

**GRIFFITH UNIVERSITY  
HUMAN RESEARCH ETHICS COMMITTEE  
EXPEDITED ETHICAL REVIEW CHECKLIST**

# **Guidelines to assist with the completion of the Expedited Ethical Review Checklist**

## **What is the Expedited Ethical Review Checklist?**

This short form has three purposes, it is a useful tool to assist research teams determine what level of ethical review applies to their research, it assists research teams to identify those ethical issues which will be considered in the review of their research, and it is the form used to seek Expedited Ethical Review Level 1 (E1) and Expedited Ethical Review Level 1 (E2).

## **Who should complete a Checklist?**

Anyone who conducts research involving humans who suspects that their research does not require full ethical review and is not exempt from ethical review should complete a Checklist. Research involving humans requires the collection any data from persons (including opinions), including the collection of organisational data from persons, and it includes the conduct of experiments and tests for research purposes on persons. Whilst much archival work involving access to previously published data, publicly available data, or previously collected data is outside the scope of the University's human research ethics arrangements, if the data is identified personal information at the point of access by the research team and cannot be characterised as "already in the public domain" then the activity is research involving humans.

In practice this means everything from de-identified questionnaires to clinical trials, from non-invasive testing to unstructured interviews, is subject to some level of ethical review.

The conduct of animal teaching or research is subject to review by the Animal Ethics Committee. A research team planning such research should not complete a Checklist, but complete a form for full animal ethical clearance.

## **What is ethical review?**

The University's human research ethics arrangements are based upon the provisions of the *National Statement on Ethical Conduct in Research Involving Humans* and international best practice. The University has established a three level ethical review process to match the paperwork and timeliness of the review to the ethical features of a research project. At its best, ethical review is a collaborative exercise which assists the research team conduct excellent research and comply with external requirements to the highest ethical standards.

## **What happens next?**

After your completed Checklist is submitted to the Manager, Research Ethics, Office of Research, it will be checked for obvious omissions or problems, and you may be contacted by a member of the Research Ethics Team if there are matters requiring correction.

In the case of E1, the completed Checklist will be sent to the Chair or Deputy Chair of the GU Human Research Ethics Committee (HREC). Processing time is 5 – 10 days, averaging at 7 days.

In the case of E2, the completed Checklist will be sent to a three-person panel of the HREC, which includes the Chair or Deputy Chair, a nominee from your element grouping, and an external person.

Following this review, you will be sent an email to initially advise you of the interim decision. Once you have responded to any conditions attached to this review, you may be authorised to commence the research. **You cannot commence the human research component of your project until you are issued with an authorisation to do so.** The next full meeting of the HREC will be informed of the details of the review of your project and either ratify, modify or set aside the decision of the Panel. Following this review you will be issued with a letter notifying you of the final decision about your project.

## Sources of advice on research ethics matters

Many elements of the University have appointed a Research Ethics Advisor (REA) who can advise you on a range of research ethics matters. Before contacting the REA in your area, you should consult the *Griffith University Research Ethics Manual*. The Manual includes commentary on the ethical principles that underpin the University's policies in regard to these matters, guidance to assist in responding to external regulatory obligations, and an articulation of the University's established positions on these matters.

The Manual also includes the contact details of the various REAs as well as other officers who can advise you on related matters.

## “Signing” your Checklist

In the future, the full review process for E1 and E2 will be conducted online. However, for the time being the form can be partially completed and submitted online, but you will need to follow up with a printed signed copy. You will be able to save or print a copy of the Checklist at any time during its completion. **Your Checklist will not be processed until a signed copy is received.**

## Attachments to your Checklist

In most cases your Checklist will have the following attachments.

- A full list of the research team;
- A copy of the informed consent procedure;
- A copy of the data collection instrument, or indicative questions (which should supply a sense of the most intrusive elements of the instrument)
- A risk assessment form, if required; and
- A copy of any agreements or approvals obtained from other bodies.

If you have these attachments electronically there is facility to attach them to your Checklist. Otherwise you will need to provide a hard copy prior to processing.

## Answering the questions of the Checklist

The following provides the full text of the questions of the Checklist, as well as some commentary to assist with responding to these questions.

