Ethics and Research

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https://www.auckland.ac.nz/en/about/research/re-ethics.html

What is Ethics?

- Science of morals

- Norms for conduct that distinguish between acceptable and unacceptable behaviour

- Judgement of what is right and wrong
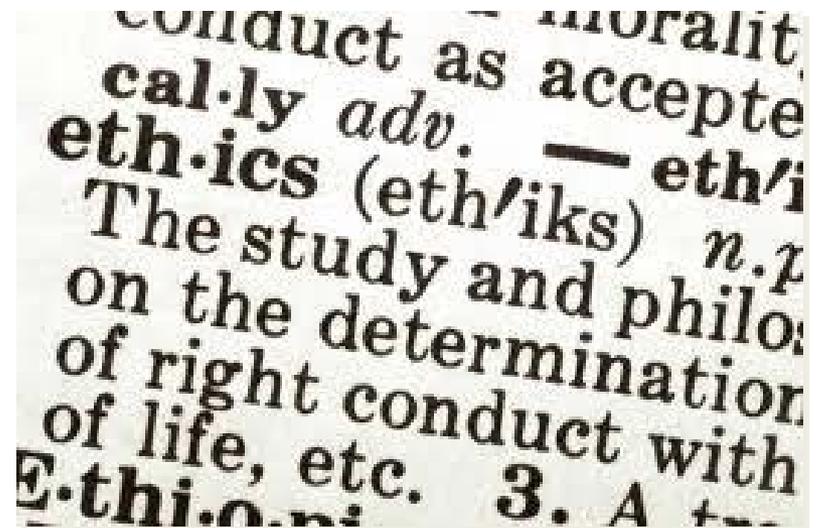
Why? What could possibly go wrong?

Nuremburg Code (in brief)

- **Voluntary participation is essential.**
- **Researchers must fully inform participants.**
- Risks are minimized.
- Researchers must protect participants against even remote harm.
- Participants free to withdraw from the study at any time.
- Research is conducted by qualified people.
- The study must stop if things are going badly (causing harm).
- **Society should benefit from study findings (not frivolous).**
- Research on humans, should be based on previous animal or other previous work (where applicable).
- A research study should never begin if there is a reason to believe that death or injury may result.

Of course not here in NZ

METRO

An
UNFORTUNATE
EXPERIMENT
at
National
Women's

by SANDRA CONEY
and
PHILLIDA BUNKLE
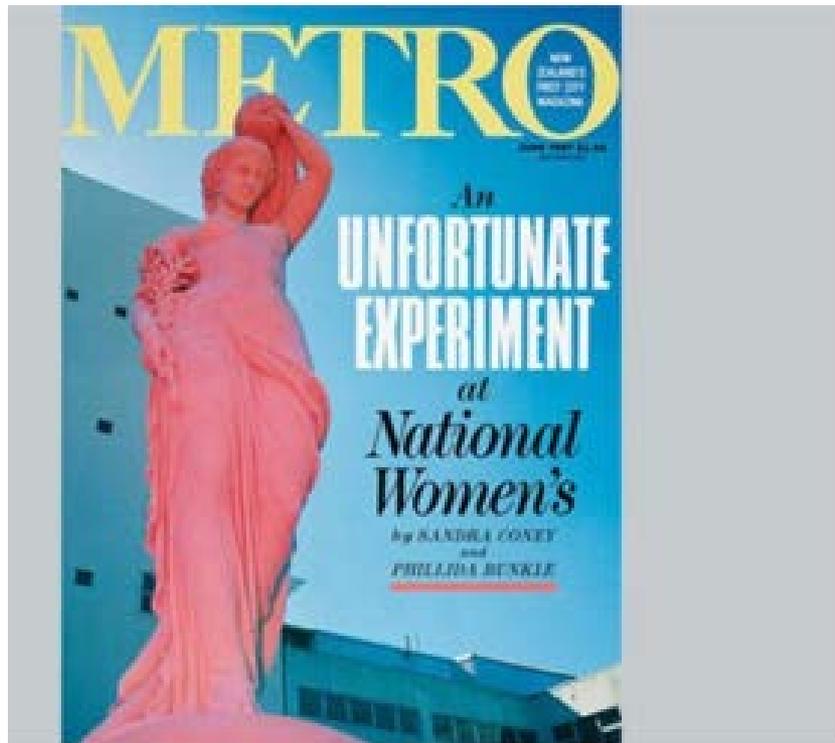
Read the original Metro article, published in June 1987, that exposed the practices of doctors at New Zealand's leading women's hospital. The article by Sandra Coney and Phillida Bunkle led to a Commission of Inquiry, headed by Dame Silvia Cartwright, that helped strengthen patients' rights and saw the establishment of a national cervical screening programme.

