declaration of

1964.

5.0 April application c.f. Request to Inquiry to exercise powers under Commissions of Inquiry Act

- 5.1 The Committee had been requested to exercise powers under Section 4C of the Commissions of Inquiry Act 1908.
- 5.2 This request was for a direction that various documents be produced for examination.
- 5.3 As a result of the request, the Committee issued a subpoena duces tecum requiring that certain documents be produced from the Cancer Register and the National Cervical Screening Register.
- 5.4 TREC is concerned to ensure that the decision by the Committee to issue the subpoena duces tecum is not seen as a criticism of, or in substitution for the decision issued by TREC upon the April application by Dr Richardson and others.
- 5.5 In fact, the subpoena duces tecum would advance matters only to the extent that base information would be provided.
- 5.6 The Committee was not asked, nor has it decided, that it would be appropriate to extend permission to inspect medical records without consent of the subject women to the personal medical records held by laboratories and/or smear-takers (e.g. doctor etc.)
- 5.7 To this extent there has been no action taken contrary to the decision of TREC to require consents.

5.8 It is therefore submitted that it would be inappropriate and unreasonable for any adverse inference about TREC's decision to be drawn from the fact that the Committee issued a subpoena duces tecum.

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V L Thorpe

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Date