



Getting tangled in red tape: the challenges of doing clinical research in New Zealand

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Abstract

Regulations and the number of forms that require completion remain a major frustration for researchers attempting to establish a clinical research project. It is essential that clinical research is of the highest standard and abides by ethical principles. However, the duplication of information required and lack of co-ordination between national and local ethics and research committees is a hindrance to conducting clinical research. This publication highlights the pitfalls in our current system with a case study, and suggests changes to the ethical review process that may aid researchers in establishing clinical research.

New Zealand has recently appointed a chief science advisor to the Prime Minister, with an aim to actively promote science and research in order to help stimulate economic growth. However, a fundamental threat to research may impede scientific progress and impact economic growth.

Scientist Dr William Rolleston has spoken out against the “onerous and unnecessary regulations” that stifle research in New Zealand.¹ For new researchers a major frustration in establishing a clinical research project is the number of repetitive forms that require completion.

This over-regulation of clinical research is not a new phenomenon nor is it specific to New Zealand. A number of recent articles have been published bemoaning the overregulation of medical research in England and the United States of America.²⁻⁴

While clinical research needs to be of the highest standard with reasonable checks in place the duplication of information required and lack of co-ordination between services is a hindrance in conducting clinical research. This article will highlight the pitfalls in our current system with a case study.

Case study

In June 2008 funding was successfully obtained for the author (SL) to complete a research project as part of a Fellowship in Developmental Paediatrics. The project was a cross-sectional observational study of body composition in children with Down syndrome.

All children were seen at Starship Children’s Hospital, the paediatric service within the Auckland District Health Board (ADHB). An application for ethical approval from the regional ethics committee (using the national ethics application form) was sent in October 2008 and obtained in November 2008 with minimal changes required to the participant information sheet and consent form.

In addition to the national ethics application form, a number of forms were required in order to use an examination and interview room in the hospital. In order to apply to use a room, the project needed to be registered with the ADHB Research Office. The application form for this registration (ADHB Research Project Registration Form) required duplicate information to that in the National Ethics Application Form.

Once the project was registered with the hospital research office, a further form was required to grant use of a room for research purposes (Children's Research Centre Application Form). However, prior to gaining approval to use a room, the project required approval from the hospital Māori Research Review Committee (MRRC).

In order to identify children for the study, a search of the hospital laboratory database of abnormal karyotypes was required. Two separate forms were required to use this database. A number of minor changes were requested from the ADHB research office. Full consent from ADHB was gained in December 2008.

Table 1. Application process for research approval

Form	Approval process	Number of pages
1	Starship Foundation Research Fellowship Application Form	4
2	National Ethics Application: Main form Unable to give informed consent form Patient information sheet Consent form	17 2 4 1
3	NRL Application Form to get ratification for using DXA	1
4	Locality Assessment for ADHB	3
5	Locality Assessment for University of Auckland	3
6	Application Form for Approval of a Research Project at ADHB	5
7	Children's Research Centre Application Form	2
8	ADHB Māori Review Committee Approval	(Send forms 1–3, 5, 6)
9	Request Form for Access to Hospital Laboratory Database (LabPlus)	1
10	Acceptance of Services for Data Retrieval Provided by LabPlus	1
11	Locality Assessment for CMDHB	3
12	CMDHB Research Application	2
13	CMDHB Māori Research Review Committee Application Form	3
14	Locality Assessment for WDHB	3
15	WDHB Māori Research Review Committee Approval Form	(Send forms 1, 2, and ADHB approval)
16	WDHB Knowledge Centre Approval of Research Application Form	Online application

Abbreviations: ADHB – Auckland District Health Board; CMDHB – Counties Manukau District Health Board; DXA – dual energy X-ray absorbiometry; NRL – National Radiation Laboratory; WDHB – Waitemata District Health Board.

The study required enrolment of children living in areas of Auckland outside of the ADHB area, although all children were seen only at Starship Children's Hospital. Locality assessment forms were completed for the other two district health boards in Auckland, Counties Manukau District Health Board (CMDHB) and Waitemata District Health Board (WDHB). This required several forms including CMDHB Research Application, CMDHB MRRC Application Form, CMDHB Budget Form,

Knowledge Centre Approval of Research Application Form and WDHB MRRC Approval Form.

