THE UNIVERSITY OF AUCKLAND
NEW ZEALAND
Te Whare Wānanga o Tāmaki Makaurau

UNIVERSITY OF AUCKLAND
HUMAN PARTICIPANTS ETHICS COMMITTEE
(UAHPEC)

APPLICANT'S MANUAL

(updated 10 October, 2011)

NOTE: This is a living document and will be updated periodically.

INTRODUCTION

This manual is designed to assist those making applications to the University of Auckland Human Participants Ethics Committee (UAHPEC). In addition to outlining the mandatory items that must be included in each application, this manual also represents the distilled wisdom of ethical decision making by the University of Auckland Human Participants Ethics Committee. The Committee generally assesses over 600 applications each year, so it is only natural it will reach consensus positions based on precedents.

It is hoped that this manual will provide a valuable reference for those designing research and highlight areas of research design to which particular attention should be paid in order research of high integrity can be maintained.

TABLE OF CONTENTS

Section 1: Applications

Section 2: Application Documentation

Section 3: Essential aspects of research to be considered

Section 4: Guidelines Relating to Particular Types of Research

Section 5: Other Information

Section 1: Applications

All applications from students (including Doctoral, Masters, Honours) are to be submitted by the appropriate supervisor, who will be named as the Principal Investigator (PI).

Incomplete, poorly constructed applications will be returned to the PI. The UAHPEC will not review the application until an adequate, revised application is submitted.

Please be aware that all correspond3ence regarding individual ethics applications will be addressed to the PI, and it will be the responsibility of the PI to ensure that the relevant correspondence is passed on to any students who are involved in an ethics application.

For assistance with completing the ethics application, faculties and high user departments have designated **Ethics Advisors** who are available to assist. Please check with the faculties / departments / or our webpage http://www.auckland.ac.nz/University of Auckland/re-uahpec for the names of the Ethics Advisors. The Research Integrity Unit (Research Office) can also be contacted for advice and guidance.

If a project has multiple phases, it is preferable to submit a single application stating that there are different phases. These can be approved consecutively, as the researcher moves through the research. (For example, UAHPEC will approve Phase 3 only after Phases 1 and 2). This way UAHPEC has all the information about the whole project and is better able to understand the sub-sections.

1a) Levels of Review

There are two routes to ethical review at the University. The determination of the route depends on the requirement that potential participants must be adequately informed so that they can make a voluntary decision to participate. The choice of route will include evaluation of risks of participation and the impediments to clear understanding by the participants. Together, these will determine the appropriate level of ethical review.

The two levels of review are:

(i) Low Risk Review

A low risk research project is one where there is no risk of physical harm, psychological harm, exploitation or other potential adverse effect. Participants must give full informed consent and must have the right to choose anonymity in all reporting.

Upon receipt of the application, RIU will check whether the application meets the criteria of low risk. If it does meet the criteria, it will be considered immediately. If the application is not deemed low risk after consideration, it will be automatically put into the next agenda for Full Review.

(ii) Full Review

Any research involving human participants other than the low risk research mentioned above.

1b) Types of Application Form

(i) Research Project Application Form

To be used for all research, including Masters and Doctoral theses and staff research projects.

(ii) Coursework Application Form

To be used by the course coordinator where the research is part of student coursework. To be used for class projects that either focus on a common set of research questions using procedures that do not vary from student to student (for example, laboratories), or where students are to choose their own research questions and procedures that do not vary significantly. The completion of a single application form covering multiple research projects or laboratories is acceptable, as long as the application is for no more than one course and a description is given of all projects. All applications should be made in the name of the staff member coordinating that course. Where there is a Course Book/Laboratory Manual it may be appended to a Coursework Application, but in any case the nature of the research activities should be clearly described.

Where the course coordinator requires the students to choose their own questions and procedures, the course coordinator may choose to let each student complete a separate research application form including appropriate Participant Information Sheet (PIS) and Consent Form (CF). The course coordinator may submit the whole as a single (omnibus) coursework application.

1c) Deadline for submitting the application

Refer to the **Agenda closing dates** on our webpage http://www.auckland.ac.nz/University_of_Auckland/re-uahpec for deadline in submitting application. The Agenda closes around two weeks prior to the meeting to allow for processing and to allow Committee members to conduct preliminary reviews of the applications prior to the meeting. Applications received after the agenda closing date will be included in the next agenda.

1d) Expedited Review

Only in exceptional circumstances will UAHPEC consider a request for Expedited Review, that is, for a review outside normal committee meeting dates. Upon written request from the Principal Investigator, the Chair of UAHPEC will consider whether such a review can be undertaken.

1e) Approval

Approval is normally given for three years. At the end of this time a researcher may apply for an extension for another three years.

At the end of six years, a new application must be submitted. A researcher requiring an extension of approval should write to UAHPEC in good time requesting the extension. If there are no substantial changes to the documentation provided at the time of the original approval, this should be stated in the letter to UAHPEC requesting the extension. If there are changes, even minor ones, the resubmitted document should clearly indicate the nature of the changes.

1f) Retrospective approval

UAHPEC does **not** grant retrospective approval.

1g) Outcomes

After each meeting the Research Integrity Unit usually sends letters of outcome from Full Review via email to the PI in around five working days.

The (anticipated) turnaround time for each Low Risk application is around 2 weeks.

Types of outcomes:

(i) Approved

This means that ethics approval is given for three years. The researcher can proceed with the study.

(ii) Approved with comment

UAHPEC has given ethics approval for three years with some comments that do not necessarily require changes. The researcher can proceed with the study, taking into account these comments.

(iii) Conditional approval

Conditional approval means that the researcher has to make the required amendments or provide further documentation as per the letter of outcome. The researcher must first provide the requested revisions/modifications/clarifications and wait for confirmation from the Research Integrity Unit before commencing the research.

Until the PI has submitted the amendments and received an approval letter, the application does not have ethics approval.

(iv) Pending approval

UAHPEC has not granted approval yet. The researcher has to provide the required changes outlined in the letter of outcome back to Research Integrity Unit before the next closing date. The changes have to be highlighted in the text of the application, along with a covering memo addressing each concern mentioned in the letter of outcome. The changes will be put on the next agenda for full review by the UAHPEC.

(v) Empowered

The researcher has to contact the nominated Committee Member and arrange a meeting/exchange of correspondence with them to clarify the concerns of UAHPEC. These details will appear in the letter of outcome. After this discussion the researcher makes whatever changes are required to the documentation and submits this to the Committee Member. When he/she is satisfied with the changes, the researcher then submits the revisions to the Research Integrity Unit, for formal approval by UAHPEC, and may then proceed with the research.

Until this has been done the researcher does not have approval. The researcher will receive the letter of approval after the next Committee meeting.

(vi) Declined

No approval is granted. The project cannot proceed.

1h) Changes to the research

If changes need to be made during the course of the research, write to the UAHPEC stating the reference number, the need for the change, and what the change entails, along with any revised Participant Information Sheet and Consent Forms and any other relevant documents that have been changed. If the change is substantial, a new application may be required. The request for changes will be put on the next agenda for the Committee to consider.

1i) Completion of research

Advise UAHPEC in writing that the research is complete and provide a brief report on the project.

Section 2: Application Documentation

2a) Introduction/Aims/Objectives

The Introduction/Aims/Objectives serves two purposes:

- To show UAHPEC that the project has been fully considered both for its efficacy as a project and its ethical treatment of participants,
- To demonstrate that the request to potential participants provides them with adequate information to make an informed decision as to whether to participate or not.

2b) Types of Documents

All documentation to be received by participants (or other third parties approached by the researcher) must be submitted in final format on University of Auckland Departmental letterhead.

Do not put headers such as Appendix A, B, etc on the accompanying documents such as the Participant Information Sheet (PIS), Consent Form (CF) and advertisement, as participants are not receiving an appendix to the application. These documents should be separated from the application and must carry UAHPEC approval wording (see 2c xv) at the end.

i. The UAHPEC Application Form

The UAHPEC Application Form asks the applicant to clearly and succinctly outline the purpose, method and supporting information for the project. Use language that is free from jargon and comprehensible to lay people. For applicants for whom English is not their mother tongue, UAHPEC recommends that the applicant has the documents read by someone who can assist with grammar, syntax and spelling.

ii. The Participant Information Sheet (PIS)

The Participant Information Sheet is a critical document in which the researcher addresses the participant. It is the piece of paper that you, the researcher provide to participants, and that they retain for their information.

It provides the information that enables the potential participant to make an informed decision as to whether or not to volunteer to participate.

This document is to be kept by the participant for future reference.

(See Section 2c for the checklist for developing a PIS and Section 5a for the sample)

iii. The Consent Form (CF)

The Consent Form is also a critical document, since it represents the participant's explicit declaration that he or she understands all the relevant conditions of participation and voluntarily agrees to take part. It is an abbreviated statement in which the participants consent to the key points that you, the researcher, have told them in the Participant Information Sheet.

This document, once signed by the participant, has to be kept by the researcher on University of Auckland premises securely by the PI.

Those persons whose consent is a prerequisite for a given individual's participation should also sign a CF.

Recorded oral consent may be acceptable, but only under specific circumstances.

(See section 2d for the checklist for developing a CF and section 5b for the sample)

iv. Questionnaires

A Questionnaire is a specifically designed set of questions that a participant completes independently and returns to the researcher. It can be anonymous or may contain identifiers.

An **Anonymous Questionnaire** has no coding or identifying information from which the researcher, or anyone else, could identify who had completed the questionnaire. The Committee believes that the act of completing an anonymous questionnaire implies consent. However if you need to access an organisation/school in order to circulate an anonymous questionnaire you would need to provide a Participant Information Sheet and a Consent Form for the Chief Executive Officer/Principal seeking permission to access that organisation/school.