### **PART A – PROJECT DETAILS**

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#### **Project / Subject Title**

Space is provided for you to indicate the title for the clearance. This is the title which will be recorded on the register of ethical clearances and will be used in all correspondence in relation to this clearance.

#### **Element**

Please indicate the ‘host’ element for this project. This information is recorded for monitoring and statistical purposes.

## **PART B – CONTACT PERSON**

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Space is provided to record the name and contact details of the contact person for the application. This is the nominated person whom the research team wishes the HREC to correspond with about this project and ethical clearance. Ordinarily this will be the Chief Investigator or Research Supervisor, but the research team may elect to nominate another member of the research team as the contact person.

In the case of student research, a member of the student's supervisory team must be listed as the contact person. The research student cannot be the listed contact person.

Only Griffith University researchers can be listed as contact persons for an ethical clearance application. Appendix 1 provides space for you to list all members of the research team.

## **PART C – IDENTIFICATION OF ETHICAL ISSUES**

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Your response to this section of the Checklist serves two purposes: it identifies the ethical issues associated with the planned research; and it helps the research team to determine which level of ethical review applies to the project.

### **QC1 - Is it possible for third parties to identify participants, and should this identification be characterized as significant?**

In any publication or reporting arising from this research, will participants be identifiable by third parties, either directly or by inference?

If participants will be identifiable, are there factors which mean that this identification should not be considered to be significant. For example, the fact that a public figure would be identifiable by third parties may not be considered significant, depending upon the nature of the data involved. On the other hand, identification is significant when participants are vulnerable or their identification could otherwise expose them to risks. As a default position, the HREC will prefer that respondents are not identifiable. The onus is on the research team to establish the appropriateness of any identification.

If you are conducting case study based research, please include in your response to QE4 the mechanism which will be used to protect the confidentiality of participants (eg in terms of consulting with participants and data storage).

### **QC2 - Does the research involve the participation of people who legally cannot provide voluntary and informed consent for their participation in research?**

This refers to persons who are unconscious or otherwise unable to communicate, as well as persons whose judgement is impaired and so are unable to legally consent to their participation in research. The participation of such persons may be an intentional component of the recruitment / sampling processes, or may occur coincidentally because of the nature of the potential participant pool.

In any general population study there is the possibility that a person whose judgement is impaired may be coincidentally included in the potential participant pool. Even though it is appropriate to answer this question "no" for such studies, the research team must always monitor the operation of their recruitment and consent procedures to ensure that all participants have exercised voluntary and informed consent.

### **QC3 – Does the research involve the participation of minors, other than an activity which is highly consistent with standard educational practice?**

Defining a research activity in terms of its relationship to a standard educational context involves considering the venue of the activity and whether the activity is something which the minors would be likely to undertake within that context. Other research activity involving minors requires E2 or full review. Even when research is conducted within a standard educational context, the presence of significant ethical issues or risks, or the presence of significant burdens on participants means that this question should be answered "yes".

### **QC4 - Are the potential participants in an unequal relationship that is likely to impact, or could be perceived to impact, upon either the recruitment process, or the risks associated with the research?**

Unequal relationships include: students as participants, when the research team includes their lecturer or tutor; employees as participants, when the research team includes their employer or supervisor; and patient as participants, when the research team includes part of their clinical care team. Unequal relationships also exist where the party with

power over the potential participants could be perceived to have significant interest in the research or is a significant stakeholder in the research.

When potential participants are in an unequal relationship there is the potential for this situation to compromise the voluntary nature of their consent, and to expose them to heightened risks.

**QC5 - Does the research involve the intentional recruitment of Indigenous persons, a significant coincidental recruitment of Indigenous persons, and / or issues likely to be considered significant to Indigenous people?**

Research projects can involve the intentional recruitment of Indigenous persons, or the nature of the potential participant pool may mean that there is likely to be a significant coincidental recruitment of Indigenous persons.

Furthermore, some research will involve issues which for social justice, political, cultural or economic reasons are likely to be considered of significance to Indigenous people.

Even though such research can be valid and ethical – indeed the conduct of such research can be extremely useful to Indigenous people – there are additional ethical issues to be considered before such research can be conducted.