As the author was not an employee of CMDHB or WDHB, a credentialing form needed to be completed for both sites, even though all that the study required was to enrol children living in the CMDHB and WDHB areas. At each stage each research committee required slightly different modifications to either the participant information sheet or the consent form.

Final ethical approval to enrol children living in the wider Auckland area was obtained in March 2009 5 months after the initial application was made. The application process required 16 separate steps, with considerable duplication of information required on the forms (Table 1).

History of health and disability ethics in New Zealand

The Medical Research Council was established in 1950.⁵ Applications to conduct research required applicants to sign an ethical agreement in order to obtain funding. Over time ethical standards were developed and published and a committee on ethics in research was established in 1984. The Auckland hospital ethics committee was established in 1971 with considerable debate at its inception as to the necessity of ethical surveillance.⁶

A turning point in New Zealand's history of research ethics was the 1987 Cartwright Inquiry of the treatment of cervical cancer at National Women's Hospital. Following this ethical review was seen as not only important but a necessity and ethical standards "must be applied rigorously to research and treatment protocols on behalf of patients".⁵

The Health Research Council was established with an ethics committee under the Health Research Council Act of 1990. Regional health authorities were required to establish ethics committees or to contract ethics committees to provide ethical review by 1993. Further health reforms lead to minor changes in the inter-relationship between the ethics committees and the HRC.

The New Zealand Public Health and Disability Act of 2000 established a National Ethics Committee. Currently New Zealand has seven Health and Disability Ethics Committees of which six are regional. Applications to conduct research are submitted either to a regional committee or to the multiregional committee as appropriate. District Health Boards (DHBs) retain Research Review Committees to advise the clinical board of local research initiatives and contracts.

Principles of ethical review

The primary role of ethical review of research in New Zealand is two-fold: firstly to prevent unacceptable risk of harm to participants, and secondly to ensure that all participants are aware of what their participation will involve and have given informed consent.⁷ The underlying principles of ethical review are respect of persons, informed consent, privacy and confidentiality, validity of research proposal, minimisation of harm, justice, and social and cultural responsibility.

Respect of persons encompasses the recognition of the beliefs, autonomy and privacy of individuals while protecting those who have reduced competence. Informed

consent requires adequate information to be given which is understandable to the participants and that consent is voluntary without coercion.

Privacy and confidentiality are essential for the protection and promotion of human dignity and wellbeing. It is important that research is methodologically valid to ensure it is worthwhile and participants are not unduly exposed to risks entailed in research.

The ethical principle of justice requires the burdens and benefits of research to be fairly distributed over a population without discrimination. In addition ethical review in New Zealand upholds respect for the social and cultural sensitivity of the study population. The National Ethics Committee form encompasses all of these principles.

Improving systems

Having multiple forms to address the same principles has given rise to considerable red tape in the process of gaining approval to conduct clinical research. This duplication threatens to overwhelm researchers with paper work, and may delay the final approval by several months as described in our case study.

Several improvements could be made in our current ethical approval process with no threat to appropriate clinical standards or the principles governing ethical review.

Firstly, the amount of duplication required could be mitigated by each DHB research committee accepting the national ethics application form instead of requiring duplication of all the same information in a DHB-specific form. If additional information is required, then only this should be included in a DHB-specific form.

Similarly, a national Māori Research Review Committee form should be developed which would be accepted in all sites. Conducting research in Auckland is a unique experience within New Zealand as patients are divided into three DHB areas. However, for the purposes of research Auckland should be treated as one area.

In addition, a more common sense approach needs to be taken when looking at ethical consent for new research. A cross-sectional observational study in which participants simply undergo anthropometric measurements is very different from a study in which participants are exposed to a novel medication or intervention.

Our current system makes no allowance for the potential harm to participants and the same numbers of forms are required for both. If, in New Zealand, we are serious about stimulating clinical research, then the current impediments of over-regulation must be addressed.

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