- **Cartwright Inquiry - Cartwright Report 1988**

Why do you need ethics approval?

- **Education Act 1989**
  Research and teaching should be maintained to the highest ethical standard

- **Guidelines for the Conduct of Research**
  Integrity of research programmes cannot be placed in doubt

- **Funding**
  Funding for approved research will not be released

- **Publication**
  Journals will not publish research without ethics approval

Role and function of UAHPEC

- Ensure research complies with the highest ethical standards

- Protect the interests of participants, researcher and the UOA

- Promote awareness of ethical issues relating to research with human participants

- Provide advice and assistance in regard to ethical principles

- Provide an avenue for handling complaints or queries

- Receive and record information concerning adverse events

University of Auckland: four key principles of ethical research

- **Autonomy**
  - Respect for persons capacity for self-determination (informed and voluntary consent)

- **Beneficence**
  - acting in the public good and promoting the good of other people (assessment of risks and benefits)

- **Non-maleficence**
  - consider the harm that the research project might cause (minimising harm)

- **Justice**
  - treating others equitably and distributing burdens and benefits fairly (selection of participants)

What does the committee look for in the application?

There are a number of Ethical Issues that the committee will look for.

- These should be summarised in question L3 – "Identify the ethical issues arising from this project and explain how they can be resolved."

- Ensure that you put a full answer which identifies the relevant issues with your project as well as the steps you will take to find a resolution.

What does the committee look for in the application?

Recruitment

- Informed and voluntary consent
  Participants should be given all of the relevant information and the freedom to decide if they would like to participate without coercion.

Important things to consider:

- How are the participants chosen?
- What are the participants asked to do?
- Are participants given sufficient time and support to make their decisions?

What does the committee look for in the application?

Respect for privacy and confidentiality

It is important that you handle the data you collect confidentially and that participants understand how you will do this.

Important things to consider:

- Who will know about their participation?
- How will results of the research be disseminated?
- Will you be publishing your work and if so will participants be identified.

It is important to understand the difference between confidentiality and anonymity – a study is only anonymous if you do not know the identities of your participants.

What does the committee look for in the application?

Participants' rights to withdraw

It is important that participants know and understand that they have the right to withdraw from the study at any time.
This includes:

- Withdrawing their participation completely
- Withdrawing their data or parts of their data

Participants should always feel free of any pressure to continue participation.

It is ok to use time frames and deadlines to ensure that you have time to complete your work. Your participants must be informed of the exact time they have to withdraw.

What does the committee look for in the application?

The researcher and the research

Important considerations:

Research adequacy / methodological validity

Is the researcher qualified to do it?

Have the participants adequate information to be able to contact the researcher or the University after participation?

Spelling, grammar and general formatting

What is a Conflict of Interest

The Board of **Ethics** defines a "**conflict of interest**" as a situation in which personal and/or financial considerations have the potential to influence or compromise professional judgment in clinical service, **research**, consultation, instruction, administration, or any other professional activity.

Examples of conflicts of interest

- A teacher who plans to carry out research in their own school.

- Research team members who have a relationship/role or position within the organisation/workplace they are planning to recruit from.

- An Academic staff member planning to recruit their own students as participants

Conflict of interest – research in own setting

Undertaking research in your own workplace can present conflicts of interest from the distinct roles and responsibilities of teacher and researcher. It can also raise issues of power relationships and perceptions of pressure or coercion on participants.

Check Sections 6.4.3 and 13.11 in the Applicants' Reference Manual and ensure that your study design complies with the guidelines. If you still wish to carry out the research in your own school check Section 13.10 Practitioner applied research, in the Applicants' Reference manual.