Questionnaires are to be submitted in the format in which they will be presented to the participants, or in the case of an internet version, as closely as possible to the final format.

If the questionnaire is to be distributed on the internet and encryption is used, this should be described in the Information Sheet. If encryption is not used, indicate in the Information Sheet that neither confidentiality nor anonymity can be guaranteed.

If the researcher wishes to use a database obtained from an organisation (the organisation will need to consent to the use of the database), the Committee requires that the researcher arranges for the mail-out, or first contact, to be conducted by the organisation so that the researcher does not have access to individuals' personal details. The instructions supplied with the questionnaire can then direct the participants to return the completed questionnaire to the researcher.

Questionnaires that are not part of teaching must be completed outside of class time. One solution is to distribute the questionnaire at the end of the class and provide a box somewhere for the completed questionnaires to be returned.

If the researcher wishes to send out a reminder for the survey (not anonymous), a statement to the effect that a reminder, or second letter (PIS) may be sent out to everyone again seeking responses from those who have not yet responded, should be included in wording of the original Participant Information Sheet. The researcher could state that those who have responded should ignore this reminder.

v. List of Interview Questions

An interview is where the researcher sits down with the participants and asks a set of questions, which may or may not be open ended. An interview may be audio or video recorded.

A list of interview questions is to be submitted in the format in which it will be used when data is to be gathered in structured or semi-structured interviews, or in focus groups.

vi. The Advertisement, Notice or Media Release for recruiting participants (Please also see 3a)

This is to be submitted in the format in which it will be presented or displayed to prospective participants.

This document does not need to be on letterhead, but it should include the approval wording (see Section 2c xv). Do not state that "The University of Auckland is conducting …", but ensure that it is the researcher who is nominated as conducting the research.

vii. Confidentiality Agreements (Please see Section 5c for the sample)

If a third party is involved in the research process UAHPEC would expect to see a Confidentiality Agreement.

Where Confidentiality Agreements are necessary, they should be provided for Transcribers, Translators or Data entry persons.

The researcher should devise the Confidentiality Agreement to suit the nature of the research. It should be kept simple and a statement about it included in the Participant Information Sheet.

viii. Translations

Where any document is to be distributed to participants it is to be provided for those participants in the language that will provide the most readily accessible presentation of adequate information. The UAHPEC requires English versions of documents to be submitted with an application. The UAHPEC does not require translations to be submitted with the application, but does expect to receive them after approval of the application and before they are used.

The researcher is reminded that the accuracy of the translation is critical to the ethics of the research.

ix. Other documents

These should be included where appropriate. Examples might be, correspondence from co-operating parties such as commercial or Māori organisations. Where documents are to be transferred to a public repository then special documentation may be required.

2c) Checklist for the Participant Information Sheet

(Please refer to section 5a for the sample)

The Participant Information Sheet (PIS) is to be provided on University of Auckland Departmental letterhead with complete postal address and telephone contacts. It is not sufficient to use the shell letterhead without the full contacts for the Department. Electronically generated logos of letterhead are acceptable. These are available from the Department.

The Participant Information Sheet is to be retained by the participant, and therefore should be presented separately from questionnaires, consent forms or other material that will be returned to the researcher.

Further details about the matters raised with regard to preparation of the Participant Information Sheet are available in Section 3 and the reader is advised to consult this Section.

The Participant Information Sheet must meet the following requirements.

i. **The Document**

- Start with the project title.
- Address the document to the participant by category, for example, "Participant Information Sheet (Manager)".
- Include the name of the researcher and appropriate identifying information, whether a staff member or a student. If a student, state the name of the degree and the department or faculty in which the researcher is enrolled.
- Invite potential participants to be involved in the research and explain why and how they have been selected.
- State the rationale for the research.
- If the research involves a group (such as students in a class), members of which may decline to participate, indicate what these non-participants will do while the research is being conducted and indicate how the anonymity of non-participants will be preserved.

ii. **Data Retention** (Please also see Section 3n)

- Explain how, where, how long and in what format data will be stored and subsequently destroyed including tapes, disks, videos, computer files and paper records.
- State if data is to be transferred to a public repository; normally a special document is required. The conditions under which this is done must be acceptable to both the repository and the participant, and a copy of these provided to UAHPEC.

iii. **Language**

- Where consent is required from persons whose language preference is other than English, the documents must comply with that preference. (Please see also 2b viii, 3j and 3p.)

iv. **Participating Organisations (Workplaces, Schools)**

- If the research is to be conducted in any organisation, such as a business, non-government organisation or school, a separate PIS needs to be provided for the Chief Executive Officer, Principal or the owner of the business (i.e. the

effective employer) seeking permission to access the employees as participants.

- The PIS for the Chief Executive Officer, Principal or the owner of the business should clearly seek their permission for access to the organisation's facilities and employees/teachers/staff/students. The PIS to the Chief Executive Officer, Principal or the owner of the business should neither indicate nor suggest that they can give permission on the behalf of the participant to participate, withdraw or be recorded in any way.
- The researcher should state in the PIS(s) to the Chief Executive Officer, Principal or the owner of the business and to the participants what information will be reported back to the Chief Executive Officer, Principal or the owner of the business, when this will occur and how the confidentiality of participants will be protected. Under most circumstances, it would not be appropriate for the Chief Executive Officer, Principal or the owner of the business to have access to information that compromised an employee's/ teacher's/staff's/student's confidentiality. Any proposed exceptions to this provision should be clearly explained in the application form.
- The researcher should explicitly seek from the Chief Executive Officer, Principal or the owner of the business, assurances that participation, or non-participation, will not affect the employment status (in case of students, will not affect the grades) of the participants. Any proposed exceptions to this provision should be clearly explained in the application form.
- Where the research is to be conducted in a school, separate and distinct PIS(s) need to be provided for (a) the Principal and/or (if more appropriate), the Board of Trustees, seeking permission to access the teachers, (b) the teachers for access to the students in class, (c) the parents of participating students (if the students are under 16 years) and (d) the students themselves. Additionally, the researcher must describe how non participating members of the class/group will be managed and whether any information will be obtained about non participants in the course of the research.

v. **Participants under 16 years of Age** (Please also see Section 4d)

- If participants are aged less than 16 years of age, parents, guardians, or carers should first be approached for their consent.
- The assent of the participants aged less than 16 is also required if they are of an age (usually 7 or above) to understand the project and their role in it.
- In some cases children under 16 may be able to consent without parental approval. Researchers must justify this preference. Normally, the researcher will still be expected to inform parents of the research.
- It is important that the PIS and assent form (if required) are written to the reading age of the child.
- The researcher must also consider whether the language describing the research is appropriate for the parent or guardian in their PIS.

vi. **Right to Withdraw from Participation** (Please also see Section 3r)

- Participants have the right to withdraw from participating in the research at any time.
- Participants must also be given the right to withdraw their data from the research up to a specified date or period of time. Obviously this cannot happen with anonymous questionnaires.

vii. **Use of Audio, Electronic or Other Media** (Please also see Section 3d)

- If audio, video, electronic, or other means of recording are involved this should be indicated. If such recording is optional, the PIS should indicate this and should also include a statement to the effect "Even if you agree to being recorded, you may choose to have the recorder turned off at any time".
- If it is intended that a participant's recordings (audio, video, or pictures) can be reviewed by the participant, the researcher should explain the process. If third parties are involved (for example, in transcription, translation, editing), explanations should be given as to how confidentiality of information and participation will be preserved.
- The PIS for third parties, such as Chief Executive Officers, or Board of Trustees should indicate that interviews will be recorded only with the consent of the interviewee. Normally, recorded interviews of this type cannot be shared with third parties, however if this is intended it must be clearly documented for all concerned.
- If the research is web-based, if encryption is used, or if some other method is used to preserve the anonymity of participants this should be described. Indicate that only those aged 16 years or older should participate and provide data.

viii. **Non-anonymous Data**

- If non-anonymous data are shown to people other than the named researchers, (for translation, transcription, or cultural comment), indicate who will view the data, for what purpose, and how the confidentiality of the participant will be preserved.

ix. **Research outside New Zealand**

- If the research is conducted outside New Zealand provide local contact details, as well as those of contacts at the University. It may be appropriate to allow for withdrawal at a local address.
- The researcher should also provide an undertaking, within the application, to abide by any local laws relating to data collection and retention.

x. **Research involving Māori** (Please see also Section 3q)

- The application has to be signed off by the Pro Vice-Chancellor (Māori) or faculty nominee of the Pro Vice-Chancellor (Māori).
- If the research involves participants who are recruited because they are Māori (or the research involves a topic of particular interest to Māori) the Māori researcher should list his or her tribal affiliations. Where relevant, documents should be translated. The completed application must be signed off by the faculty nominee of the Pro Vice-Chancellor (Māori).
- Contacts for advice on protocols can be obtained from the Office of the Pro-Vice Chancellor (Māori), extn. 82525 or from the nominee of the Pro Vice-Chancellor (Māori) of each faculty. Contact the Dean's office in the faculty of the researcher for the name of the nominee.
- All relevant documents should be provided in Māori and English (The translations need to be provided only after approval is granted).

xi. **Anonymity and Confidentiality** (Please also see Section 3b)

- If the primary researchers come from more than one institution provide the relevant institutional contact details of all the primary researchers.

