

LA TROBE UNIVERSITY
FACULTY OF HEALTH SCIENCES
FACULTY HUMAN ETHICS COMMITTEE

INSTRUCTIONS TO STAFF SUPERVISING TEACHING PROJECTS/PRACTICAL CLASSES INVOLVING HUMAN PARTICIPANTS

Teaching Projects/Practical Classes involving human participants require the approval of an Ethics Committee in the following circumstances:

- (a) Where the procedures could be associated with potentially unpleasant, stressful, noxious, aversive or harmful effects
- (b) Where the participants will be asked to commit any acts which might diminish self-esteem or cause them to experience embarrassment or regret
- (c) Where samples of body fluid or body tissue will be taken
- (d) Where the project/class involves the administration or withdrawal of any substances or agents
- (e) Where the project/class involves deception of participants
- (f) Where people other than students enrolled in the subject(s) will be participants
- (g) Where the project/class involves data collection for research purposes

Master Classes are considered the equivalent of practical classes and refer to classes where students observe a clinician demonstrating practice on a real client rather than on a simulated patient. The client/clinician may be internal or external to the University. These classes require the approval of an Ethics Committee and a full ethics application must be submitted to the FHEC.

Note Carefully:

1. Regardless of whether the teaching project/practical class requires approval of an Ethics Committee, the attached "CHECKLIST AND ETHICAL PRINCIPLES DECLARATION FOR TEACHING PROJECTS/PRACTICAL CLASSES" must be completed (see below).

2. In cases where data will be collected for research purposes during the teaching projects/practical class, the researcher should complete the standard Application for Ethics Approval: Research Projects.

Further information about the principles and procedures involved may be found in the brochure entitled ***Ethics Approval for Research with Human Subjects: Guidelines for Research and Teaching*** available from the Secretary of the Faculty Human Ethics Committee (FHEC), Faculty Office, Bundoora - telephone 9479 3583. A copy of these guidelines is also available on the Faculty Office Public file server.

GENERAL ADVICE

Ethics approval for teaching projects/practical classes is given for a maximum period of 5 years. Where there are changes to the teaching project/practical class within this period, the staff member responsible for the teaching project/practical class must seek approval from FHEC to modify the procedures.

Normally, enrolment in the relevant subject(s)/class(es) constitutes consent to participate in the teaching project/practical class. Participants must, however, be informed in advance (through the subject outline, workbook, or similar) of the procedures or activities involved.

This advice must include reference to the FHEC as the authority approving teaching projects/practical classes involving human participation and advice that complaints or queries, not able to be dealt with by the staff member in charge, should be addressed to the Secretary of the FHEC. In cases where participants are people other than students, standard information sheets must be provided and, in most cases, standard informed consent procedures should be followed (see Guidelines for Completion of FHEC Application Form for Teaching Projects/Practical Classes).

Please note that some applications require approval by the University's Human Ethics Committee (HEC). University HEC approval may be required when the teaching project/practical class involves:

- (a) risk of physical, mental, or social harm - e.g. the collection of body tissues or fluid samples, the administration of pain, the administration of any substances or agents
- (b) possible breaches of legislation (usually relating to access to personal records)
- (c) secondary use of existing human specimens

Applications which require approval by the University's HEC will be forwarded to HEC by the Secretary of FHEC, and the staff member will be notified.

APPLICATION FORMS

Staff seeking ethics approval for teaching projects/practical classes should first complete the "CHECKLIST AND ETHICAL PRINCIPALS DECLARATION FOR TEACHING PROJECTS/PRACTICAL CLASSES". Where the responses to the checklist indicate that no items with asterisks have been ticked for that teaching project/practical class, no further documentation is required by FHEC. In cases where one or more items with an asterisk on the checklist have been ticked, a full application for ethics approval must be submitted along with the checklist.

The attached forms may be photocopied as required. Additional copies of the forms may be obtained from the Secretary, FHEC, Faculty Office, Bundoora - telephone 9479 3583. A copy of the forms is also available on the Faculty Office Public file server or on disk (Word) on request.

Please ensure that your application:

- is typed
- uses lay language
- is complete (all questions answered/signatures included).

Please note that one application form may be used for teaching projects/practical classes associated with more than one subject as long as the projects/classes involve the same procedures.