**QC6 - Does the research involve the intentional recruitment of members of a collectivity, a significant coincidental recruitment of members of a collectivity, and / or issues likely to be considered significant to the collectivity?**

The term collectivity is carefully defined in Chapter 8 of the National Statement on Ethical Conduct in Research Involving Humans, but broadly it refers to members of a cultural, religious or ethnic group with a strong sense of communal leadership and decision making. Research projects can involve the intentional recruitment of members of a collectivity, or the nature of the potential participant pool may mean that there is likely to be a significant coincidental recruitment of members of a collectivity.

Furthermore, some research will involve issues which for social justice, political, cultural or economic reasons are likely to be considered of significance to the members of a collectivity.

Even though such research can be valid and ethical – indeed the conduct of such research can be extremely useful to the collectivity – there are additional ethical issues to be considered before such research can be conducted.

**QC7 - Are drugs, narcotics, poisons, placebo to be ingested / injected, or are invasive procedures to be administered?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC8 - Does the research involve tissue, blood or other body fluid collection / extraction?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC9 - Does the research involve a risk of physical injury?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC10 - Does the research involve exposure to disease or infection?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC11 - Does the research involve pain or significant discomfort?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC12 - Does the research involve human exposure to ionising radiation / X-Ray?**

This material risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC13 - Does the research involve psychological or emotional stress?**

This psychological risk question refers to risk factors that apply to the participants, research team, University and wider community. In answering this question, the research team should identify risks which exist prior to the application of any strategies to negate, minimise or manage the risk factor.

**QC14 - Could the research expose participants to potential civil, criminal or other proceedings?**

If the results or data from this research become known, or are reported, to third parties, could the data and disclosure expose participants to potential civil, criminal or other proceedings? There are areas of research where such exposure is arguably both ethically justified and appropriate. However, such research cannot qualify for E1.

**QC15 - Does the research involve sensitive personal information?**

Information should be characterised as sensitive personal information if it relates to an identified (either directly or by inference) individual's sexual identity, substance abuse, illegal behaviour, membership of a disadvantaged group, attitudes on contentious issues, religious or some other beliefs, etc. In this case, information should be considered identified if the research team can identify individual respondents.

**QC16 - Could the research expose participants to potential loss of professional reputation, market standing, or employability?**

Some research can have a negative economic impact on participants if the results or data from this research become known, or are reported, to third parties. There are areas of research where such exposure is arguably both ethically justified and appropriate. However, such research cannot qualify for E1.

**QC17 - Could the research result in significant negative impact upon personal relations?**

Some research can have a negative impact upon the participant's personal relations (eg damage the relationship between a participant and another family member). There are areas of research where such exposure is arguably both ethically justified and appropriate. However, such research cannot qualify for E1.

**QC18 - Will potential participants be offered inducements which could be considered coercive?**

It is accepted ethical practice to offer potential participants reimbursements for any expenses associated with their participation. It can also be appropriate to offer an inducement to encourage their participation. However, the research team must consider whether such an inducement should be considered coercive (ie if a potential participant would otherwise want nothing to do with the research, but the inducement is so significant they feel that they cannot afford not to participate). By definition, the reflection on these matters must be on a case-by-case basis looking at the specifics of the participant pool, the context and the inducement. Where a reimbursement or inducement is to be offered, which the research team considers is not coercive, the details must be included in the response to QE3.

**QC19 - Does the research involve covert observation?**

Will the research involve the observation of others without their knowledge? This does not apply to the observation of legal behaviour in a public place.

#### **QC20 - Does the research involve deception?**

Will the research involve the participants being deceived? Chapter 17 of the National Statement includes some commentary and guidance on the conduct of such research. The research team will need to present a compelling argument to the HREC for the need and ethical justification for deception.

#### **QC21 - Does IS42 or the Commonwealth Privacy Act apply to the research (eg access to identified personal data held by third parties subject to privacy regimes)?**

Both the Commonwealth and the State government have established privacy regimes which can impact upon the conduct of research – these largely relate to situations where the research team will be accessing identified personal data held by third parties (including access to databases or files to identify potential participants or to obtain the contact details of potential participants). These arrangements apply to Commonwealth agencies, bodies established under Queensland legislation (including universities), healthcare entities, and private bodies with a turnover above \$2 million. This question can be answered “no” if the organisation / agency / body will identify and conduct the initial contact with the potential participants on behalf of the research team.

