APPLICATION AND SUBMISSION GUIDELINES

HUMAN RESEARCH ETHICS APPLICATIONS
FULL HREC REVIEW

HUMAN RESEARCH ETHICS COMMITTEE
JAMES COOK UNIVERSITY

PLEASE READ

THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL'S *National Statement On Ethical Conduct In Human Research, 2007.*

THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL'S *Values and Ethics; Guidelines for Ethical conduct in Aboriginal and Torres Strait Islander Health Research, 2003.*

BEFORE SUBMITTING AN ETHICS APPLICATION
TO THE HUMAN RESEARCH ETHICS COMMITTEE

All research or teaching project involving the participation of human subjects shall be conducted in accordance with:

National Statement on Ethics Conduct in Human Research National Health and Medical Research Council (NHMRC), 2007.

NHMRC/ARC, Universities Australia, *Australian Code for the Responsible Conduct of Research.* National Health and Medical Research Council (NHMRC), 2007.

HUMAN ETHICS AT JAMES COOK UNIVERSITY

THE IMPORTANCE OF ETHICS

"All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures."
National Statement on Ethical Conduct in Human Research, 2007

WHO HAS TO SUBMIT AN APPLICATION?

Anyone employed by James Cook University **OR** studying at the University who intends to undertake a research or teaching project involving any form of human participation has an ethical and legal responsibility toward the subjects of that project. The James Cook University Ethics Review Committee along with the Human Research Ethics Committee is the body that reviews and approves such projects to ensure that the ethical and legal responsibilities are appropriately addressed in the project. Their review is based on details provided by the completion of an ethics application for research or teaching involving human participants.

WHAT IS HUMAN RESEARCH

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: taking part in surveys, interviews or focus groups; undergoing psychological, physiological or medical testing or treatment; being observed by researchers; researchers having access to their personal documents or other materials; the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumor and other biopsy specimens) or their exhaled breath; access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database. *National Statement on Ethical Conduct in Human Research, 2007*

ETHICS AND LAW IN HUMAN RESEARCH

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants. Contractual arrangements may impose obligations on research funders and institutions. *National Statement on Ethical Conduct in Human Research, 2007*

COMPOSITION OF THE HUMAN RESEARCH ETHICS COMMITTEE

The minimum membership of a Human Research Ethics Committee (HREC) is eight members as listed below. JCU's HREC has 15 members to ensure adequate coverage of all aspects of research and teaching conducted at JCU.

(a) Chairperson;

(b) At least two lay people, one man and one woman, who have no affiliation with the institution do not currently engaged in medical, scientific, legal or academic work.

(c) At least one person with knowledge of, and current experience in, the professor care, counselling or treatment of people; for example, a nurse or allied health professional.

(d) At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion.

(e) At least one lawyer, where possible one who is not engaged to advise the institution.

(f) At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

PLEASE NOTE:
THE HREC DOES NOT GRANT RETROSPECTIVE APPROVAL

PROCEDURES TO SUBMIT AN APPLICATION

Once your application has been completed you must forward the application to be reviewed by a **Human Ethics Advisor (HEA)**. If you do not know the appropriate advisor to review you're application please see the list of advisors on the human ethics website or seek advice from the Research Office, Ext *5011.*

The review of your ethics application by the HEA can take time and the advisor may require changes to your application. It is advisable to contact the advisor well before the closing date to HEA to discuss your application and provide a DRAFT application to the Advisor for review. Once the advisor is satisfied that your application is ready to proceed then the application may be finalised.

The finalised application must be **signed** by the Principal Investigator, Supervisor/s (if applicable), Dean of College/Delegate and a Human Ethics Advisor. For higher risk (category 3-6) we require a hard copy of the application **plus 1 photocopy.** For low/negligible risk (category 1-2) we require one hard copy of the application. The required copies must be forwarded to Human Ethics, Research Office (DB017) for submission to the HREC. An **electronic copy of the application in pdf format** (application form and all attachments in one document) must also be emailed to: ethics@jcu.edu.au.

Please note: applications must be reviewed by a HEA before submission to the HREC. Those applications received by the Advisor after the closing deadline will be held over to the next meeting of the HREC.