All applications should be forwarded to:

**The Secretary FHEC
Faculty of Health Sciences
La Trobe University
Bundoora, Victoria 3086**

Correspondence from FHEC will be directed to the staff member responsible for the teaching project/practical class.

La Trobe University
Human Ethics Committee
Faculty Human Ethics Committee

OFFICE USE ONLY
Register Number

**CHECK LIST & ETHICAL PRINCIPLES DECLARATION
FOR TEACHING PROJECTS/PRACTICAL CLASSES**

Date received

For each teaching project/practical class **involving human participants** the School is required to complete the following checklist to be forwarded to the Faculty Human Ethics Committee.

Tick the appropriate box for each numbered question and add explanatory comments as appropriate.

If any box containing an asterisk has been ticked, an application for ethics approval (teaching projects/practical classes) must be submitted to the Faculty of Health Sciences Human Ethics committee along with this check list.

If no box containing an asterisk has been ticked, further documentation is not required by the Ethics committee.

NA below stands for not applicable.

Title of Teaching Project / Practical Class

Subject's Name(s) And Code(s)

Semester(s) conducted

- 1 a). Is equipment to be used which employs a main electrical supply? [] Yes [] No
- b). Is the equipment standard, commonly used equipment such as computer keyboard or data analysis equipment which can normally assumed to be safe? [] Yes [*] No [] NA
- -----

- c). Will appropriate biological isolation be used if the participant is physically connected to such equipment (e.g. EMG, ECG, audiometer)? [] Yes [*] No [] NA
- -----

- d). Will participants be electrically or magnetically stimulated? [*] Yes [] No [] NA
- -----

2. Is it likely participants will experience pain? Yes No
- 3 a). Will participants be asked to exercise? Yes No
- b). Will participants be required to pass a Physical Activity Readiness questionnaire before participation?
(a questionnaire which covers major risk factors identified by the American College of Sports Medicine is available from Faculty Office)

- c). Will appropriate safeguards be in place to ensure that heart rate does not exceed 80% of age predicted maximum? Yes No NA

- d). Will VO₂ max testing be performed? Yes No
- e). Will participants be under the age of 35 years? Yes No NA
4. Will deception be used? Yes No
- 5 a). If interviews are to be conducted will they be tape-recorded? Yes No NA
- b). Will tape-recording be destroyed after the completion and/or on completion of student assessment of that subject? Yes No NA
- 6 a). Will participants have pictures taken of them (eg. photographs, videos)? Yes No
- b). Will pictures be destroyed after the completion and/or on completion of student assessment of that subject? Yes No NA
7. Will participants be asked to commit any acts, be subjected to procedures (e.g. videos, photographs, tape recordings) or questions which might diminish self-esteem or cause them to experience embarrassment or regret? Yes No
8. Does the project/class involve any stimuli, tasks, investigation or procedures which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the procedures? Yes No
9. Will samples of human body fluid or body tissue be required specifically for the project/class? Yes No
- 10 a). Will participants handle samples of animal tissue or fluids in

- the project/class? Yes No
- b). If yes, will reasonable precautions be taken to ensure against infection? Yes * No NA
- -----

- 11** a). Will participants be administered any substance or agent? Yes No
- b). Will participants be required to breathe a gas mixture other than room air? Yes No
- c). If yes, is the gas standard medical oxygen, medical air or oxygen/carbon dioxide mixture ? Yes * No NA
- d). Will subjects be asked to breath gas mixtures which could cause harm if accidentally breathed for longer than stipulated? * Yes No
- e). Will any substance be ingested, inhaled or snorted in a quantity which could be harmful? * Yes No
- f). Will administration be via injection or skin prick? * Yes No NA
- 12.** Will the practical class or project involve the withdrawal of any substance or agent (e.g. food, medication)? * Yes No
- 13.** Is any equipment which could potentially be a source of infection appropriately sterile and/or disinfected before and after use? Yes * No NA
- -----

- 14.** For respiratory classes will precautions be undertaken to ensure that dribbled human saliva does not contaminate equipment and working space? Yes * No NA
- -----

- 15.** Will students with relevant health problems be exempt from participation? (eg. hyperventilation by students with respiratory problems): Yes * No NA
- 16.** Will anybody other than students enrolled in the subject be participants? * Yes No
- 17** a). Will the project / practical class be on campus? Yes No

