HUMAN ETHICS APPLICATION GUIDELINE

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1 PURPOSE

1.1. This guideline contains information extracted from the National Statement on Ethical Conduct in Human Research 2007 (National Statement).

"The purpose of this National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community." National Statement (page six)

1.2. This guideline outlines how to submit an application for human ethics clearance.

2 SCOPE

2.1 This guideline applies to all CQUniversity employees and students conducting research involving humans and/or their data.

3 GUIDELINE

Contact details

3.1 CQUniversity Human Research Ethics Committee Secretary
Ethics Officer
Tel: +61 (7) 4923 2603
Fax: +61 (7) 4923 2600
Email: ethics@cqu.edu.au

General guidelines

3.2 Students need to consult their supervisory team to determine if their project requires human ethics clearance. Usually clearance is required if the project intrudes into the lives of other human beings.

3.3 Applications should be completed with the guidance of the supervisor/s, with the principal supervisor shown as first named principal researcher. Both student and supervisors must read and electronically complete the declaration at the end of the application prior to submission.

3.4 Applications for human research ethics clearance is available online via Research Master. The following guidelines apply:

- applications will be written in plain English and with all spelling checked
- all terminology and acronyms will be defined and explained
- applications should be as detailed as possible, and
- if 'not applicable' is selected, a response as to why this is not applicable should be included.

3.5 The CQUniversity Ethics Officers are able to assist in interpreting and completing the application, or accessing the online system.

3.6 Approval will be granted according to the particular details in the application. If, after approval has been given, there is any change to the application, the ethics office must be informed and approval obtained using the Modification Form, located on the Research Division Moodle Site.

Guidelines for specific questions

3.7 Research Master will automatically allocate a number when commencing a new application.

3.8 Many of the questions in the online application are self-explanatory, so the following table is not an exhaustive list of all questions.

Section	Title/What is required	Justification/Comments
P2	Exemption	If applying for an exemption from ethical review, complete the exemption section, making sure to provide a full justification for seeking an exemption.
P3 and P4	Data collection dates	Indicate the start and end dates for the data collection phase of the project.
PR1	Other Human Research Ethics Committee (HREC) approval	Option to seek reciprocal approval where a project has received ethical approval from another HREC. A copy of the approval letter and full application that was considered by that HREC must be supplied.
PR2	Project description – in **plain English**	Limit of 400 words – ensure that it can be readily understood by a layperson, and includes the aims, design and methods to be used. Avoid jargon – keep it simple and easy to understand.
PR3	Peer review. Provide description of the review process that has been undertaken, or will be undertaken.	Examples of peer review can include: confirmation of candidature process (for students), internal or external grant application process (e.g. ARC, NHMRC or Internal Grant programs).
PR4	Justify why no peer review undertaken	This could include the fact that the project is unfunded, or is a service evaluation activity
RL1	Research participants. Select boxes which match the participants the project seeking to recruit.	Note – select boxes where the project is deliberately targeting participants, or where there is a high probability that a number of participants may be in this category.
RL2	Excluded categories of participants	Enter as appropriate, noting that exclusions are required to be justified
RL3	Data collection methods	Select the data collection methods intending to be used for the project. Select 'Other' and provide details for methods not specifically listed (eg observation, sleep protocols etc),