Conflict of interest

Research in own School

C7 – Is there any special relationship between participants and researchers?
Provide justification (other than convenience) of why this research should be done in a school where the researcher is a teacher. Alternatively, consider completing the research in another school.
Or
Refer to Section 13.10 – 'Practitioner applied research' in the Applicants' Reference Manual 2017. The questions from the manual, and your response, should be outlined within Section B:5 of the Protocol application form

Application process

- Complete the online application form: Access through the Human Ethics website or https://researchmanagement.auckland.ac.nz

- The Word form and the online form have identical questions, but differ in layout

- The Word form can be used for drafting the content of the application

- All questions must be answered. The system will not allow you to submit if answers are missing.

Submission and Pre-screening

- The PI is the only person to submit the form (if you are a student your supervisor will be the PI)

- After submission the application has to be signed off by your department <u>before</u> it reaches the research office.

- All applications are pre-screened by the Ethics team before they are placed on the agenda.

- The pre-screener may ask for modifications to be made and then the application needs to be resubmitted.

- It is recommended that you make the pre-screening changes as the committee will often ask for these to be done.

Process
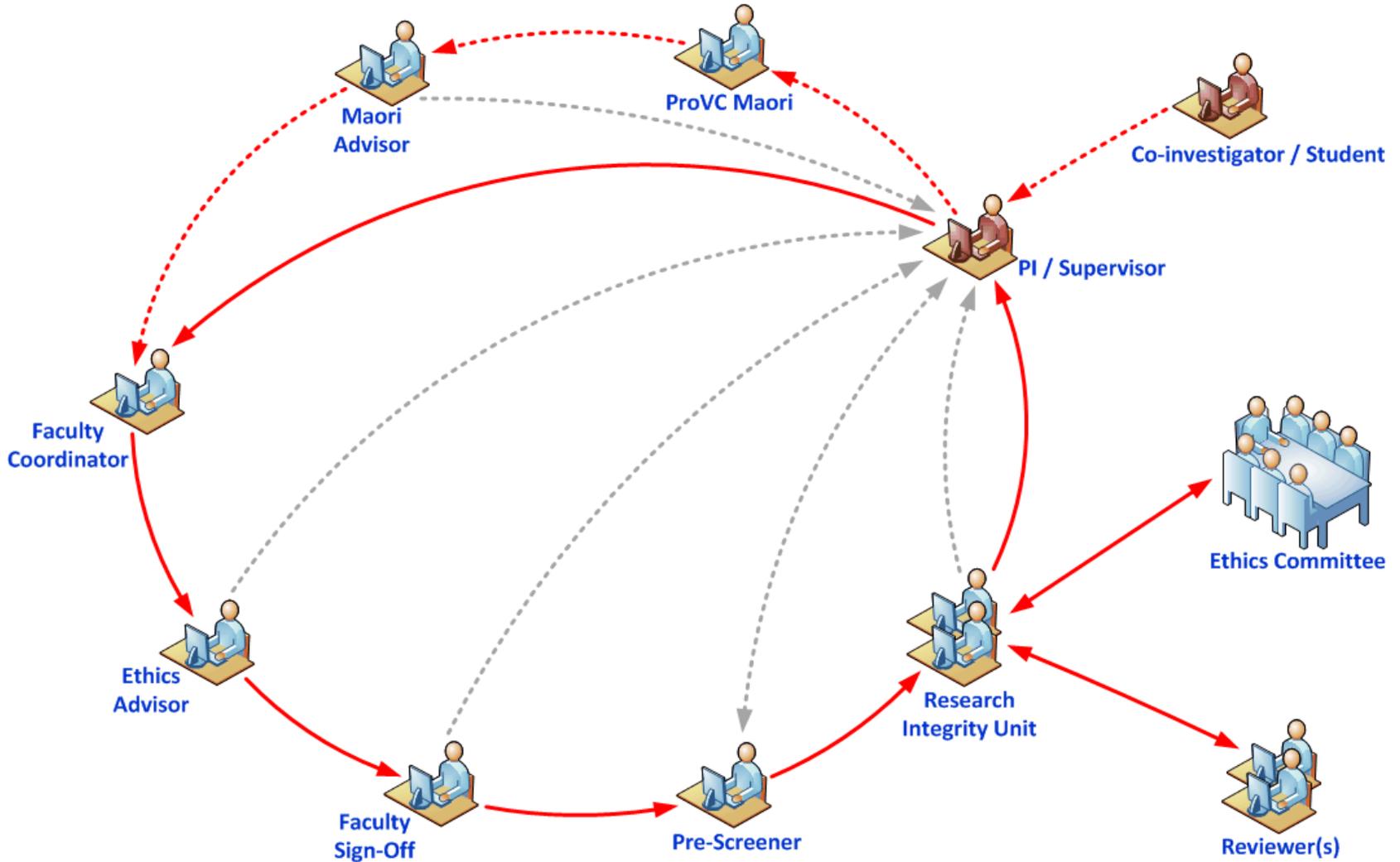
Levels of review

- Low Risk Review

- Full Review

Low Risk Review

- An application where there is no risk of physical or psychological harm (e.g. research that encourages suicidal thoughts, depression, feelings of helplessness or inadequacy) or one where there is no risk of exploitation or potential for prejudice

- All answers are "NO" in the checklist

- The Committee reserves the right to decide whether an application is low risk. If not deemed low risk, it is automatically put into the next Agenda for a full review

- The average time from date of submission to receiving an outcome is around 3 weeks

- NOTE: There is no specific closing date for low risk applications

Full Review

- At least one answer is "YES" in the checklist

- Time between submission and pre-screening is one week.

- Application is placed on the Agenda and sent to Committee for reviewing.

- Time required for Committee review is one week.

- Outcome decided at a UAHPEC meeting and a letter is sent to the applicant within 3 working days of the meeting.

Outcomes

Low Risk
Approved/Approved with Comment
Conditional Approval
Requires Full Review

Full Review
Approved/ Approved with Comment
Conditional Approval
Pending Resubmission
Empowered
Declined

Sources of information for preparation