- b). State the Building and Room Number [] Yes [] No
- c). Will the project/practical class take place in another Institution? [] Yes [] No
- d). If permission is required by another Institution, has permission been obtained [] Yes [*] No [] NA
- 18.** Will participants be fingerprinted or DNA "fingerprinted"? [*] Yes [] No
- 19.** Are there in your opinion other ethical issues involved in the project/practical class? [*] Yes [] No
- 20.** Is the project/practical class documented in a student manual or similar? [] Yes [] No
- 21.** Are instructions for the safe conduct of procedures provided for subjects where required? [] Yes [*] No [] NA
- 22.** Will data be collected for research purposes during the project/practical class? (If yes the researcher must complete the standard Application for Ethics Approval: Research Projects) [*] Yes [] No

If you have answered each question and one or more boxes containing an asterisk has been ticked, please complete a full application for ethics approval.

If you have answered each question and no box containing an asterisk has been ticked please sign the declaration below.

DECLARATION BY STAFF MEMBER IN CHARGE

I/We accept responsibility for the conduct of this class in accordance with the ethical principles specified by the La Trobe University Human Ethics Committee.

Name

Signature

Date

Name

Signature

Date

LA TROBE UNIVERSITY
FACULTY OF HEALTH SCIENCES
FACULTY HUMAN ETHICS COMMITTEE (FHEC)

Guidelines for Completion of FHEC Application Form for Teaching Projects/Practical Classes

Section A. General Information

1. (a) Title of Teaching Project/Practical Class

Choose a short, simple and self explanatory title which will identify for participants and FHEC members the essential point of the teaching project/practical class.

(b) Subject Name(s) and Code(s)

In cases where more than one subject involves essentially the same teaching project/practical class, only one application is required.

Section B. Teaching Project/Practical Class Particulars

1. Educational Aims and Brief Description of Procedures

State clearly and simply the educational aims of the teaching project/practical class, who the participants will be, and outline all procedures to which the participants will be subjected. Attach relevant extracts from subject manuals/handbooks/handouts which provide details of the procedures involved. If a questionnaire or interview schedule will be used, please attach a copy to the application form.

FHEC needs to form a clear understanding of the aims and value of the teaching project/practical class if it is to weigh the possible benefits of the project or class against the burden for participants. Burden for the participants includes discomfort, inconvenience, risk to psycho-social or physical health and loss of privacy. Where there is considerable burden for participants, it is important to explain how the burden will be minimised.

2. Participant Details

In cases where participants include people other than the students enrolled in the subject, details of the participants who are not students enrolled in the subject must be provided. Be as precise as possible about the number of such participants, their state of health, the method of recruitment, compensation and the involvement of special groups.

(c) If participants other than the students enrolled in the subject will have any psychological, cognitive or physical impairment or disability, tick 'Other' and state clearly the nature of the impairment or disability.

(d) Explain clearly how you will gain access to participants other than the students enrolled in the subject for the teaching project/practical class. Include details of how you will gain access to confidential data and/or names and contact details for participants and who will make the first contact with potential participants to ask if they wish to participate in the project.

(f) This section needs to be completed if participants other than the students enrolled in the subject are groups or persons in dependent relationships (e.g., children, persons with certain disabilities) or persons who are not legally competent to give informed consent; these groups will require special permission to participate in the teaching project/practical class. Some other types of practical classes (e.g., those conducted in schools or workplaces or in remote Aboriginal communities) may also require special permission or consultation. If special permission or consultation is required, describe the cases involved and the procedures to be followed to obtain permission or for consultation.

3. Samples

Note that this section covers access to banks of data of any kind (e.g. medical records, data held by Commonwealth departments or agencies), not only human pathology and diagnostic specimens. You should indicate here the sources(s) of such data and ensure that Section B, item 5 is completed.

4. Location of Teaching Project/Practical Class

Indicate the precise location of the teaching project/practical class and how permission will be obtained if it will be located outside of the University. Give details such as the School and Campus of the University and the name and address of locations external to the University. State whether the study will be located in the participant's home or workplace. Ensure that Section B, item 5 is completed if permission is required to use locations external to the University.