RL4	Risk – likelihood and severity of risks	This is a major section. Sections 2.1, 3.1.12 and 3.1.13 of the National Statement should be read for the different categories of risk (including harm, discomfort and inconvenience). This section will be looked at closely by the CQUniversity Human Research Ethics Committee. They will be concerned more with how risk will be managed rather than the risk per se.
RL5	Identification of participants by other members of their group	This section relates to data collected via focus groups, or with a sample population who are known to each other (eg a sporting club, or students in a specific course. If not part of the project, respond 'Not applicable to this project'
RL6	Risk – mechanisms taken to minimise or manage the risk	Detail how risks will be minimised or managed
RL7 and RL8	Monitoring of risk and harms (or adverse events)	Indicate what steps will be taken for adverse events (eg a complaint from a participant, or an injury sustained). Note adverse events must always be reported to the Ethics Office.
PD1, PD2 PD3	Research aims and significance and justification	State the aims, research objectives, key research questions, and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of the relevance of the project to current research, a justification as to why this research should proceed and an explanation of any expected benefits to the community or its potential to contribute to existing knowledge.
PD4	Research plan. Background, aims, research design, methodology.	Include as much information as possible, including literature review (where appropriate, dependent upon chosen methodology). Outline methodology and rationale for selecting it.
PD5	Is this a service evaluation activity?	Only select yes if the project is one of the following: 1. you are a CQUniversity employee using course evaluations as data, and plan on producing a journal article or conference paper, or 2. you have been commissioned by an external organisation to conduct data analysis on de-identified data that has been provided.
PD9	Participant experience	Explain what participants will be asked to do – e.g. 'participants will be emailed an invitation to complete an online survey, asking for their responses to a set of questions'. Include here how long participants will be involved
PD11	Benefits and to whom	Indicate the benefits that will arise from this research – as a researcher, to participants (if there are direct benefits), to the wider community or the potential to contribute to existing knowledge.
PD12	Benefits vs risk	Provide an explanation about how the benefits of the research will outweigh the risks
PD16	Monitoring	Normally this will consist of the provision of annual and final reports to the HREC. Student projects should also include details of how the supervisor will be involved in assessing progress. There may also be progress reports due to external granting bodies.
Funding	Searchable table, using name of the Chief Investigator, title of project, or funding organisation	The online form has been designed to allow researchers to link their ethics application to the funding that supports the project.

D1	Ownership of the information collected during the research project and resulting from the research project	The first named principal researcher should be a CQUniversity employee. Therefore the owner of the information will normally be the University. An alternate option arises where a contract is in place with an external funding body, detailing ownership of research data through the Office of Research. Data ownership can only be reassigned by the University. Note: assignment of data ownership does not affect the moral rights to the intellectual property.
D4	Data management plan	From 1 January 2017, all research projects are required to have a Data Management Plan. This plan should be uploaded to the application. Refer to the Research Data Management Policy and Procedure for further information.
D10	Information collected directly from participants.	Outline the data that is being collected. Describe all of the data participants are required to provide and what the data will be used for (both demographic data and other data about the research topic).
C2, C3	Waiver of consent	This option is rarely approved – but if there are genuine reasons why the project is not obtaining consent from participants, provide justification here, ensuring to address Chapter 2.3.10 of the National Statement
C4	Opt out consent	This option is available where it is impracticable to see consent – provide a justification, ensuring to address Chapters 2.3.5 – 2.3.8 of the National Statement
C7 and C8	Consent process	Describe the process of obtaining consent from the participants (including parental consent if your participants are under 18 years of age). Generally written consent should be obtained if interviewing people, however, if it involves completion of a survey, it is appropriate to consider completion of the survey as being consent to participate.
C10	Remuneration for participants	Include any reimbursement, prize or other payments that may be awarded to participants in return for their time.
DB1 to DB10	Database questions	Specify the databases being used, if applicable, so that the HREC can determine whether Section 95 or section 95A of the *Privacy Act 1998* (Cwlth) apply.
DS6	Dissemination of results	Include details on how the research will be published (e.g. thesis, conference papers, journal articles, report to funding agency, etc.). It is recommended that conference papers and journal articles are included, even if the project is not currently planning to do so, as participants may need to be recontacted if the project is published later. A brief statement of results (in plain English) should also be prepared for participants.
R1	Presented as a searchable table. Add researchers by using the search function. Do not select any codes which start with 'LIB' as this is an internal personnel code used for the publications module of Research Master. For external researchers not located, please add their details in R2	The best way to search is to use either the surname, **or** given name of the researcher. There is a glitch in the system whereby searching on both the given and surname of a researcher will only result in the inactive LIB record, which will not allow your co researchers to access the application. Ensure that 'Relevant experience and training' is completed for each team member before clicking on the OK box at the bottom of the table