WHEN STRUCTURING YOUR RESEARCH PLAN - PLEASE ALLOW 2 MONTHS FOR THE PASSAGE OF YOUR ETHICS APPLICATION FROM SUBMISSION TO APPROVAL AS THE HREC MAY REQUIRE FURTHER CLARIFICATION OF SOME ISSUES BEFORE FINAL APPROVAL

APPLICATION

1. TITLE OF PROJECT

A short descriptive title for your project is required, in lay rather than scientific language.

2. CATEGORY

Under the National Statement you must indicate the potential of risk to the participants of your project. Please see the examples below to determine the risk.

EXPERIMENTAL CATEGORIES

CATEGORY	PROCEDURE	EXAMPLE
1	**Negligible Risk: Research or teaching projects with no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience. No deception involved and no invasion of privacy.**	*Non-intrusive questionnaires; non-aversive stimulus manipulation and/or response measures; development, learning, teaching processes; dietary controls.*
2	**Low Risk: Research or teaching projects where the only foreseeable risk is one of discomfort. Could include some form of personality or clinical assessment. (Cite tests or enclose copies if unpublished instruments are to be used.)**	*Clinical examinations; Manifest Anxiety Scale.*
3	**Information requested or provided which might result in some mild psychological distress, or clinical procedures resulting in mild physical stress. (If there is a possibility of minor deviation from the complete and frank disclosure as to the true nature of a project, classify as Category 3.)**	*Insignificant deprivations, manipulations or stimuli; clinical treatments; blood sampling.*
4	**Projects similar to Category 3 which could result in genuine but not severe psychological distress or physical pain with no long term effects. (Where some deception may be involved in the explanation given to participants, classify as Category 4.)**	*Exposure to toy spiders in phobia treatment; hypnosis.*
5	**As for Categories 3 and 4 but with a greater degree of psychological distress or physical pain. (If there is any possibility of long term effects or if substantial deception will be involved, classify as Category 5.)**	*Aversive behavioural conditioning; exposure to real snakes or spiders in phobia treatment; surgery.*
6	**Projects which, in addition to Categories 2 to 5, pose some serious ethical problems.**	*Projects with at risk populations such as disturbed children or adults, prisoners, or the terminally ill.*

3. PERIOD DURING WHICH ACTIVITIES REQUIRING ETHICS APPROVAL WILL OCCUR

Enter the date on which the human participation part of your project is expected to begin, ***e.g. the date surveys are mailed out, or the date of the first interviews*** and the date when participation will end.

If there is some aspect of your project that makes this date difficult to ascertain, provide details.

4. PRINCIPAL INVESTIGATOR'S DETAILS

Provide ALL details as requested.
In the **ESN** column, enter (E)mployee, (S)tudent or (N)ot affiliated with JCU.
For staff members and students the 4-digit **ORGU** number of their **discipline** should be entered if known. Please note: an **ORGU** number identifies an organisational unit within the JCU [finance] data systems; this number is made up of the first four digits of your discipline charge number.

Please include the qualifications of the researcher and indicate if this research contributes to a formal degree.

4ab. CO-INVESTIGATORS (If applicable)

Provide ALL details of Co-investigators as requested (spaces for two names allocated, if more than two Co-investigators – please attach an extra sheet to Part 1 as required). In the **ESN** column, enter (E)mployee, (S)tudent or (N)ot affiliated with JCU. Where applicable enter the **ORGU** number. Please also complete all the qualification details for Co-Investigators.

(*Please note: the inclusions of research assistant's authorship of any publications arising from research projects should follow disciplinary norms).*

Please note: All investigators/researchers involved in your project (including students and postgraduate students) must be named in the ethics application to be covered by ethics approval. For example, if a supervisor submits an ethics application and does not name the student researcher on the project, then the student is not covered by the ethics approval.

5.a. SUPERVISOR (If applicable)

If you are a student, or in a supervised position for the project, your supervisor's name and qualifications must be inserted, and both you and your supervisor must sign the Application.

6. FUNDING SOURCE

Must be completed. You must provide details of the funding source of the research (internal or external) and any pending grant applications that are related to the ethics application.