5. External Approvals

Regardless of whether approval has been obtained, state which institution, ethics committee, or next of kin approvals are required. If approvals have not been obtained, state when approvals are likely to be obtained. Please note that no teaching project/practical class may commence until such approvals are provided.

Ensure that external approvals are on the institution's or organisation's letterhead and that the approvals are very specific as to what approval is given for (i.e. a general statement of permission to conduct teaching project project/practical class 'x' is not sufficient). Ensure that you have applied for approval from external Institutional Ethics Committees when required.

6. Informed Consent

Normally, enrolment in the relevant subject(s)/class(es) constitutes consent to participate in the teaching project/practical class. Participants must, however, be informed in advance (through the subject outline, workbook, or similar) of the details of all procedures or activities involved. This advice must include reference to the FHEC as the authority approving teaching projects/practical classes involving human participation and advice that complaints or queries, not able to be dealt with by the staff member in charge, should be addressed to the Secretary of the FHEC.

In cases where participants are people other than students enrolled in the subject, standard Information Sheets must be provided in virtually every case. Exceptions to the requirement for information sheets include cases where participants are employed by the University to be participants in the teaching project/practical class (e.g., simulated patients) (i.e., where conditions of employment have been specified and where health and safety requirements have been met).

In addition, in most cases where participants are people other than students enrolled in the subject, standard written informed consent procedures should be followed. Written consent is required:

- a) where the procedures could be associated with potentially unpleasant, stressful, noxious, aversive or harmful effects
- b) where the participants will be asked to commit any acts which might diminish self-esteem or cause them to experience embarrassment or regret
- c) where samples of body fluid or body tissue will be taken
- d) where the project/class involves the administration or withdrawal of any substances or agents or
- e) where the project/class involves deception of participants

Exceptions to the requirement for written consent include teaching projects/practical classes which do not involve any of a) to e) above, and may also include mass-distribution questionnaires where return of the questionnaire is reasonably taken as an indication of voluntary consent to participate. Please note that if questionnaires are to be coded for any purpose (e.g. further mail-outs), participants must be informed of this procedure.

An outline of the required components of Information Sheets and Consent Forms and a possible format of such forms is attached to these guidelines.

7. Is there any Risk to the Participant?

This item asks you to outline any physical or psycho-social harm or risks to the participants. You should also explain how those risks will be minimised and state what procedures will be in place to ensure the well being of participants should the risk events occur.

8. Administration of Substances/Agents , 9. Sampling of Body Fluids or Tissues, & 10. Withdrawal of Substances/Agents

Please note that teaching projects/practical classes which involve administration or withdrawal of substances or sampling of body fluids or tissues will normally be directed to the University HEC rather than to FHEC.

11. Medical or Paramedical Statement

If the teaching project/practical class involves administration or withdrawal of substances or invasive procedures, please attach a statement accepting responsibility for those procedures by a medical or paramedical practitioner with indemnity insurance.

12. First Aid

If the teaching project/practical class involves possible physical risk, a person trained in first aid should be on call and FHEC approval will rarely be given unless this is the case.

13. Students with Health Problems

If particular health problems could lead to physical or psycho-social risks to the participants, please explain whether or not students with such health problems will be exempt from the teaching project/practical class; FHEC approval will rarely be given in such cases unless exemption criteria are in place.

Section C. Confidentiality of Records

1. Recording of Data

(a) How will data be recorded?

State whether data will be computer records, written records, photographic records, audiotapes, videotapes and/or CD-ROMs. Please note that materials collected in the teaching project/practical class which would allow identification of individuals, cannot be used for teaching purposes, reports or presentations unless participants provide explicit permission to do so.

(b) Will confidentiality of results be maintained?

State how your data collection and recording procedures will maintain the participants' confidentiality. Confidentiality can be maintained by not recording participant names or any other identifying information, using participant codes for identification, keeping results separately from lists of names and codes, and by ensuring that no individual can be identified in any reports or presentations arising from the teaching project/practical class.

2. Security of Data

If data is to be kept after completion of the teaching project/practical class, specify the precise location of the storage place and explain who will have access to the data. Give details such as the storage medium (e.g. locked filing cabinet, secure computer files) and location (e.g., School and Campus of the University, department in a specified external institution). If data obtained from participants is to be kept by students after completion of the teaching project/practical class, this should also be stated here.