- If anonymity with respect to the participant's identity cannot be guaranteed this must be indicated.
- If anonymity with respect to the identity of non-participants cannot be guaranteed this must be indicated.
- If confidentiality with respect to the participant's identity cannot be guaranteed this must be indicated.
- If confidentiality is offered, it should be made clear how the information the participants provide will be reported or published.
- If the research involves focus groups, interviews with small numbers of individuals, or interviews with well-known members of the community it must be indicated that confidentiality with respect to the participant's identity cannot be guaranteed.

xii. **Distress and Discomfort**

- If the research involves any procedure that may reasonably be expected to cause physical, psychological, social discomfort or incapacity this must be indicated, as should plans for subsequent assistance or referral.

xiii. **Research within the University**

- If students in the department of the researcher (or PI) are prospective participants there must be an explicit statement that neither grades nor academic relationships with the department or members of staff will be affected by either refusal or agreement to participate. It should be made clear that participation is voluntary.

xiv. **Compensation, Financial Inducement and Funding**

- If compensation or financial inducements are offered the terms and conditions should be stated. The absolute right of participants to withdraw at any time, irrespective of whether or not inducements are involved should be made clear.
- If funding for the research is being sought or obtained, this needs to be stated, as does the source.

xv. **Closing statements**

At the end of the last page include the following:

- **Contact details for the researcher, supervisor and Head of Department**. This should include name, phone number, email and/or postal address. Please do not provide any home phone numbers or and addresses.
- **Chair contact details**: "For any concerns regarding ethical issues you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 extn. 87830/83761. Email: humanethics@auckland.ac.nz".
- **Approval wording**: "APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON …… for (3) years, Reference Number …../……" (The researcher has to complete the approval date and reference number after receipt of the letter of approval and prior to distribution to the participants.)

2d) Checklist for the Consent Form

(Please see Section 5b for the sample)

The Consent Form (CF) is the document stating the terms upon which a person agrees to participate in research. It is signed by the participant and stored in a locked cabinet separated from other data on university premises under the control of the Supervisor or Principal Investigator, normally for six years.

The CF is addressed to the researcher by the participant. Therefore it is a mirror image précis of the information given in the PIS. It is written in the first person, for example phrased as "I understand …" "I agree …" as appropriate.

Bullet points work well for this document.

On occasion, the UAHPEC may give permission for consent to be obtained orally, where there are cultural, safety or other special reasons.

The CF is to be provided on University of Auckland departmental letterhead with complete postal address and telephone contacts. It is not sufficient to use the shell letterhead without the full contacts for the University of Auckland Department. Electronically generated logos of Departmental letterhead are acceptable. These are available from the Department.

- Include in the heading information about how long the CF will be stored. Normally the statement is "This form will be held for six years".
- State the category of the participant at the beginning of the document, for example, "Consent Form (Manager)".
- The name of the researcher should appear at the beginning of the CF.
- State the title of the research.
- State "I agree to take part in this research".
- Provide an introductory generic paragraph in which the participant states that he or she has read the PIS, has understood the nature of the research and why he or she has been selected and has had the opportunity to ask questions and have them answered to his or her satisfaction. Include a statement about the voluntary nature of the participation.
- Follow this by a set of bullet points in which the important points in the PIS are itemised in an "I understand..." or "I agree …" format. These will be the key elements that affect the commitment of the participants to the research. Consideration should be given to including topics from the following list:
  - Any physical activity.
  - Procedures that may reasonably be expected to cause physical, psychological, social discomfort or incapacity.
  - Anonymity and confidentiality limits.
  - Recording procedures.
  - Withdrawal in person, and of information.
  - Transcription.
  - Publication of information.
  - Storage and later use of data.
  - Information concerning any involvement of third parties.
  - Benefits that will be made available to participants.
  - Length of time involved for participants.
- Provide space for the participant's name, signature and the date.
- At the end include the following: "APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON …… for (3) years, Reference Number …../……" (The researcher has to complete the approval date and reference number after receipt of the letter of approval and prior to distribution to the participants.)

Section 3: Essential aspects of research to be considered

3a) Advertisements

If you intend to use an advertisement, a copy must be submitted along with the application. It must give a preliminary idea of the research to potential participants. It should enable readers to judge whether or not they might be potential participants. Advertisements must include the source of funding, contact details and have the UAHPEC approval wording at the end (see Section 2c xv).

3b) Anonymity and Confidentiality

A response is **anonymous** when the researcher and those who read the published results of the research cannot identify it as belonging to any particular respondent.

The UAHPEC takes **confidential** to mean that the information is held between the parties sharing the confidence. It may be misleading to describe the information collected during the research as confidential if it will be reported or published. An appropriate phrasing for the PIS might be: "If the information you provide is reported/published, this will be done in a way that does not identify you as its source."

If potential participants cannot be guaranteed anonymity then this should be drawn to their attention in the PIS. This is likely to occur where the number of possible participants is small, where the outcomes of the research will be released among a small group of informed (knowing) persons or where research is being undertaken with identifiable members of the community.

It may be necessary to protect the anonymity of non-participants in group situations. For example, if a questionnaire is used in a class, the preservation of anonymity may make it appropriate that those who have declined to participate should return a blank questionnaire.

A questionnaire is anonymous if the researcher cannot identify the participants. One way in which this can be achieved, as may be necessary where the data is collected over the internet or where follow-ups are envisaged, is by having a third party separate the identifiers from the data which is then coded. The third party would normally be required to sign a confidentiality agreement.

Where questionnaires are anonymous, UAHPEC accepts a completed written questionnaire as evidence of informed consent provided that the research involves no other component, such as interviews or follow-up questionnaires. If there are follow-ups, CFs should be provided.

In the case of non-anonymous telephone interviews, verbal consent should be sought, and recorded, for the interview and for any subsequent telephone contacts.

If potential participants cannot be guaranteed confidentiality, this should be drawn to their attention in the PIS. Participants must be told that confidentiality cannot be guaranteed where participants meet together, for example, in focus groups.

It is not possible to give an absolute guarantee of confidentiality where information is being recorded. The researcher can only give an assurance of confidentiality to the extent allowed by law. Some government agencies and departments such as the police, IRD, and customs have a legal right of access to certain information. In some circumstances a court has jurisdiction to require disclosure of information relevant to a

matter being heard by the court. Also, there is always a risk of inadvertent disclosure whenever information is collected and recorded.

Where third parties, that is people other than the named researchers, are given access to data that is not anonymous (for instance, for the purposes of transcription or translation), they must sign a Confidentiality Agreement and the PIS for those who supplied the data should indicate how the confidentiality is preserved. Any agreement with transcribers/translators must be submitted along with the application to UAHPEC.

Where there is a possibility that the researcher may be given information that reveals a reasonable possibility that the life or health of any person may be at serious risk then the researcher has a moral and legal obligation to breach confidentiality and report that risk to the appropriate authorities and appropriate others. The PIS should inform the participant of this.

Where an assurance of confidentiality has been given as a condition for participating in the research, the researcher must be active in protecting that confidentiality. This applies both to the contents of theses, reports, or publications and to the treatment, storage, and destruction of data. All data should be stored securely, and identifying materials (including key words or codenames) should be stored separately from coded data.

Where there is the intention, or desire, to make the names of participants public; this should be clearly stated in the PISs and CFs.

3c) Adverse events in research

An important part of the responsibility of UAHPEC is the evaluation of events in which research participants, and the researchers, have been unexpectedly harmed or exposed to unanticipated risk. In order to fulfil its responsibility to protect all research participants, and to the extent that it is possible to do so, UAHPEC requires written reports to be submitted describing any unanticipated problems involving risks to participants or unexpected serious harm to participants.

Assessing the safety of particular interventions on participants and others is central to the design and implementation of ethical research protocols. In a carefully designed project, many negative outcomes can be expected, for example, 'discomfort' at receiving an injection or distress at talking about a sensitive subject, and these, as well as the provisions that are in place to deal with them, should be described in the PIS and CF. However, some event might occur that is unexpected or that is worse than anticipated.

i. Researcher responsibilities:

All death or life threatening adverse events must be reported in writing by the researcher to UAHPEC within 5 calendar days. All other adverse events should be reported within 15 days.

When reporting an adverse event, the researcher should address the need and method to communicate relevant information to his or her research participants, the need to redesign or amend the research plans, and whether or not a change in description of risk is warranted in the protocol and consent form.

ii. UAHPEC responsibilities:

UAHPEC will assess all adverse events reports in order to address both immediate issues of safety for participants and, as necessary, any changes in protocol design

and implementation needed to protect the interests of current and future research participants. When evaluating an adverse event report, UAHPEC will consider:

- the seriousness of the event,
- the relationship of the event to the research,
- the expectedness (or otherwise) of the event,
- the appropriateness of the action taken or proposed by the researcher,
- the need to inform current or future participants, either by change to the research documents or verbal communication.

3d) Audio, video or other forms of electronic recording

If recording is essential to the research, it should be indicated as such in all relevant PISs. The CF should state, 'I understand that I will be recorded'.

If recording is optional, this should be explained in the PIS and the CF should state "I agree / do not agree to be recorded". It should also state that, 'Even if you agree to being recorded, you may choose to have the recorder turned off at any time'. The PIS to Chief Executive Officers, Principals, and Board of Trustees should state recordings will be made only with the agreement of those recorded.

i. Transcription or translation

The PIS will explain who will do this and, if not the researcher, how confidentiality of information will be preserved.

ii. Review and storage

Only those who are recorded should be given the opportunity to review tapes or transcripts. Chief Executive Officers, for example, normally should not be given access to recordings made of their employees, nor to transcripts of these. If those who have been recorded are permitted to review tapes or transcripts, a clear description should be provided in the PIS of the procedures for doing this.

iii. Ownership and storage of recordings

Indicate in the PIS who will own the recorded data and how the data will be disposed of at the completion of the study. Options include the participants retaining the recording, agreeing that the recording be destroyed, or consenting to its storage in a research archive. If the data have not been publicly archived, which requires the participant's agreement, storage should be accessible by the researcher and supervisor only.