#### **QC22 - Does the research involve genetic testing, work with human embryos or foetuses, or other testing which would determine paternity or predilection for a significant medical condition?**

Such testing can raise significant ethical issues. Additional guidelines and requirements apply to the conduct of such work.

#### **QC23 - Does the research require approval as a clinical trial under the CTN or CTX schemes?**

Such research requires additional review.

#### **QC24 - Will the research be conducted in an overseas setting which is politically unstable and / or where perceived criticism of the government or institutions could attract punitive action?**

Such testing can raise significant ethical issues.

### **PART D – ELIGIBILITY FOR EXPEDITED ETHICAL REVIEW LEVEL 2**

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Only complete the questions in this part if instructed to do so on the basis of a response to a question in Part C.

#### Questions initiated by an affirmative answer to QC1

##### **QD1a – Are potential participants given prior warning that they will be identifiable?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent procedure.

##### **QD1b – Is specific consent for the identification to be obtained?**

The informed consent mechanism should specifically seek consent for this identification. If it is possible for someone to participate in the research who does not wish to be identified, the informed consent procedure should enable a potential participant to express consent for participation and separately express their consent for identification.

##### **QD1c – Are there strategies to confirm the accuracy of the attributed comments?**

The data collection procedures should include some procedure to enable the research team to confirm the accuracy of the attributed comments (eg showing the proposed attributed commentary to the participant for them to confirm its accuracy).

#### Questions initiated by an affirmative answer to QC2

##### **QD2a – Are appropriate (and legal) supplementary consent mechanisms to be used?**

Different jurisdictions have processes (mostly articulated in law) in relation to who can appropriately consent for participation in research on behalf of a person who is unable to themselves consent. Chapters 5 and 6 of the National Statement outline the appropriate processes to follow when such supplementary consent mechanisms are to be employed.

Questions initiated by an affirmative answer to QC3

**QD3a – Are the minors capable of consenting in their own right, and / or will appropriate parental / guardian consent be sought?**

The decision of whether or not minors can participate in their own right is a function of their ability to understand the research and the implications of their participation, and the presence of significant ethical issues and risks. There is no simple age point above which young people can consent in their own right. For simple research, without significant ethical issues or risks, it may be appropriate for quite young children to consent to research in their own right. For complex research with serious potential implications associated with participation, no person under 18 may be able to provide consent in their own right. However, in nearly all cases, some form of assent / consent should be sought from the children.

The default position for human research involving the participation of minors is that express consent should be sought from their parent / guardian. However, depending upon the above consideration in relation to the ability for the minor to consent in their own right, it may be appropriate to obtain: passive consent from parent / guardian (where an information sheet is sent to the parent / guardian, who only contacts the research team if they do not want their child to participate); young person initiated passive consent from the parent / guardian (where the young person decides whether or not to consult with their parent / guardian, who could then elect to contact the research team if they do not wish for their child to participate); no parental / guardian consent (where the minor is considered to be capable of consenting in their own right, where the absence of any significant ethical issues or risks justifies not seeking parental / guardian consent, and it is inappropriate / impractical to obtain parent / guardian consent).

The applicant should provide a justification of the proposed position on these matters in their response to QE3.

**QD3b – Is the research contrary the best interests and /or welfare of the minors?**

Research would not ordinarily qualify for E2 if it should be characterised as being contrary to the best interests and / or welfare of the minors.

Questions initiated by an affirmative answer to QC4

**QD4a. Can the issues in relation to the dependent relationship be managed through ensuring participant anonymity or special recruitment processes?**

Often the most obvious way to address the issues which arise from a dependent relationship is by ensuring that the person in a position of authority is unaware who participates and who does not, is unable to identify respondents, and is only provided with aggregated data.

**QD4b. Should this relationship be characterized as captive?**

A captive relationship is a situation where the participant is under the control of another, and this control extends to their being instructed to participate against their will (eg prisoners, members of the defence forces), or tacitly coerced into doing so (eg members of an organisation who have been 'strongly encouraged' to participate).

Questions initiated by an affirmative answer to QC5

**QD5a. Has there been appropriate consultation with the community?**

Such consultation might involve discussions with elders, community leaders or representative organizations.