3. How and When Will Recorded Data be Destroyed?

Where appropriate, describe the procedures to be used to destroy computer records, written records, photographic records, audiotapes, videotapes and/or data on CD-ROM.

4. Declarations

All La Trobe University staff involved in the teaching /practical class must sign the Declaration.

PREPARATION OF INFORMATION SHEET AND CONSENT FORM FOR PEOPLE OTHER THAN STUDENTS ENROLLED IN THE SUBJECT(S)

Persons who are asked to participate in a teaching project/practical class must be properly informed as to what they are being asked to do and the likely consequences for them if they choose to participate. You are required to provide participants with a written statement describing the project and its associated harms and risks so that they may make an **informed** choice as to whether or not they will participate. What is required is a summary written from the participant's point of view, in **simple non-technical language**, of the essential points which any reasonable person would wish to know before agreeing to participate. Participants must be provided with their own copy of the Information Sheet to keep.

The format and content of the Information Sheet should not normally vary from the format below:

1. La Trobe University School/Department Letterhead must appear at the top of the page;
2. Title of the teaching project/practical class (Block Letters) in words the participants will understand and name and code of the relevant subject(s);
3. Name and position of the staff member responsible for the teaching project/practical class;
4. A description of the aims of the teaching project/practical class and how the participant has come to be selected to participate;
5. A description of the teaching project/practical class procedures including the anticipated time commitment expected of the participant, the information you will be obtaining, the sources of that information, and any actual physical interventions;
6. A statement of any risks, discomforts or harms which may result from participation in the teaching project/practical class. Include an explanation of how any such risks or harms will be minimised and a statement of who would **not** be able to participate (e.g. pregnant women, asthmatics etc);
7. A statement which details the use of the data. This must be explained in sufficient detail that participants will be able to give informed consent as to the actual use of the data. This statement must include:
 - procedures to be followed to ensure security and confidentiality of data
 - where appropriate, an explanation of how data will be used after completion of the practical class (e.g., for student assignments, for teaching purposes)
 - when and how raw data will be destroyed
8. A statement which explains that there are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the teaching project/practical class. This is particularly important where participants are dependent on the researcher or their professional colleagues for continuing treatment or care (e.g., persons who are clients in clinical settings associated with the research) or where the participants are students of the researcher;
11. An offer to answer any questions concerning the teaching project/practical class in the following terms: Any questions regarding this teaching project/practical class titled (teaching project/practical class title) may be directed to (name) of the (school,

department, etc) on telephone number (insert number).

12. A statement advising method of complaint/query as follows: If you have any complaints or queries that the staff member has been unable to answer, you may contact the Secretary of the Faculty Human Ethics Committee, Faculty of Health Sciences, La Trobe University, Bundoora, Victoria 3086 Ph: (03) 9479 3583.

Where a written consent form is also required, the format and content of the Consent Form should not normally vary from the format below and should be appended to the Information Sheet. Participants must be provided with their own copy of the Consent form to keep. Please note that if the staff member wishes to use materials collected during the teaching project/practical class which would allow identification of individuals, for teaching purposes, reports or professional presentations, participants must be asked to provide explicit permission to do so; this permission should be included within item 1 below:

1. A signed statement of agreement to participate, as follows: I....., have read and understood the above information, and any questions I have asked have been answered to my satisfaction. I agree to participate in this teaching project/practical class, realising that I may withdraw at any time.

2. Provision for signatures of the participant (or guardian) and staff member responsible for the teaching project/practical class at the end of the form, as follows:

NAME OF PARTICIPANT (in block letters):

Signature: DATE:

NAME OF PARENT OR GUARDIAN (in block letters):

Signature: DATE:

NAME OF STAFF MEMBER RESPONSIBLE FOR THE TEACHING PROJECT/PRACTICAL CLASS:

.....