3e) Compensation and Remuneration

Researchers may compensate students or members of the public for reasonable expenses they may incur as participants in research. These expenses may include opportunity costs: for example, for time, or other costs, such as for travel. When there is evidence for actual costs (receipts, bus tickets), reimbursement of these should be processed through normal departmental reimbursement procedures. The case for payment of opportunity costs for participation in the research is less clear, however, and some guidelines are given. It is acknowledged that payment for participation in research is ethically acceptable and this is stated in the codes of ethics of a number of international learned bodies.

There are a number of conditions regarding compensation or financial remuneration that must be taken into account:

- Payments to participants must not be used to encourage participants to undertake dangerous or harmful acts they would not perform in their normal lifestyle.
- No inducements should be offered to parents, guardians, or carers to persuade them to enter their children aged less than 16 into a research project.
- No financial inducements should be offered to participants aged less than 16. Small gifts by way of thanks for participation may be appropriate.
- Where the purpose of payment is to show gratitude to participants, the payment should apply to all participants, irrespective of whether they withdraw during the project.
- When alternative methods of payment are proposed, these will need to be justified.
- The reason for, and the level of, the payments should be clearly spelt out in the PIS, CF and in any advertising or promotion of the research.
- The opportunity must be given for the participant to decline payment or seek recompense in an equivalent or culturally appropriate manner, such as koha payment to an iwi.

3f) Conflicts of interest

Research in which the researcher has a conflicting interest, or the appearance of conflict of interest, is not ethically acceptable and is often methodologically suspect.

The sponsorship or funding of a project must not compromise its research adequacy or ethical acceptability.

In general, researchers need to be sensitive to the potential conflicts of interest that arise in using their students as participants, those who may perceive themselves as being in a dependent relationship with the researcher, their family, or their friends. To avoid conflicts of interest, or the appearance of conflicts of interests, researchers may not use their own children aged less than 16 as participants, except in exceptional circumstances that must be explained to UAHPEC.

In addition, the researcher should consider potential conflicts of interest that could arise in a potential dependant relationship.

3g) Consent

Ethical research requires the informed consent of participants. To be informed, consent must be based on an understanding of the objectives, procedures, and materials involved, and of the rights of participants. Normally, full details about all of these will be provided in a written PIS.

In general, where participants are not mentally competent to give informed consent, or are aged less than 16 years, their agreement and the consent of their parents, guardians, or carers, is required. (Please also see Section 4d).

Some of the observations listed under Section 4d may also be relevant to research involving adult participants who are not competent to give informed consent as a result, for example, of being brain damaged.

A separate PIS is required for each of the different types of participants in a project - Chief Executive Officers, Boards of Trustees, teachers, parents, interviewees, participants aged less than 16, and so on.

The PIS and CF should be written in language appropriate to the intended audience. The PIS must be headed with an indication of the type of participant to whom it is directed, for example, the Chief Executive Officer (or person with authority to grant permission for research to occur within the organisation or section), Board of Trustees, Principal, teacher, student, and the contents should address the specific role of that participant in the research project. Where organisations are involved, the executive officers must consent for the research to proceed in their organisation and during work time, but only the participant employees can give consent for their own participation. However, where the research requires the view of the organisation the principal executive may direct employees to take part. (Please also see Section 4c).

For informed consent, participants must explicitly indicate that they understand what is involved and freely agree to take part. Passive or assumed 'consent' is not acceptable. In the case of anonymous questionnaires accompanied by an approved PIS, UAHPEC accepts the return of the completed questionnaire as evidence of informed consent, for example it is not necessary to have participants sign a CF as well as fill out an anonymous questionnaire.

Usually, oral consent will be approved only if it is recorded on audio or videotape and stored, as is the case for written consent. In some cases, it will be culturally appropriate for participants to indicate their informed consent orally, rather than in writing. In such instances, the research process must include a procedure for obtaining consent and for recording that consent has been actively obtained.

For any project based on interviews or observations involving the researcher's family members or friends, all the usual rules for informed consent apply.

3h) Deception

In very few cases it will be necessary to deceive the participants about the purpose of the research. The use of deception will need to be justified in the application. Where deception is used, it will be appropriate usually, to disclose (debrief) the purpose of the research to the participants when the participation is completed.

It is never appropriate to deceive the participants about the procedures they will have to undertake or undergo, or the time this will take, in the course of the research.

In making application for ethical approval, researchers must explain in detail any proposed deception or methods that depart from the use of the written PIS retained by the participants or from the use of signed CFs.

3i) Focus groups or small interview samples

Research involving the simultaneous participation of more than one person (such as in focus groups) raises particular issues. By its nature, such group participation prevents anonymity and compromises confidentiality. In addition, settings such as focus groups may make it difficult for an individual participant to expect to be able to withdraw any information once provided. Researchers are obliged to forewarn participants (in the PIS usually) of these issues and to actively encourage participants (in the CF) to maintain confidentiality of information shared under such conditions.

3j) Languages other than English

It may be appropriate, depending on the participants involved, that documentation be issued in a language other than English. English language versions of all documents to be translated must be submitted with the original application. UAHPEC recommends that translations be completed after UAHPEC has given approval, as minor amendments are often required. UAHPEC will expect to receive the translation as soon as possible after the approval has been granted and before documents go to participants.

The researcher is reminded that the accuracy of the translation is critical to the ethics of the research.

In the course of the research, should any participant at any time require a translation, it should be provided. This applies to all persons from whom consent is sought.

Where interviews, focus groups, or discussions are involved, these should normally be conducted in the preferred language of the participants. This should be indicated in the PIS.

3k) Privacy Act

Refer to the Privacy Act document in the Appendix.

3l) Recruitment of participants

In the application, the researcher must describe in detail how he or she will identify potential participants and the method by which participants are invited to take part in the research.

Public records of names and addresses, such as the telephone book, or the register of medical practitioners, may be used in the recruitment of participants.

Private records of names and addresses, such as membership or enrolment lists of societies, clubs, companies, universities etc, are protected under the Privacy Act. Researchers cannot ask the holders of private records to supply the researcher directly with names and addresses of potential participants. Researchers can, however, formally request that holders of such records forward to potential participants information about the research supplied by the researcher. Those indirectly contacted by this method can then approach the researcher to take part in the research if they so desire.

If the researcher has access to private records of names and addresses in a capacity other than that of researcher in the given project, or where the records are protected by the Privacy Act it is not acceptable for him or her to recruit participants on the basis of this access. In such a case, the researcher should seek the form of indirect contact described above, by formally requesting the senior administrator of those records to forward information to potential participants.

As an exception to this rule, staff of the University with access to student records via nDeva may identify potential participants and their addresses, provided that participation in the subsequent research is voluntary and that the identity of participants is not apparent in the report of the research.

It will not be appropriate, usually, for the researcher to recruit, as participants, members of their own family or friends. As an exception to this general rule, small-scale research projects on 'stress free' topics conducted by students in the course of studying research methodology may involve the use of family and friends as participants, provided these

are aged 16 or above. Because of the conflict of interest involved, researchers cannot recruit their own children or siblings as participants if these are aged less than 16, except in exceptional circumstances that must be explained to UAHPEC.

3m) Snowballing

Snowball sampling is an approach that uses existing participants to identify potential participants. There are two ethical issues in the use of snowball sampling.

First, UAHPEC requires that researchers use indirect contact when using information on potential participants held by a third party. The Privacy Act (1993) prevents the use of contact details collected for a purpose by a third party for other than the stated purpose. However, UAHPEC recognises that contact details held by individuals about other individuals, such as friends, relatives, workmates or schoolmates, are not typically covered by the Act.

Second, UAHPEC requires that researchers consider the sensitivity of the data to be gathered from potential participants. Where these data are sensitive, with the potential to cause harm to participants, snowball sampling should not typically be used. In this situation researchers may ask their contacts to approach other potential participants with information about the research and ask those who are interested to contact the researcher directly.

3n) Storage, retention and eventual destruction of data

Information gathered should be handled in a way that protects the confidentiality of the participant and ensures the safe custody of the data. Care should be taken to protect the legitimate privacy of individuals, institutions, communities and ethnic groups. Where research involves the use of audio, video or other recording, special attention is required to protect confidentiality and security of data.

Storage for the purpose of the original research should be accessible by the researcher and supervisor only.

Practical steps to ensure the security of the data may include:

- coded storage of information,
- separation and storage of physical records at remote sites,
- identification of participants through the use of key words or codenames,
- separate storage of taped information from transcripts or other identifying material,
- keeping the whereabouts of information, key words, and codes secret,
- arranging for the data to be destroyed as soon as they are no longer required for the particular research.

If data is to be destroyed eventually, a clear indication should be given to UAHPEC and to participants regarding the timing and manner of this. If data is not to be destroyed this must be indicated to participants along with the purpose of retaining it.

CFs should be headed with information about how long they will be stored before they are destroyed. The University requires that CFs be retained in secure storage by the PI for a period of six years.

Storage for the purposes of posterity and general research that might involve transfer to a public repository requires a suitable release form negotiated with the interviewee that clarifies conditions of access. Advice on the nature of the release form can be found in

the Code of Ethics devised by the National Oral History Association of New Zealand. Established repositories have their own conditions for this type of archiving.

3o) Publication of results

Researchers should be aware that there is an ethical dimension to the formulation and publication of results and loss of copyright. The researcher must remain sensitive to the uses to which the research findings may be put. Whenever possible, the findings should be conveyed in a comprehensible form to those who participated in the research.