RP1 to RP8	Recruitment of participants	Provide number, age range and source of participants. This explanation should also include how potential participants will be identified and how initial contact will be made. For CQUniversity employees recruiting students as participants, approval to access students must be obtained from either the Dean of School, or from the Deputy Vice-Chancellor and Provost, depending on whether you are involving students from one School, or from across the University. Describe how participants will be contacted (e.g. advertisement in the general press, place a posting on a website, place a link to the survey on a Facebook page), and provide the text for any advertisement, or email.
Various participant specific sections	Participants specific – questions will only appear if you are targeting groups identified in the National Statement as requiring additional information.	These questions should be straightforward and will contain information on how to deal with the issues arising from conducting research with these groups of participants. For information on each category, refer to the relevant chapter of section 4 of the National Statement
There are also a number of specialised sections for Clinical Trials, Human Stem Cell Research, and Ionising Radiation. If the project falls within these areas, please contact the CQUniversity Ethics Officers for assistance with these sections		
Upload	This is the page where you attach additional documents such as any external approvals, information sheet for participants, consent form (if applicable) and research instruments such as surveys or interview questions.	The 'Add New Document' hyperlink shown will allow necessary documents such as certification emails, Information sheets, consent forms and research instruments to be attached. Note: there is a 40MB limit for all attachments. Once selecting 'Add New Document', another form will appear to enter a document description. Enter the document description and click the OK button to confirm. Click the upload button to open to the Upload file window. Browse the file to be uploaded, Enter a description and click OK. Check if the correct attachment has been uploaded. A checkbox will be automatically ticked on the Soft Copy column. Repeat this process until all documents have been attached

3.9 It is imperative that all named personnel complete the declaration. Internal CQUniversity employees and students MUST make their declaration electronically on the application. Where external researchers cannot access the online form, they must be sent a PDF copy of the application, and then send an email to the ethics office to make that declaration.

Attachments

Information sheet for participants

3.10 Information sheets, for projects being conducted by CQUniversity employees or students, must be printed on CQUniversity letterhead or display the CQUniversity logo. Requests for use of the CQUniversity logo should be sent to the Marketing Directorate using the online form located in StaffNet *(available to employees only)*. Research students unable to access this form should contact the Marketing Directorate.

3.11 It is essential that an information sheet be submitted with the application or approval will be delayed.

3.12 The information sheet must remain separate from the informed consent form. The information sheet will be retained by the participant; the informed consent form will be part of the data of the study and will be retained by the researcher.

3.13 The information sheet must:

- state the title of the project
- include the contact details of the Principal Researcher. If one of the Researchers is a student, then contact details for both the student and principal supervisor must be included
- outline the purpose and aims of the project
- state who can participate
- outline the risks involved in participating and the benefits of the research
- state how the participants privacy will be protected
- specify how the data collected will be used, including if any publications are likely to arise from the project
- outline what is involved and the duration required
- outline the period that data will be stored for
- make it clear that the participant is free at any time to withdraw consent to further participation without prejudice in any way. In such cases, the record of that participant is to be destroyed, where possible, or unless otherwise agreed by the participant, and
- include the following statement; *"Please contact CQUniversity's Ethics Office (Tel +61 (7) 4923 2603, email: ethics@cqu.edu.au) should there be any concerns about the nature and/or conduct of this research project."*

Informed consent guidelines

3.14 Consent forms, for projects being conducted by CQUniversity employees or students, must be printed on CQUniversity letterhead or display the CQUniversity logo. Requests for use of the CQUniversity logo should be sent to the Marketing Directorate using the online form located in StaffNet *(available to employees only)*. Research students unable to access this form should contact the Marketing Directorate.