Signature: DATE:

(Sample Information Sheet and Consent Form)

Title of practical class: HEARING SCREENING PRACTICAL

Subject: HC1HS1 AUDIOLOGY 1

Responsible staff member: DR JANE HOLFORT, SENIOR LECTURER
SCHOOL OF HUMAN COMMUNICATION SCIENCES
LA TROBE UNIVERSITY

This practical class aims to provide first year speech pathology students with supervised experience in conducting brief hearing assessments of people with hearing impairment. All clients who have consulted Dr Holfort in the Audiology Clinic at the La Trobe Communication Clinic in the past 12 months and who are between the ages of 18 and 80 years and have a slight, mild, or moderate hearing impairment are being asked if they would like to participate.

If you agree to participate in this practical class, you will be asked to undergo a hearing screening assessment involving three tests:

- (i) a test of your ability to hear tones (sounds) of varying levels of loudness and pitch when presented through headphones into each ear separately
- (ii) a test of your ability to hear tones of varying levels of loudness and pitch when presented through a small microphone-like vibrating device (bone conductor) placed over the skin behind each ear
- (iii) a test of the mobility (movement) of the ear drum to tones and varying air pressures presented directly to your ear via a small probe or ear piece which is fitted into your ear canal; the probe will be in place in the ear for between 15 and 45 seconds

The tones will be produced by a standard audiometer which is similar to that used for the hearing assessments you have had previously in Dr Holfort's Audiology Clinic. In addition to the hearing assessment, the students will ask you to tell them your age, the length of time for which you have been aware of your hearing impairment, your view as to the probable cause of your hearing impairment and the extent to which the hearing impairment affects your daily life.

The three hearing tests will be conducted by a pair of first year speech pathology students under the supervision of Dr Holfort in the La Trobe Communication Clinic at the Bundoora campus of La Trobe University. You will be at the clinic for a total of 30 minutes.

While the first two hearing tests described above will involve no discomfort, the insertion of the probes into the ear canal for the third test may cause some discomfort in your ear. This discomfort, however, is slight and ceases as soon as the probe is removed. None of the hearing tests involves any risks or potential harm.

The results of your hearing tests and the information you give the students about your age and your hearing impairment will be written on to a printed form. Although the students and Dr Holfort will know who you are during this practical class, only your initials will be written on the printed forms. You will therefore remain anonymous to everyone apart from the staff member and the two students. After the practical class has been completed the students will keep the results of your hearing tests for a maximum of 2 weeks during which time they will prepare a 500 word written assignment about your hearing impairment; again, your name will not be printed on the assignment. The students will then submit the results of your hearing tests and the

assignment to Dr Holfort for marking; when marked, the assignment and results of your hearing test will be returned to the students to keep.

The management of your hearing impairment by Dr Holfort will not be affected in any way by your participation in this project. Similarly, the management of your hearing impairment by Dr Holfort will not be affected if you decide not to participate or to withdraw from the practical class at any time.

Any questions regarding this practical class titled "Hearing Screening Practical" may be directed to the responsible staff member, Dr Jane Holfort, of the School of Human Communication Sciences at La Trobe University on the telephone number (03) 9479 1940.

If you have any complaints or queries that the staff member has been unable to answer, you may contact the Secretary of the Faculty Human Ethics Committee, Faculty of Health Sciences, La Trobe University, Bundoora, Victoria 3083, telephone (03) 9479 3583.

I,, have read and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in this practical class, realising that I may withdraw at any time. I agree that information collected during the practical class may be included in the students' assignments, on condition that my name is not used.

NAME OF PARTICIPANT:

Signature: DATE:

NAME OF STUDENT:

Signature: DATE:

NAME OF STAFF MEMBER RESPONSIBLE FOR THE TEACHING PROJECT/PRACTICAL CLASS:

.....

Signature: DATE:

La Trobe University
Human Ethics Committee
Faculty Human Ethics Committee

OFFICE USE ONLY
Register Number

**APPLICATION FOR ETHICS APPROVAL
TEACHING PROJECTS/PRACTICAL CLASSES**

Date received

*TEACHING PROJECTS/PRACTICAL CLASSES SHOULD NOT COMMENCE WITHOUT
PRIOR WRITTEN APPROVAL FROM THE FHEC OR HEC*

SECTION A GENERAL INFORMATION

1. (a) Title of Teaching Project/Practical Class:

(b) Subject Name(s) and Code(s):

(c) Semester(s) when the Teaching Project/Practical Class will be conducted:

2. STAFF MEMBER RESPONSIBLE FOR TEACHING PROJECT(S)/PRACTICAL CLASS(ES)

Name Department

Position Telephone No.