3p) Translation or transcription

Where a third party is involved in the translation or transcription of data, including from electronic recordings that are not anonymous, he or she should sign a Confidentiality Agreement (to be submitted to UAHPEC). The PIS for those who supplied the data should indicate how confidentiality is preserved.

3q) Acknowledging the Treaty of Waitangi

This section considers research in the light of the Treaty of Waitangi. At the outset of any research project it is appropriate to consider the relevance of these notes. Note that many of these features will be found appropriate in dealing with the closely held cultural determinants in any unified group of people.

Obligations and responsibilities toward Māori arise from the Treaty of Waitangi. These relate to the partnership embodied in Articles I and II, and to equity as outlined in Article III. Inherent in these two concepts are:

a) respect shown by the researcher for cultural differences and ways of knowing;
b) regard for participants' physical, mental, spiritual, and social well being;
c) reciprocity in terms of sharing of knowledge, outcomes, control, and benefits of the research, subject to the University policy on Intellectual Property. (Refer to the Research Guide on the University website).

Researchers who recruit Māori participants should therefore make every effort to give practical effect to these concepts and values. An approach is to ensure participants' active involvement in the project at every stage and in a way that empowers and builds capacity. This may be by means of:

- developing a partnership between whānau, hapū, or iwi and the university researchers,
- involving Māori in the organisation, management, and conduct of the project,
- ensuring the outcomes directly or indirectly benefit Māori.

i. Consultation:

The key to achieving the respect, regard and reciprocity described in the Applicants' Manual and in the Guiding Principles lies in an appropriate consultation process for all research pertaining to Māori. While the overall aim of this consultation process is to obtain informed and voluntary consent, an appropriate consultation procedure will facilitate cooperative and collaborative working relationships between researchers and Māori organisations, groups and individuals. This consultation process is likely to require more than the approval of the individual, particularly if it involves collectively owned knowledge or relates to collectively owned resources. In all such cases, consultation with the wider

group is strongly recommended. However care is needed where there are real or apparent conflicts between group consents and those of the individual participant.

The Pro Vice-Chancellor (Māori) (PVC(M)) has a nominee in each faculty. Researchers who are conducting research pertaining to or interacting with Māori must have the sign-off of that nominee.

Information concerning appropriate Māori groups with whom to consult, for example, the hapu with mana whenua for a particular area, can be obtained from the Office of the PVC(M) on ext. 82525. This Office will also provide advice on how to consult, and suggest the names of persons who can be approached if assistance is required with the consultation process.

In order to reduce the impact of research on the Māori community (many of whom are over-burdened with such requests), as well as minimising the difficulties faced by first-time student researchers embarking on projects involving Māori, UAHPEC advises researchers to consult first with the PVC Māori to discuss the proposed research.

As outlined above, consultation involving issues other than those aimed at obtaining prior informed consent is encouraged. The following provides a more detailed guide as to what might be discussed and resolved with each participant or group prior to commencing the research.

ii. Design, implementation and outcomes of the proposed study

Researchers need to be open to suggested changes, particularly those that provide for participation by the cultural group involved.

The accountability of the researchers to the participants and their communities is an important aspect of proposed areas of research. Researchers include an explanation of what the likely uses and applications of the information provided will be, and how accountability of the researchers to the participants is to be achieved. It will likely be good practice to provide participants with a draft of the final outcome(s).

Participants' rights and responsibilities with respect to the final result should have been negotiated at the outset. This input could range from the right of the individual to correct his or her statements through to having the veto of some content.

Also included within the scope of participant adaptations is the protection of individual or group rights concerning intellectual or other property, including the ownership or control of the outcomes of the research, and protection from any negative impacts that release or publication of the outcomes might incur.

Obviously the earlier in the design of the project that consultation takes place, the better. Leaving it until last is not only likely to cause offence, but may result in costly delays as properly conducted consultation with some groups, for example Māori, can be a lengthy process. UAHPEC will not be inclined to expedite approvals that have ignored this advice.

3r) Withdrawal from Participation

i. Withdrawal of participation in research

Agreeing to participate and continuing to participate in research must be voluntary. A participant is entitled to withdraw from involvement in a research

project at any stage without explanation. The PIS must inform potential participants of this right.

ii. Withdrawal of data from research

As a general rule a participant whose identity is known to the researcher is entitled to withdraw data he or she has provided. The PIS must inform participants of this right and give a specific date by which the right must be exercised. Typically, this will be at some time before the analysis of research results commences. If the time constraints of the research or the method of recording data (for example, an audio recording of a focus group) make withdrawal of data by the participant impractical, this must be stated in the PIS and must be specifically consented to by the participant. If anyone other than the person who provided the data is entitled to withdraw the data this must be stated in the PIS.

3s) Requirements imposed from outside the University

Researchers should be aware that there is an ethical dimension where the research involves requirements imposed by an organisation outside the University (e.g. a funding organisation, a journal in which the researcher wishes to publish, embargo of thesis). Justification and the rationale for such requirement are to be provided in the application.

Research by outside organisations which affect the design of studies or the use of research data may raise particular ethical issues, such as conflict of interest between researchers, the University, and the outside organisation. Researchers should ensure that such requirements are justified and reasonable.

Section 4: Guidelines Relating to Particular Types of Research

4a) Internet Research with Human Participants

All staff and students contemplating use of the Internet should ensure that their research observes the principles and requirements of UAHPEC. In particular see 3b).

i. Informed and voluntary consent

Researchers are usually exempt from the need to secure informed consent where the data are collected from the public domain. Data in the form of postings to usernet and newsgroups are readily accessible and may usually be considered as falling in the public domain. Informed consent may be required to use data from public usernet and newsgroups dealing with sensitive issues. An increasing number of communication methods straddle the private and public divide. The requirement for informed consent in these fora will be determined by the sensitivity of subject matter, by the means of access and the basis of membership.

A special feature is the use of pseudonyms in Internet communication. As a result, the profile of any Internet 'community' and of individual research subjects usually cannot be guaranteed. This raises significant logistical problems in securing informed consent. It also makes it difficult to judge the capacity of research participants to assess risk and to give informed consent; for example, impaired and vulnerable subjects, including minors, cannot be readily eliminated from the research.

ii. Respect for privacy and confidentiality

A guarantee of privacy and confidentiality is problematic in Internet research because of the relative ease with which text, in the form of quotes used in research outputs, can be tracked to the original forum. Identification of the forum usually means it is possible to identify individual participants and to track and profile them electronically.

Similarly, the respondents to apparently anonymous Internet questionnaires can normally be tracked and profiled. Internet research should not claim to take the form of an Anonymous Questionnaire unless encryption, proxy servers, anonymous FTP sites or similar techniques are used.

Researchers should take particular care in the storage of data and should avoid the use of online accessible forms of record keeping.

iii. Avoidance of harm

Internet research makes the risk to research participants difficult to assess.

iv. Limitation of deception

Internet research facilitates the use of deception by researchers, while at the same time, making it more difficult for researchers to notify individual participants and communities that they have been deceived. The researcher will need to clearly explain such a situation to UAHPEC for consideration.

v. Research adequacy

Researchers' intent on using the Internet must meet the usual ethical criteria for all research and also display an appreciation of the interface of technical and ethical issues peculiar to Internet research with human participants.

Applications to UAHPEC and accompanying documentation must avoid or explain technical jargon.

vi. Web-based Questionnaires

Web-based questionnaires are deemed by UAHPEC not to be anonymous.

A PIS for participants should accompany the questionnaire. It should include the instruction that the questionnaire is to be completed only by people aged 16 or older. If there is secure encryption, this should be described. Otherwise, the PIS should indicate that neither confidentiality nor anonymity can be guaranteed.

The questionnaire must begin with a statement that the participant is aged 16 or older, which the participant ticks or affirms in some explicit fashion. A suitable declaration would be the following: "I have read and understood the information describing the aims and content of the following questionnaire. I am aged 16 years or older. I understand that, by submitting this questionnaire electronically I agree to take part in this research under the terms indicated in the information supplied."

4b) Laboratory courses with human participants

Approval for laboratory-based courses or other student projects that involve human participants and are part of undergraduate or graduate coursework requirements should be obtained from UAHPEC by the course coordinator(s). Course coordinators are responsible for ensuring that students understand and observe the ethical principles and requirements applicable to such projects and for ensuring compliance with UAPHEC requirements.

If laboratory participation is a formal requirement of the course, it is expected that the University Calendar, department handbooks and other course descriptions state this explicitly. In such circumstances, individual students' written consent is not required; enrolment is considered sufficient. Nonetheless, this provision cannot force a student to participate in any particular research activity should he or she choose not to. UAPHEC still expects that participation in a given research exercise remains voluntary.

If laboratory participation is not a formal requirement of the course, or if the University Calendar, department handbooks and other course descriptions do not state this explicitly, then participation in the laboratory activities is considered to be voluntary, and written informed consent must be obtained from each student participant.

In either case, UAPHEC expects that student-participants will be informed of

- the purpose of the research activity,
- the use to which information that they provide will be put and the extent to which their participation or their information will be kept confidential, and
- any potential risks and the health and safety provisions available, as and where appropriate.

4c) Organisation Research

Where an organisation or part of its operations is the subject of research, and the research is to be carried out with members of the organisation as participants, it will normally be expected that the researcher will approach the appropriate level of management in the organisation for permission for the research to take place.

When the organisation gives permission for the research to take place, each potential participant has the right to decide whether to participate or not. This condition also applies to all methods of recording the participants. Individual participants have the right to have their participation or non-participation kept confidential from their employers, and the right to have the content of their participation confidential to themselves and the researcher. Deviations from these rights need to be justified. At all times, the fact that employees are in a dependent relationship with their employers should be borne in mind.