3.15 It is essential that a consent form, where required, be submitted with the application or approval will be delayed.

3.16 The informed consent form must remain separate from the information sheet. The information sheet will be retained by the participant; the informed consent form will part of the data of the study and will be retained by the researcher.

3.17 The informed consent form should only be one page.

3.18 The free consent of participants, and/or their guardians where appropriate, must be obtained before research is undertaken. The Principal Researcher will be responsible for providing the participant, at his or her level of comprehension (use everyday language), with information about the purpose, methods, demands, risks, inconveniences and discomforts associated with the study. If the participants are likely to have difficulty comprehending a consent form, the principal researcher should seek expert advice on how best to word the document. In any event, researcher/s should keep the wording of consent forms as simple as possible.

3.19 Consent should be obtained in writing unless there is a good reason to the contrary. If consent is not obtained in writing, the reason for not doing so, and the circumstances under which it will be obtained, must be noted on the application. The major exception to this rule is where an online or hard copy survey is used. In these instances, it is appropriate to state in the Information Sheet that *'completion and submission of the survey will be assumed as consent to participate'*. Where the consent form involves the use of any other medium of communication (such as an accompanying video) this must also be supplied to the HREC.

3.20 The researcher/s must offer to answer any questions the participant has concerning the research, before they give consent.

3.21 Where children or dependent adults are involved, separate consent forms are required - one for the child or dependent adult, and the other for participant's parent/legal guardian.

3.22 The consent form must:

- state the title of the project
- list what the participant is actually consenting to

- make it clear that the participant is free at any time to withdraw consent to further participation without prejudice in any way. In such cases, the record of that participant is to be destroyed, where possible, or unless otherwise agreed by the participant, and the consent form should state this
- include a section for participants to request a plain English statement of results, and
- include a section for the participant to print their name, sign and date.

Letters of approval/support

3.23 It is essential that letters of approval/support from relevant organisations, where required, be submitted with the application.

3.24 If the research involves inmates of an institution, employees of a company, or similar, then approval must be obtained from the institution (or the organisation that runs the institution), the company, or other appropriate organisation.

3.25 If research involves any school, approvals must be sought in writing from the School Principals and Education Queensland, Catholic Education Office, or other authorising body, as appropriate

3.26 If research involves an Indigenous community, approval must be obtained in writing from representatives of the particular community and, if relevant, from an organisation representing Indigenous people.

3.27 If there is likely to be a delay in obtaining these letters of approval/support, the HREC may conditionally approve the project subject to such approval being obtained.

Surveys/questionnaires/interview questions

3.28 If a survey/questionnaire is not in its final form, a representative sample of the type of questions to be asked, and a brief explanation of the purpose and type of the questions should be included in the application. The HREC may conditionally approve the project subject to the provision of the final research instrument. Where possible the final version of the survey should be lodged.

3.29 Psychology questionnaires/tests should include reference details and a short description of all standard published test/measures used in the study.

4 DEFINITIONS

4.1 Terms not defined in this document may be in the University glossary.

5 RELATED LEGISLATION AND DOCUMENTS

Human Ethics Application User Guide

Modification Form (located in the Research Division Moodle Site)

National Statement on Ethical Conduct in Human Research 2007

Privacy Act 1998 (Cwlth)

Research Data Management Policy and Procedure

6 FEEDBACK

6.2 University staff and students may provide feedback about this document by emailing policy@cqu.edu.au.

7 APPROVAL AND REVIEW DETAILS

Approval and Review	Details
Approval Authority	Academic Board
Advisory Committee to Approval Authority	Research Committee
Administrator	Deputy Vice-Chancellor (Research)
Next Review Date	28/03/2021

Approval and Amendment History	Details
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Amendment Authority and Date	
Notes	This document replaced the Human Research Ethics Committee Application Form Guideline and the Human Research Ethics Committee Low Risk Application Form Guideline (28/03/2018).