Email address

Note: If the organisation and supervision of this project/class will be the responsibility of someone other than the staff member in charge (e.g. Senior Demonstrator), give name and contact number of that person.

Name Telephone No.

5. EXTERNAL APPROVALS (Note: If the teaching project/practical class requires approval from other institutions or ethics committees, next of kin etc. in case of Special Groups, a copy of such approvals must be provided to the HEC/FHEC at time of application or be made available as soon as possible. No teaching project/practical class may commence until such approvals are provided)

Please indicate as appropriate if formal clearance/permission has been obtained or sought:

(a) Institutional

Attached To follow (estimate when likely to be obtained) -----

(b) Next of Kin (for Special groups)

Attached To follow (estimate when likely to be obtained) -----

6. INFORMED CONSENT (Indicate whether individual Informed Consent forms will be used)

Yes (If yes, attach copy to the application)

No (Please explain)

7. IS THERE ANY RISK TO THE PARTICIPANT? NO YES
(If yes, explain and describe protective measures to be taken)

8. ADMINISTRATION OF SUBSTANCES/AGENTS (any chemical compounds, food, drugs or biological agents, dosage, frequency of administration and anticipated effects)

Name of substance(s):

Dosage per administration:

Frequency of administration:

Total amounts to be administered:

Anticipated effects: Not applicable

13. WILL STUDENTS WITH RELEVANT HEALTH PROBLEMS BE EXEMPT FROM PARTICIPATION? (eg. hyperventilation by students with respiratory problems): *(please explain)*

- N/A []
- Yes [] *(please explain exemption criteria)*
- No [] *(please explain)*

14. IN YOUR OPINION, ARE THERE ANY ETHICAL ISSUES INVOLVED IN THIS TEACHING PROJECT/PRACTICAL CLASS WHICH HAVE NOT BEEN COVERED BY THE ABOVE ITEMS? *(please explain)*

SECTION C CONFIDENTIALITY OF RECORDS

1. RECORDING OF DATA

(a) How will data be recorded?

(b) Will confidentiality of results be maintained?

- [] Yes *(detail below)*
- [] No *(please explain)*

2. SECURITY OF DATA *(indicate how security will be maintained if data is to be kept after completion of the teaching laboratory/practical class)*

3. HOW AND WHEN WILL RECORDED DATA BE DESTROYED?

4. DECLARATION BY STAFF MEMBER RESPONSIBLE FOR THE TEACHING PROJECT/PRACTICAL CLASS

I/We accept responsibility for the conduct of this class in accordance with the ethical principles specified by the La Trobe University Human Ethics Committee.

NameSignature

Date

NameSignature

Date

CHECKLIST

The following documents are attached *(please indicate)*

COPY OF PROPOSED INFORMED CONSENT FORM	[]
EVIDENCE OF PERMISSION TO USE PLACES OFF CAMPUS <i>(if applicable)</i>	[]
OF APPROVAL BY ANOTHER ETHICS COMMITTEE <i>(if applicable)</i>	EVIDENCE []
INSTITUTIONAL APPROVAL FOR ACCESS TO PARTICIPANTS	EXTERNAL []
COPY OF STATEMENT FROM MEDICAL/PARAMEDICAL ER ACCEPTING RESPONSIBILITY FOR	[] PRACTITION
S [Section B, Paragraph 11] <i>(if applicable)</i>	PROCEDURE
DETAILS OF ARRANGEMENTS FOR FIRST AID	[]
QUESTIONNAIRE /INTERVIEW SCHEDULE	[]
EXTRACTS FROM SUBJECT MANUALS/HANDBOOKS ETC.	RELEVANT []

***YOU ARE REMINDED THAT TEACHING PROJECTS/PRACTICAL CLASSES
SHOULD NOT COMMENCE WITHOUT PRIOR WRITTEN APPROVAL FROM FHEC
OR HEC.***

**PLEASE RETURN THE COMPLETED FORM AND RELEVANT ATTACHMENTS
TO THE SECRETARY, FHEC, FACULTY OF HEALTH SCIENCES, LA TROBE
UNIVERSITY, BUNDOORA, VICTORIA 3086.**