If the organisation or any other party with an interest in the activities of the organisation or participants sponsors the research this must be stated in the PIS. If a report is to go to the organisation this must be stated. Where the statements of participants are reported to the organisation, anonymity should be preserved, however it should be recognised by the researcher, and indicated to the participant, that anonymity cannot be guaranteed

Where several levels of status or authority within the organisation are to be involved, the researcher will need to consider the protocols of the organisation for approach and authority/permission when preparing to meet participants.

In situations involving participant observation, all potential participants must be informed of the observation. They should be given the opportunity to minimise their participation.

4d) Research with participants aged less than 16 years

Because participants aged less than 16 are vulnerable, they need special protection and to have their membership of their families respected. This section sets out the requirements, additional to those applying to normal adults, for research with such participants.

Research with participants who are less than 16 should not be undertaken unless there is a specific and demonstrable need to perform it, and no other reasonable route to the relevant knowledge is available.

A prime consideration in any such research is that it is not against the interest of any individual participant. Research procedures should not be carried out if they involve greater than minimal risk of harm to the participant.

Usually it is sufficient for only one of the child's guardians or caregivers to consent to the child's participation in research. However, the Committee may require the consent of all the child’s legal guardians in special circumstances. Such circumstances would include, but are not limited to, where the research is on a topic of particular sensitivity to the child and/or the guardians; where there is any risk to the child’s physical, emotional or psychological well-being; where the child will be asked to discuss any matter relating to their guardians.

Consent and assent

Because of the special vulnerability of children, UAHPEC will in general require that the consent of a parent, guardian, or carer be obtained for the participation of a child in research.

In order to protect against inadvertently exposing the child to an allergen or other harmful item, or infringing the family's beliefs, UAHPEC will always require that the child's parent, guardian or carer be informed of the nature of the research.

Where the consent of the parent, guardian or carer is required, the informed assent of the child is also required if he or she is of an age to understand the project. Because of the conflict of interest involved, parents, guardians and carers cannot give valid consent on behalf of their child aged less than 16 if the parent, guardian or carer is also the researcher. The researcher must be sensitive to potential conflicts of interest between the parent, guardian or carer and the under-age participant.

UAHPEC may accept as sufficient the consent or refusal of a child where the applicant satisfies UAHPEC with adequate information that the intended child participant will be able to understand their part in the research and the requirements of participation.

In the exercise of this discretion, UAHPEC will have regard to:

- the nature of the research topic and whether it would normally be regarded as being within the comprehension of a child of the age and experience of the intended participants,
- whether the research concerns a topic, or involves ascertaining the child's views on a matter, that a reasonable parent, guardian or carer would wish to have knowledge of because it may affect the child's relations with his or her parent, guardian or carer, or cause the child some concern,
- whether the research methodology is adequate to ensure that the child participant has the information, time and support required to give informed consent. In certain circumstances, UAHPEC may require that a child's competence to consent is to be individually determined,
- whether the research is designed or supervised and carried out by people experienced in working with children,
- whether the consequences (educational, social, emotional, physical) of participation might be of concern to the parent, guardian or carer.

Where a child is not competent to give his or her own consent

- The consent of the child's parent, guardian or carer must be given before the child is approached for assent.
- A child who is able to understand the nature of the project must be asked to give his or her assent to participation. A separate PIS directed to the child should be prepared at the level of language that reflects the child's age and reading ability. Where appropriate, assent may be given orally. The researcher should check, by asking a few simple questions, that the nature of the project and of the participation is understood. The researcher must keep a record of the written/recorded assent given.
- Whether or not the parent, guardian or carer has consented on behalf of the child, the child still has a right to refuse to participate.

Information

- Where children are invited to participate in research he or she, and the parents, guardians or carers, must be adequately informed in a manner best suited to their individual needs about the research and what the child will be asked to do.
- Each child must be given information about the research in a form that he or she can readily understand.
- Each child must be advised of his or her right to decline to participate and his or her right to withdraw from the research at any time without giving a reason.

Researchers must give the child an opportunity to ask questions and to have those questions answered to the child's satisfaction.

Where, pursuant to these Guidelines, a child is not competent to give his or her own consent the researcher is obliged to obtain the written consent for the child to be a participant.

- The parent, guardian or carer must be given information about the research and be advised of the child's right to decline to participate or to withdraw from the research at any time without giving a reason.
- The parent, guardian or carer must be given an opportunity to ask questions and have them answered to his or her satisfaction.

Inducements

No financial inducements should be offered to parents, guardians or carers to persuade them to enter a child in their care into a research project. Compensation for expenses incurred by reason of participation may be offered. After their participation children may be offered small gifts, so long as the nature of the gift has been described in the PIS.

4e) Research in Schools

Educational researchers need to be careful in working with children in schools given the critical importance of instructional time and activities, as well as the vulnerability of children. In order to make the best use of the time at the school, the efforts of the children and for the research to have maximum relevance and validity, educational researchers need to work cooperatively with schools to ensure that:

- the integrity of ongoing school activities is maintained and that principals are alerted to possible disturbances that may result from the conduct of the research,
- the aims of the investigation are communicated as clearly as possible to parents, students, Boards of Trustees and principals, and that they are updated about any significant changes in the research programme,
- the findings and the practical significance of the research are communicated in clear, straightforward and appropriate language to relevant research populations, institutional representatives and other stakeholders,
- the use of research techniques such as experimental interventions that might deprive students of important parts of the standard curriculum, and in this way have the potential for negative social consequences, are minimised.

It is important to note, however, that standards intended to protect the rights of human participants should not be interpreted to prohibit teacher research, action research, and/or other forms of practitioner inquiry, so long as the data are those that could be

derived from normal classroom processes, that confidentiality is maintained, the safety and welfare of teachers and students are protected, informed consent is obtained when appropriate, and the use of the collected information is primarily intended to benefit those receiving instruction in that setting.

The following sections are not intended to cover new ground but to organise and summarise issues and policy that are particularly relevant to conducting research in schools.

Consent Process

- The PIS must request parents to discuss the research invitation with their child and state that, where parents' consent to their child participating in a research project, the final decision typically will be that of the child.
- Issues of anonymity and confidentiality need to be clearly specified and differentiated within the PIS. Anonymous indicates that the researcher and those who read the published results cannot identify specific participants, while confidential indicates that the researcher can identify the participants and promises not to make the identity of participants public.
- Parents and students are to be assured in the PIS that participation or non-participation will not affect the student's school learning, standing or assessment (if appropriate) and principals should be asked to guarantee this.
- It is not acceptable to include children in the absence of written consent being returned by parents. The presumption of consent in the absence of a signed CF is not acceptable. People should not be expected to identify themselves for the sole purpose of refusing consent.
- Since much research in schools involves audio and/or video recording, there are special considerations that need to be addressed:
  - researchers need to be clear about whether participation in research requires the agreement of the participants to being video or audio taped, or whether they have a choice.
  - each PIS and CF must indicate clearly whether recording is a requirement of participation or is optional.
  - When third parties such as transcribers, are involved in the processing and coding of data, that is not anonymous, they need to sign a confidentiality agreement to maintain the confidentiality of participants. This should be clearly indicated on the relevant PIS.
- Issues related to review, storage, ownership, and disposal of recordings need to be clearly specified within the PIS.

Research on teacher behaviour within schools

When the research is focused on observing and describing teacher practice during the course of normal classroom interactions and tasks, there is no need to secure child and parental consent. However, the children, and the parents, should be informed that researchers will be observing the teacher within the classroom and the focus will be on the teacher only.

Recruitment and participation

- If children in a classroom or other group setting are asked to participate in a research project, procedures must be put in place to protect the anonymity of those children who do not wish to participate, or whose parents do not wish them to do so.
- Prior arrangements should be made with the school to provide alternative activities for students for whom written consent is not received. These should be clearly specified in each appropriate PIS.

- If the research topic is of a sensitive nature, then it must be demonstrated that a protocol exists that identifies and caters for students who might suffer emotional harm or psychological discomfort.
- The law does not let the school give consent in loco parentis.

4f) Research on or about professions

Most professions have organisations such as Associations, Societies, Councils, and Guilds. These organisations frequently have libraries, databases, and other resources. It would be in the researcher's best interest to check with the appropriate organisation before the research methods/design are finalised.

4g) Telephone research

Research conducted by telephone interview is generally regarded as anonymous, so long as no identifiable data is collected that can be traced to any particular individual. Potential participants should be given an oral explanation of the research, and asked whether they agree to participate in the research under the terms specified. (The researcher must also confirm that the participant is aged 16 or more by asking them if this is so). Ideally, this oral consent should be audio-recorded. Along with a copy of the research questions to be asked, UAHPEC needs to see a script of the information to be given orally to participants. At the end of the interview, the researcher should thank the participant, and provide a contact telephone number at the University for complaints.

In some circumstances—for example, where potential participants are readily identified, their addresses are known, and the sample is not large—it may be appropriate to send an information sheet before conducting the research. This should state that the participant will be telephoned to be invited to participate in the research, or should explain that if interested, the participant can telephone the researcher.

4h) Overseas research

Where research is conducted overseas, it may be necessary for the PI to demonstrate that he or she has considered the safety of the researchers and the participants and taken into account ethical conditions appropriate to the region in which the research will take place.

In the application, the researcher must demonstrate that he or she has paid attention to linguistic, political, cultural, social and other relevant contextual issues and how he or she has addressed these.