7. OTHER ETHICS COMMITTEE APPROVALS

If the project has been submitted to any other Ethics Committee you must name the Committee and provide details of any approvals. Please attach copies of the approval notices from other Ethics Committees. Please seek advice from the Human Ethics Officer as a JCU application may not be required.

8. IS THIS PROJECT A CLINCIAL TRIAL

If this project is a clinical trial, please contact the Research Office as a clinical trial ethics application form must be submitted.

9. PRIVACY INFORMATION

Please tick where appropriate. Collection of personal and health information must be in compliance with the Commonwealth's Privacy legislation and the National Health and Medical Research Council, *Guidelines under Section 95 of the Privacy Act 1988* and *Guidelines approved under Section 95A of the Privacy Act 1988.*

10 BACKGROUND AND SIGNIFICANCE OF THE PROJECT

Give a brief description of your project that will be informative to people outside your discipline (lay people). State the purpose of the project including brief background to the project, i.e. why should this project be done – why is it needed? Please explain the potential benefits to the participants and to the general community. You must provide references for your project outline. **NO MORE THAN HALF A PAGE**

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11 AIMS OF THE PROJECT

Please clearly outline the aims of your project and the expected research outcomes.
NO MORE THAN HALF A PAGE

12. ROLE AND EXPERTISE OF INVESTIGATORS IN THIS PROJECT

12.1 Please include details of the role of the Principal Investigator, Co-Investigators, Supervisors, students and other collaborators involved in the project. Please also explain the involvement of cultural brokers, mentors and reference or community groups in the project.

12.2 Please provide details of the expertise of the Principal Investigator, Co-Investigators, Supervisors, students and other collaborators in the research methods proposed in this project.

13. PARTICIPANT DETAILS

Please provide details of the participants to be recruited to the study.

13.1. Please detail the number of participants in your study. Where applicable, also indicate the number of males/females and persons under 18 years involved in the study. Please also indicate how many participants are students of JCU.

13.2 Please advise how many participants are expected to be members of an Aboriginal and Torres Strait Islander community. If an Aboriginal and Torres Strait Islander community is involved in the study, or if you expect a large number of the recruited participants to be Aboriginal and Torres Strait Islander peoples should be submitted. Please contact the Research Office for advice.

13.3 Please advise if your project involves patients from health service district. Applications for research involving health service district patients, whether they reside in the hospital or in the community, will be reviewed as required by the relevant Health Service District Human Research Ethics Committee (HSD HREC).

13.4 The Commission for Children and Young People Act 2000 (Qld) requires that people seeking to work or conduct research/ teaching with children undergo a working with children check. Once this check is completed you will be issued with a “suitability card”. A copy of the “suitability card” should be included in any ethics application submitted to the HREC. Ethics approval will not be granted until it is confirmed that a copy of the “suitability card” will be forwarded to the Senior Ethics Officer when received.

If you are deemed to be exempt under the Act, you must provide evidence of this exemption, i.e. a copy of your Teacher Registration Certificate, Medical Registration or evidence of employment under an exempt category in a government department.

14. PARTICIPANT GROUPS

Please describe the participant groups that will be recruited to the study. Please include all recruitment criteria for each group, i.e. exclusion criteria, age groups etc. Please list all sites where the project will be conducted, or where participants will be recruited. Letters of approval/support from any organisation involved in the study should be attached to the application. “Involvement” can mean organisations allowing access to data, premises and staff, schools, sporting, welfare or cultural organisations.

15. DETAILED METHODOLOGY

Explain clearly and concisely how the project will be carried out, including brief justifications of specific methods used, completion time for protocols, timeline for

human participation in the project, how the data will be analysed etc. Please also explain how you will protect the confidentiality (and privacy) of the participants i.e. how will the data be used and in what form, are personal identifiers being recorded, what confidentiality assurances will be made to participants. The methodology should be referenced where appropriate. Note facilities required if relevant. Please also include details of the role of each investigator/co-investigator in the project. (The role of any student in the research team should also be explained.) **NO MORE THAN 1 PAGE**
Please indicate what data collection techniques will be used in the project.
Photographs and Videotaping: Please ensure that you explain why photographs and videotaping is essential to the project. Please also ensure that participants are advised of the use of these images.