- UAHPEC website:

  http://www.auckland.ac.nz/uoa/home/about/research/

  re-ethics

- Guiding Principles

- Applicants' Reference Manual

- User Guides

- Application form help boxes

- AskIT

Required Documents

- Application Form

- Participant Information Sheet (PIS) on letterhead

- Consent Form (CF) on letterhead

- Questionnaire

- Interview questions / focus group questions

- Advertisement, Email, Invitations, Posters (with statement of approval)

- Confidentiality agreement on letterhead

- Translations (after approval is granted)

Tips for PIS and CF

- Focus group: when more than 1 person is being interviewed at same time.
- In focus groups, participants cannot withdraw data after it is collected, but they can withdraw their presence or not answer questions.

- A questionnaire or survey is anonymous if you do not know who has participated.
- In an anonymous questionnaire, withdrawal of data after it has been collected is not possible.
- A Consent Form (CF) is not required for an anonymous survey or questionnaire.

- Add a participation or non-participation statement wherever applicable Refer to section 6.4.3 of the Manual

Tips for InfoEd

- Use either Firefox or Chrome (never use IE)!!!

- InfoEd UoA network, or on a Virtual Private Network (VPN) at home.

- PI/Supervisor can view application from Show/List.

- All other personnel must search for an application by protocol number.

- Technical errors - resolve by changing browsers, clear cookies and relogging onto the network

- "Edit Mode" in green text in the top right-hand corner is not a button; it is informational

- The online application can hide or show questions based on previous responses.

Starting your application in the online system (InfoEd)

- Please log on to your computers now

- We will now show you how to create an online application

- Remember to make a note of your protocol number

- NB: Please use Chrome or Firefox, but NOT Internet Explorer

SECTION A: PERSONNEL

*Are you a Student?
Yes ☐ No ☐

Click any ?☐ icon for Help with the questions.

University Personnel

This section is for all University staff, PhD and Masters students

Add yourself if you are a student by clicking the ✚ icon. Also add co-investigators and/or ethic advisors one at a time.

Note: Ensure you select their correct role each time you add personnel.
Ensure you click the box to the left of the PI name if it is not ticked.

Non-University Personnel

Add personnel that are **not** associated with the University of Auckland, or Honours/Fourth Year Students in the next section:

Add any other research team members here (non-University of Auckland researchers and Honours/Fourth year students)	➕

Full Name (and ID)	Institution / Department	Project Role	Email address	
				🗑

If you are a Student, make sure you select "Research" for the type of application.