It is also a requirement that local ethical approval is obtained if that is necessary or appropriate, and that local laws are complied with: a researcher must be familiar with local law, including in relation to the protection of privacy and data.

Section 5: Other Information

5a) Participant Information Sheet

Please note that this is only a sample. To develop your own document, please refer to the Applicants' Manual Section 2c): Checklist for the Participant Information Sheet (PIS).

THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

Department Name
Department address
Department phone no

The University of Auckland
Private Bag 92019
Auckland, New Zealand

PARTICIPANT INFORMATION SHEET
(Address by category, e.g. Manager)

Project title:
Name(s) of Researcher(s):

Researcher introduction

Include the name of the researcher and appropriate identifying information, whether a staff member or a student. If a student, state the name of the degree and the department or faculty in which the researcher is enrolled. If a staff member, state the department and position.

Project description and invitation

State the rationale and aims for the project. Invite potential participants to be involved in the research. Explain why and how they have been selected. If the research involves a group (such as students in a class), members of which may decline to participate, indicate what these non-participants will do while the research is being conducted and indicate how the anonymity of non-participants will be preserved.

Project Procedures

Explain the procedures in which the participants will be involved. Explain the length of time involvement. If the research involves any procedure that may reasonably be expected to cause physical, psychological, social discomfort or incapacity this must be indicated, as should plans for subsequent assistance or referral. If students in the department of the researcher (or supervisor) are prospective participants there must be an explicit statement that neither grades nor academic relationships with the department or members of staff will be affected by either refusal or agreement to participate. It should be made clear that participation is voluntary. If compensation or financial inducements are offered the terms and conditions should be stated. If funding for the research is being sought or obtained, this needs to be stated, as does the source.

Data storage/retention/destruction/future use

Explain how, where, for how long and in what format data will be stored and subsequently destroyed. If data will be retained beyond the completion of the research for which it was collected, explain why. State if data is to be transferred to a public repository.

If audio, video, electronic, or other means of recording are involved this should be indicated. If such recording is optional, the PIS should indicate this. If it is intended that a participant's recordings (audio, video, or pictures) can be reviewed by the participant, the researcher should explain the process. If third parties are involved (for example, in transcription, translation, editing or cultural comment), indicate who will view the data, for what purpose, and how confidentiality of information and participation will be preserved.

The PIS for third parties, such as Chief Executive Officers, Boards of Trustees should indicate that interviews will be recorded only with the consent of the interviewee. Recorded interviews of this type cannot be shared with third parties. If this is intended it must be clearly documented for all concerned.

Right to Withdraw from Participation

Participants have the right to withdraw from participation at any time. Participants must be given the right to withdraw their data from the research up to a specified date or period of time. (Note: Obviously this cannot happen with anonymous questionnaires.)

Anonymity and Confidentiality

If anonymity with respect to the participant's identity cannot be guaranteed this must be indicated. If anonymity with respect to the identity of non-participants cannot be guaranteed this must be indicated. If confidentiality with respect to the participant's identity cannot be guaranteed this must be indicated. If confidentiality is offered, it should be made clear how the information the participants provide will be reported or published. If the research involves focus groups, interviews with small numbers of individuals, or interviews with well-known members of the community it must be indicated that confidentiality with respect to the participant's identity cannot be guaranteed. If the research is web-based, if encryption is used, or if some other method is used to preserve the anonymity of participants this should be described.

Contact Details and Approval Wording
Provide contact details for the researcher, supervisor and HOD. These should include name, email and /or postal address, and phone no. If the research is conducted outside New Zealand provide local contact details, as well as those of contacts at the University.

Chair contact details: "For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 extn. 87830/83761. Email: humanethics@auckland.ac.nz."

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON …… for (3) years, Reference Number …../……

5b) Consent Form

Please note that this is only a sample. To develop your own document, please refer to the Applicants' Manual Section 2d): Checklist for the Consent Form (CF).

Department name
Department address
Department phone no

The University of Auckland
Private Bag 92019
Auckland, New Zealand

CONSENT FORM
(Address by category, e.g. Manager)
THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS

Project title:
Name(s) of Researcher(s):

I have read the Participant Information Sheet, have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.

- I agree to take part in this research.
- I understand that I am free to withdraw participation at any time, and to withdraw any data traceable to me up to a specified date (give an actual date) / period.
- I agree / do not agree to be audiotaped.
- I wish / do not wish to have my tapes returned to me.
- I wish / do not wish to receive the summary of findings.
- I agree to not disclose anything discussed in the focus group.
- I understand that a third party who has signed a confidentiality agreement will transcribe the tapes.
- I understand that data will be kept for 6 years, after which they will be destroyed.

Name _____

Signature _____ Date _____

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON ……FOR (3) YEARS REFERENCE NUMBER ..../…

5c) Transcriber Confidentiality Agreement

Please note this is only a sample.

Department Name
Department address
Department phone no

The University of Auckland
Private Bag 92019
Auckland, New Zealand

TRANSCRIBER CONFIDENTIALITY AGREEMENT

Project Title:
Researcher:
Supervisor:
Transcriber:

I agree to transcribe the audiotapes/videotapes for the above research project. I understand that the information contained within them is confidential and must not be disclosed to, or discussed with, anyone other than the researcher and his/her supervisor(s).

Name: _____

Signature: _____

Date: _____

5d) Forms A and B

Form A: Declaration of eligibility of a clinical trial for consideration of coverage under accident compensation legislation

This form is to be completed and the statutory declaration signed by the registered health practitioner who is providing treatment as part of the research. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study.

The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that the proposed research is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for cover under accident compensation legislation for injury caused as a result of their participation in the research.

Note: Applicants conducting a research study that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

Declaration A trials: to be included on information sheet under the heading "Compensation"

'In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Accident Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

'If you have any questions about ACC, contact your nearest ACC office or the investigator.

'You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.'

Form A: Declaration of Eligibility of a Clinical Trial for Consideration of Coverage under Accident Compensation Legislation

Instructions: This form is to be completed and the statutory declaration signed by the most senior registered health professional providing or directing the provision of treatment as part of the research. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that the proposed research is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for coverage under accident compensation legislation for injury caused as a result of their participation in the research.

Details of proposed research study

Title of research project:	
Name of research director/investigator:	
Location/s of proposed study:	
Number of participants:	
Organisations providing support (in money or kind) for the direct and indirect costs of the research *(please provide names of organisations and details of the type of support provided)*:	
Relationship of proposed research to the pharmaceutical industry or other company involved in health research *(please describe the involvement of industry in your proposed research and provide details of support to be received from them)*:	

Statutory declaration

I (name) of (town/city) solemnly and sincerely declare that as the most senior registered health professional providing or directing the provision of treatment as part of the research, the proposed study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name *(please print)* Signature this day of

before me

Name of witness *(please print)*	Signature of witness
a Justice of the Peace, or	☐
a Solicitor of the High Court	☐
or other person authorised to take a statutory declaration.	☐

Warning: Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

Form B: Declaration of provision of compensation for injury for participants in a research study for a pharmaceutical company or any other company involved in health research

This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research.

The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

- the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
- participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research study.
- researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.

Note: Applicants applying for approval for a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out should complete Form A.

Declaration B trials: to be included on information sheet under the heading "Compensation"

'The (insert name of committee) Ethics Committee has certified that this clinical trial is being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which this trial is being carried out. This means that **if you suffer injury as a result of your participation in this trial, you will not be eligible for cover under accident compensation legislation**. Compensation, however, will be provided by (insert name of company) in accordance with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials: Compensation for injury resulting from participation in industry sponsored clinical trials*.

'These Researched Medicines Industry (RMI) Guidelines are only guidelines, and until your claim is assessed by the insurers of (insert name of company) it cannot be said with any certainty exactly what type or amount of compensation you will receive if you suffer injury as a result of your participation or what sort of injury will be covered. The guidelines require that compensation be provided by (insert name of company) where the injury you suffer is serious and not just temporary and is one caused by the trial medicine or item or where you would not have suffered injury but for your inclusion in this trial.

'The guidelines require that the compensation you receive be appropriate to the nature, severity and persistence of your injury. This means that you will be unlikely to receive compensation from (insert name of company) unless your injury is serious and not just temporary.'

You will also not receive compensation from (insert name of company) in this trial if (include other exclusions, for example, if mental injury is excluded this must be stated).

You might not receive compensation from (insert name of company) if your injury was caused by the investigators, if there is a deviation from the proposed plan of research, or if your injury was caused solely by you. If you are injured as a result of the trial, but your injury was caused by the investigators (or the institution/hospital where the trial took place) or as a result of a deviation from the proposed plan of research, you will **not be covered by** ACC and may have to pursue a civil action against the investigators (or institution). Ethics committees require that researchers and their institution have indemnity cover for such risk.

'You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.'

Note: If the trial includes placebo/standard treatment, the investigators will need to check with the company whether there is compensation for participants being using placebo treatment. If there is no compensation for this, it should be stated in the last sentence of paragraph four of the declaration above. The declaration should also make it clear why participants on placebo are not covered, for example, because there are not the same risks involved.

Form B: Declaration of Provision of Compensation for Injury for Participants in a Research Study for a Pharmaceutical Company or any Other Company Involved in Health Research

Instructions: This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

- the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
- participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research project.
- researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.