16. RECRUITMENT PROCEDURES

Please include step by step details of the recruitment procedures of the project. Please explain exactly how the participants will be selected, how contact details will be accessed in relation to privacy guidelines, e.g. public domain, database, other source, recruited by another agency on your behalf, how will participants be invited to participate and how participants will be able to volunteer for the project.

Will an **information sheet** be provided to participants? If not, please explain why not.
The information sheet is retained by participants and provides information about the study, the research team and what is expected of participants if they wish to volunteer for the study. Contact details: provided in the information sheet MUST be JCU contacts (a personal mobile phone contact is not acceptable).
The information sheet must remain separate from the informed consent form. The information page is retained by the participant; the informed consent form is part of the data of the study and is retained by the researcher.
Please note:
Participant Distress & Counselling Services: If there is the potential for participants in the project to become distressed counselling information must be provided. The provision of counselling details to participants is dependent upon the category and nature of the research conducted, i.e. with Category 1 and 2 research no counselling information would expected to be provided. If the project is a higher category, please outline exactly when and how counselling details will be provided to participants if they become distressed.

You must use the JCU Sample Information Sheet as a template for the information sheet for the study.

17. INFORMED CONSENT

Please explain step by step how informed consent will be obtained from participants. Participants must indicate that they fully understand that their participation is entirely voluntary, and that they are assured of confidentiality. All participants must understand that they have the right to withdraw from the research at any time. If there is a time limit for withdrawal or if there are limits to withdrawing consent this must be explained in the information sheet.
The Informed Consent form must be written in the first person (from the participant's point of view) and should include: the risks, right to withdraw, use, confidentiality (please note - confidentiality cannot be guaranteed when participants are part of focus groups) and consent items.
Where it is inappropriate to include an informed consent form (telephone surveys, street interviews), please ensure that the application specifically addresses how and where informed consent will be gathered, i.e. the completion of questionnaire implies consent (if no identifying data has been gathered) in the detailed methodology section of the application. For written consent **you must use the JCU Sample consent form as a template for the consent form for the study.**

If verbal informed consent is more appropriate please include a draft of what will be said to participants, for example:

"Good morning, my name is ****, and I am a researcher from James Cook University. I am studying visitor reactions to the new fun park, and was wondering whether you could spare five minutes to answer a few questions. I don't need your name or personal details, so your responses will be completely confidential. If you want to find out any more about this study, or the results of my research, please call the number on this card."***

18. RESEARCH OUTSIDE AUSTRALIA

If the project and data collection will be conducted in another country, details of approvals required must be provided. Copies of letters of approval/support from relevant countries/ethics committees and organisations must be attached to the application. If no approvals are required, please include an explanation as to why this is the case.

19. DATA RETENTION AND STORAGE

Please indicate how the data for the project will be stored. Raw data can include, completed survey forms, informed consent forms, etc.

Data storage is in adherence to the clause under **"Retain research data and primary materials"** in the **"NHMRC/Universities Australia *Australian Code for the Responsible Conduct of Research, 2007***

Clause 2.1.1

"In general, the minimum recommended period for retention of research data is 5 years from the date of publication."

And

Queensland State Archives "General Retention and Disposal Schedule for Queensland Universities, 6.8.3.

"Records relating to the consent by human research subjects … consent notices, signed consent and records of suitability card for interviewing juveniles.."

Retention rules for specific types of materials and data include:

- Signed consent forms for any research project that has been granted ethics approval must be retained for 15 years.
- Data from a clinical trial must be retained for 15 years from completion of the trial and 10 years after the last patient service provision or medico-legal action.

20. DISSEMINATION OF FINDINGS

Please include information pertaining to how findings will be disseminated and to what audience. Consider not only scholarly audiences but also broader audiences. How can participants (organisations and individuals) access information regarding the outcomes of the research in which they participated. If you do not believe that such outcomes are of interest to broader audiences or participants, please give details of your reasoning. (No more than half a page).