* Is this a Research Project or Coursework Application?
Research ▼

Attachments

ATTACHMENTS: Add attachments one at a time by clicking the ⊕ icon for each attachment, type a

document title in the textbox, then click the ⬆ icon to upload. Please ensure files are .doc, .docx, .xls, .xlsx, .pdf, .gif or .jpg.
Note: File names should not contain any special characters as it may prevent completing the form (e.g., #, &, -).

ATTACHMENTS   ⊕

Files of the following formats can be uploaded: .doc, .docx, .xls, .xlsx, .pdf, .gif and .jpg

Document title	Upload
PIS Form	👓 ⬆ ⬆ 🗑

- To view the form, click on the 'spectacle' icon

- To replace a file with an updated version, click on the blue arrow.

- To remove a file from the application, click on the Rubbish bin icon.

Completion

When you have completed the form click the [Complete ▢] box at the top right hand corner of the page.
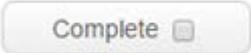
⚠️ *Note: If a warning message appears you have not completed all the mandatory questions. Click OK.*

Click the link in the **Mandatory Questions** window to navigate and answer the incomplete question(s).

Mandatory Questions		Form History	Save	🔴	Complete ▢
Page Number	Question				
1	Please add the degree you are studying towards.				
5	B:2 Aims/objectives of the project.				
5	B:3 Summary of the project.				
5	B:4 Project duration (in months).				
5	B:5 Describe the study design.				
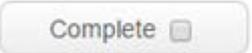
Click [Complete ▢] This will close the form and take you back to your protocol screen.

Submission

If you are the **PI** click the "Submit" button to submit your application. If you are the student researcher, please ask your supervisor to submit the application.

Submission Process

The information supplied is, to the best of my knowledge and belief, accurate. I have read the current **Guiding Principles**and **Applicant's Manual**. I clearly understand the obligations and the rights of the participants, particularly in regard to obtaining freely given informed consent.

Close

Accepted   Declined

Enter your username and password then click **Continue**:

*Note: If you are a student, ethic advisor or co-investigator, you will not be able to submit the application yourself. Notify your PI of the Protocol number at the top of the eForm and request them to submit. Refer to the full User Guide for more information.*

Only if necessary, add any additional people to the approval route by clicking **Add New Person to Review Path** or the ⊞ icon. The Routing Progress will be updated with the application submission date as confirmation. **In most cases, no additional names need to be added.**

Click the [Submit] button.

Routing Progress

Routing Progress information that shows where the application is up to in the sign-off process, can be accessed in the protocol by clicking on "Show Route":

Home > Submissions > Initial Application > Submission

Submission	**Initial Application**						Created on: 29-Oct-2015 Status: Under Signoff
Reviews	**Document/Form**	**Type**	**Status**				Show Route (Route History)
Communications	HE Application Form - v4.1	Human Ethics Application Form	Completed	PDF	(Mandatory Form)		
Personnel (1)							
Departments (1)							
Locations							
Attachments (1)							

Active Routing Progress
Open Full 📂

015407 - Dr Elizabeth S Visser "Test application"

Route Name	Route Type	Step Number/Name	Who	Notified	Decision	Insert Remove
Application Sign-Off	Final Review	Step 2 - First Nominated Sign-Off	Secretary UAHPEC	29-Oct-2015 3:55:26 PM		📇
Application Sign-Off	Final Review	Step 4 - Pre-screen Review	Secretary UAHPEC			📇

No comments have been recorded yet

And finally…

Click the "Done" link to exit the protocol at the top left of the window. (**Do not use** the [x] to close InfoEd because that locks the protocol for 1 hour and prevents anyone else from accessing it. Please call the Ethics Administrators if this happens because they can unlock the protocol to give access again).
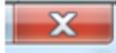
How can conflicts of interest be identified?

Considerations should be made of the research team members' professional and personal interests regarding the site or organisation where the research is planned as well as any relationships with potential participants.

The research team should also be aware if any external funding has been received for the research.

Consider what the research team can do to alleviate any perception or potential imbalances of power between the researchers and participants.

Thank you

Questions?