Details of proposed research project

Title of research project:	
Name of research director/investigator:	
Location of proposed study:	
Number of participants:	
Organisations providing support (in money or kind) for the direct and indirect costs of the research *(please provide names of organisations and details of the type of support provided)*:	
Relationship of proposed research to the pharmaceutical industry or other company involved in health research *(please describe the involvement of industry in your proposed research and provide details of support to be received from them)*:	
Details of compensation to be provided to participants in the event of injury *(documents signed by the sponsoring pharmaceutical company or other company involved in health research must be attached)*:	

Statutory declaration

I (name) of (town/city) solemnly and sincerely declare that as director of the proposed research, the proposed study is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out and that in the event of injury arising from their participation in the research, an appropriate level of compensation, in line with the *New Zealand Researched Medicines*

Industry Guidelines on Clinical Trials – Compensation for Injury Resulting from Participation in Industry Sponsored Clinical Trials, will be provided by (name of pharmaceutical company or another company involved in the research project) as detailed in the attached documents, unless the injury is a result of a significant deviation from the study protocol. I confirm that I, my research staff and the host institution have indemnity insurance that covers injury as a result of significant deviation from the study protocol. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name *(please print)*	Signature	this day of

before me

Name of witness *(please print)*	Signature of witness

a Justice of the Peace, or ☐

a Solicitor of the High Court ☐

or other person authorised to take a statutory declaration. ☐

Warning: Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form A.

Section 6: Glossary

ACC
ACC refers to where a person has cover and entitlements under the Accident Compensation Act 2001.

Adverse events in research
Adverse events are defined as any unfavourable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome, or disease that occurs during the research, or appears to worsen.

Serious adverse events are those that result in death, are life threatening, require hospitalisation, cause persistent or significant disability/ incapacity, result in birth defects, or other conditions which in the judgment of the researchers represent significant hazards.

Anonymity
A response is anonymous when neither the researcher nor those who read the published results of the research can identify that response as belonging to any particular participant.

Assent
Assent is the agreement to participate in research offered by someone able to understand what is required but not of an age or ability to give his or her consent. Assent may be given verbally. The researcher should keep a recording of it.

Child/minor
A child/minor is a participant under 16 years of age in New Zealand.

Clinical trials
UAPHEC adopts the definition of clinical trial of the World Health Organisation and New Zealand Ministry of Health. That definition is "a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".

Requirements for Ethical Approval of a Clinical Trial
The HRC provides Referral Guidelines that influence the decision to be made between ethical review at UAHPEC or a regional Health and Disabilities Ethics Committee.

Confidentiality
A response is confidential when the participants' identity is known to the researcher and will not be disclosed by the researcher in any discussion or report of the research. Confidentiality of information means that any report or discussion of the information given by the participant will be done in a way that does not identify the participant as the source of the information.

It may be misleading to describe the information collected during the research as confidential if it will be reported or published.

Consent Form (CF)
A CF is a document stating the terms upon which a person agrees to participate in research. It is signed by the participant and retained by the researcher. UAHPEC may give permission for consent to be obtained orally, where there are cultural, safety, or other special reasons.

The CF must be retained by the researcher and stored on University premises under the control of the Supervisor or Principal Investigator for a period of 6 years.

Guardian/caregiver of a child
A guardian/caregiver of a child is the person who has legal responsibility for the day-to-day care and decision-making in relation to a child.

Intervention Study
In an intervention study, the investigator controls and studies the intervention(s) provided to participants, for the purpose of adding to knowledge of the health effects of the interventions(s). The term "intervention study" is often used interchangeably with "experimental study". Many intervention studies are clinical trials.

Interview Schedule
An interview schedule is an outline of the topics to be discussed at an interview. The purpose of this schedule is to enable UAHPEC to determine whether the PIS adequately informs the participants of the nature of the interview. Such a schedule must be attached to the application.

Participant
A participant is a person with whom there is some intervention or interaction that would not be occurring or would be occurring in some other fashion but for the research, or as a result of the research. There are special requirements for ethical approval where the participants are involved in the research because of their membership of a particular community that is the focus of the research.

Participant Information Sheet (PIS)
The PIS is the document that informs the participant about the research and the nature of the involvement required. The participant retains it. Generally, the PIS must be in a written format. However in the case of telephone research, or in research in predominantly oral cultures, a researcher may make a case to present the information orally. In these cases a copy of the information to be presented orally must be submitted to UAHPEC for review.

Pilot study
A pilot study is one in which preliminary research protocols are trialled. Hence, a pilot study involves human participants in research procedures and requires the approval of UAHPEC. A pilot study can be distinguished from preliminary discussions with key informants to assist with the development of the research aims or design. Such preliminary discussions do not require the approval of UAHPEC.

Questionnaire
A questionnaire is a written or electronic list of questions to be answered by participants.

Research
UAPHEC operationally defines research as any original investigative activity by a staff member or student of the university that requires the active involvement of human participants. This activity includes, but is not restricted to, experimental research, clinical trials not involving clients of any District Health Board (see Clinical Trials), questionnaires, interviews, audits, demonstrations, course-based exercises, and evaluations (with the exception of course and teaching evaluations). Research includes investigations of any bodily materials of any person. Research includes preliminary or pilot investigations and may be quantitative or qualitative in nature. Research may involve participants in New Zealand or overseas, of any age, sex, or possessing any other characteristic or experience that is of relevance to the researcher, including being members of the general public.

Surveys
Generally the UAHPEC prefers more precise words than survey e.g. questionnaire, interview, review, etc.

Subjects
UAHPEC does not use the word "subjects" anymore. The term "participants" is used as it has a broader definition (see "**Participant**").

Appendix: The Privacy Act 1993

The protection of privacy is both a legal requirement and also a significant ethical concern. Naturally, the UAHPEC does not provide legal advice on these matters; nor can we provide anything more than basic guidance. (You should note that the Privacy Commissioner provides a significant amount of information, including on Codes of Practice which supplement the Act (and in some circumstances these may set out more stringent requirements): www.privacy.org.nz; see also the University's policy relating to privacy, which can be found at http://www.auckland.ac.nz/University of Auckland/home/privacy which gives guidance on the University's policy on the collection, use, disclosure and correction of data it holds. The University has a Privacy Officer who deals with its policy and issues arising.

The UAHPEC looks to ensure that both legal requirements relating to the Privacy Act and ethical standards relating to privacy issues are met as part of its process of reviewing whether to grant approval. For that reason, the following points should be noted, as they may be important in a particular case.

In the first place, compliance with the requirements of the Privacy Act and any relevant code is relevant to ethical approval in two separate ways. There is both the requirement that researchers collect and store information in a manner that complies with legal and ethical requirements relating to privacy. But where the research involves reviewing data that has been obtained by another organisation, it is also necessary for researchers to ensure that the organisation that is hosting the research or allowing access to data it has collected is complying with its privacy obligations in allowing access to that information for research purposes.

Of the Information Privacy Principles set out in the Privacy Act 1993, some are of particular relevance to researchers. The implications of most of these principles are self-evident, but we have added some emphases and comments:

1. Personal information can only be collected for a lawful purpose. [That would include research purposes.]

2. It shall be collected from the individual unless it is publicly available, *or authority has been given* for it to be collected from someone else, or it would *not prejudice the interests of the person*, or non-compliance is necessary for law enforcement and the like, or compliance would prejudice the purposes of the collection, or compliance is *not reasonably practicable*, or the information *will not allow the individual to be identified*, or will be *used for statistical or research purposes and will not be published so as to identify the individual*. [Note that the various exemptions are relevant only to the question of whether it is possible to *collect* personal information other than directly from the individual: see 10 and 11 below for the principles relating to the use of information.]

3. Where information is collected from individuals, they have to know the *purpose and the intended recipients* etc. However, this is subject to exceptions that are similar to those under principle 2. [Again, this is relevant only to the question of the collection of the information: see 10 and 11 below for the principles relating to the use of information.]

4. Only lawful and fair means shall be used to collect information. [This may have an impact on the methods used in research.]

5. Information has to be stored securely. [This explains the requirements the UAHPEC has about the storage of information collected.]

6. People have a basic right of access to information held about them where it can be retrieved readily.

7. People are entitled to seek correction of any inaccuracies.

8. *The holder of information shall not use it without taking reasonable steps to ensure that it is accurate, up to date, complete, relevant and not misleading.*

9. Times limits are imposed – no longer than necessary (depending on the purposes for which the information may be used).

10. Information obtained for one purpose shall not be used for another purpose unless it is publicly available, *or authority has been given* by the person, or it is necessary for law enforcement and the like, or to prevent or lessen a serious or imminent threat to public health or safety or the life or health of the individual or another, or the purpose is *directly related to that for which the information was collected*, or the information is used in a form that *will not allow the individual to be identified*, or will be *used for statistical or research purposes and will not be published so as to identify the individual*. [Note that there are some differences between the exceptions applicable under principles 2 and 3: in particular, the exceptions for not prejudicing the interests of the person or compliance not being reasonably practicable are missing. This principle and principle 11 below are of clear importance when a researcher is reviewing material stored by another organisation: the University of AucklandHPEC will look at what consent was given to the organisation at the time it collected the data as to the circumstances in which the information might be used further for the purposes of research, and if no express consent has been given for that further purpose, the Committee will look to whether or not any identifying material might be released, including to those involved in carrying out the research. It should be noted that the basic principle is that people have the right to control access to their private data and so express consent to the use of data is the most obviously suitable scenario: reliance on other circumstances may nevertheless be ethical on the facts of a particular case.]

11. The *body holding information cannot disclose it unless it is for a purpose for which it was obtained (or a directly related purpose)*, or it is publicly available, or has been *authorised by the individual*, or non-compliance with this requirement is necessary for law enforcement and the like or to prevent or lessen a serious or imminent threat to public health or safety or the life or health of the individual or another, or the purpose is *directly related to that for which the information was collected*, or the information is used in a form that *will not allow the individual to be identified*, or will be *used for statistical or research purposes and will not be published so as to identify the individual*.

12. Unique identifiers are to be used only when necessary.