21. COMMENTS

Include here any additional information that may be of use or interest to the Committee. e.g. importance of project, alignment with University, Government, or other strategies, funding body, collaborating organisations, other relevant ethics applications, deviations from ethics guidelines and policy.

22/23. DECLARATIONS

These sections must be authorised appropriately by the **Principal Investigator** and **Supervisor** (if applicable).

24. AUTHORISATION

Must be signed by **Dean of College/Delegate**. If the Dean of College/Delegate is the Principal Investigator or one of the Co-Investigators on the project the relevant Deputy Vice-Chancellor must authorise the application.

25. ADVISOR'S RECOMMENDATIONS

The Human Ethics Advisor must sign and note approval, conditions of approval.

THE APPROVAL PROCESS

APPROVAL NOTIFICATION

Once the HREC has reviewed the application formal notification will be sent of their decision. The HREC may:

1) **Approve the application without reservation**. In this case an ethics approval notice will be sent (via email). The approved application will be kept in the Ethics Office and registered as required by the NHMRC Statement.

2) **Approval with Conditions.** If the HREC does not have enough information to rule on the acceptability of the project, then additional information will be requested from the researcher. Once this additional information has been provided to the HREC and approved, an ethics approval number will be released (as 1) above).

3) **Defer the application to the next meeting.** If the project raises ethical issues that have not been adequately covered in the application, then the HREC may require the researcher to discuss the application with the ethics advisor of the project or provide additional changes until the ethical concerns have been resolved. The application and amendments will then be re-submitted to the next meeting of the HREC.

4) **Non-Approval.** Under the NHMRC Statement, the HREC may withhold approval until all ethical concerns have been addressed to the satisfaction of the Committee.

URGENT ETHICS APPROVAL

If your ethics application requires urgent approval due to extenuating circumstances you may apply for “expedited review”. To be granted expedited review you must submit a letter in writing/email stating why your application needs urgent approval ***e.g. time constraints, funding considerations.***

Please note that only low risk applications (Category 1) will be considered for expedited review.

After the application has received all the relevant authorisations, Principal Investigator, Supervisor (if applicable), Head of School and Human Ethics Advisor, the application and any other relevant supporting documentation must then be forwarded to the Research Office with your request for expedited approval. The Executive Committee may approve the application, approve with conditions, or decline to approve and recommend that the application be submitted to the HREC. You will be notified by e-mail of the outcome of their deliberations.

AMENDMENTS

If your project needs to change in any way, (i.e. change to protocol, change in the number of subject groups, extension of time, change in investigators) an amendment **must** be submitted to the HREC **before any change is implemented.**

UNEXPECTED EVENTS

The HREC must be promptly notified of any “serious or unexpected adverse events that may impact participant welfare or the conduct of the project”. You must contact the Research Office or Human Ethics Advisor of your study to report such incidences.

COMPLAINTS

If you are concerned by the way your application has been processed or by the decision of the HREC, please contact the Research Office or the Human Ethics Advisor of your project. If your concerns remain unresolved after discussing the issue with the Ethics Officer or Human Ethics Advisor, the matter may be referred to the Chair, HREC for advice and action. If still unresolved, a meeting may be called where the Chair, HREC and Deputy-Vice-Chancellor will discuss the matter with you.

If you receive a complaint about the conduct of your project (from any source, both internal or external), you must immediately advise the Research Office or Human Ethics Advisor of the nature of the complaint. If the Research Office or Human Ethics Advisor receives a complaint about your project, you will be contacted immediately. The HREC will follow up and investigate all complaints and take corrective action where necessary.

MANDATORY REPORT ON THE RESEARCH PROJECT

In accordance with the National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research", after ethics approval for your project has been granted you must advise the HREC.

- periodically of the progress of the project;
- if the project is completed or if suspended or prematurely terminated for any reason;
- if serious or adverse effects on participants occur; and if any
- unforeseen events occur that might affect continued ethical acceptability of the project.

Also in compliance with the *"National Statement on Ethical Conduct in Human Research"* it is **MANDATORY** that you provide an annual report to the HREC detailing compliance with conditions of approval (Human Ethics Report Form). The report should very briefly summarise progress or in a final report detail the outcomes of your research.