**QD5b. Does the research team include an Indigenous person?**

Such inclusion is considered useful from both an ethical and methodological point of view and is encouraged.

**QD5c. Will there be appropriate reporting back to the Indigenous community and / or a direct flow of benefits to the community?**

The Indigenous people are often over researched, and historically there has been a poor flow of direct benefits back to the communities in which the research has been conducted. Increasingly there is an expectation that the community in which the research is to be conducted will be provided with the results of the research, in an appropriate form.

Questions initiated by an affirmative answer to QC6

**QD6a. Has there been appropriate consultation with the community?**

Such consultation might involve discussions with elders, community leaders or representative organizations.

**QD6b. Does the research team include members of a collectivity?**

Such inclusion is considered useful from both an ethical and methodological point of view and is encouraged.

**QD6c. Will there be appropriate reporting back to the collectivity and / or a direct flow of benefits to the community?**

Collectivities are often over researched, and historically there has been a poor flow of direct benefits back to the communities in which the research has been conducted. Increasingly there is an expectation that the community in which the research has been conducted will be provided with the results of the research, in an appropriate form.

Questions initiated by an affirmative answer to QC9

**QD9a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent procedure.

**QD9b. If appropriate, will potential participants be screened on the basis of complicating health factors?**

If there would be no benefit from screening, this question should be answered “N/A”. Details of the screening should be included in the response to QE3.

**QD9c. Are the procedures to be conducted by experienced person(s)?**

Details should be included in the response to QE1.

**QD9d. Are standard workplace health and safety procedures to be followed, and is appropriate workplace health and safety approval in place?**

If no such standards apply, this question should be answered “N/A”. Details of the compliance with these standards should be included in the response to QE4.

**QD9e. Will there be compliance with other standards?**

If no such standards apply, this question should be answered “N/A”. Details of the compliance with these standards should be included in the response to QE4.

**QD9f. If required, are the persons conducting the procedures licensed and / or accredited?**

If no such requirement applies, this question should be answered “N/A”. Details should be included in the response to QE1.

Questions initiated by an affirmative answer to QC10

**QD10a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent procedure.

**QD10b. If appropriate, will potential participants be screened on the basis of complicating health factors?**

If there would be no benefit from screening, this question should be answered “N/A”. Details of the screening should be included in the response to QE3.

**QD10c. Is the disease or infection life-threatening, or would a reasonable person attach significance to exposure to the disease or infection?**

The question of significance should be based upon impact upon quality of life, enduring implications and stigma associated with exposure / infection.

Questions initiated by an affirmative answer to QC11

**QD11a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD11b. If appropriate, will potential participants be screened on the basis of complicating health factors?**

If there would be no benefit from screening, this question should be answered “N/A”. Details of the screening should be included in the response to QE3.

**QD11c. Would a reasonable person attach significance to exposure to the pain or discomfort?**

The question of significance should be based upon the severity, duration and nature of the pain / discomfort.

Questions initiated by an affirmative answer to QC12

**QD12a. Is prior warning given, and instructions in relation to implications – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD12b. If appropriate, will potential participants be screened on the basis of complicating health factors, pregnancy and previous exposure?**

If there would be no benefit from screening, this question should be answered “N/A”. Details of the screening should be included in the response to QE3.

**QD12c. Are the procedures to be conducted by experienced person(s)?**

Details should be included in the response to QE1.

**QD12d. Are standard workplace health and safety procedures to be followed, and is appropriate workplace health and safety approval in place?**

If no such standards apply, this question should be answered “N/A”. Details of the compliance with these standards should be included in the response to QE4.

**QD12e. Will there be compliance with other standards?**

If no such standards apply, this question should be answered “N/A”. Details of the compliance with these standards should be included in the response to QE4.

**QD12f. If required, are the persons conducting the procedures licensed and / or accredited?**

If no such requirement applies, this question should be answered “N/A”. Details should be included in the response to QE1.

Questions initiated by an affirmative answer to QC13

**QD13a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD13b. If appropriate, will potential participants be screened on the basis of complicating mental health factors?**

If there would be no benefit from screening, this question should be answered “N/A”. Details of the screening should be included in the response to QE3.

**QD13c. Would a reasonable person attach significance to exposure to the stress?**

The question of significance should be based upon impact upon quality of life, enduring implications and stigma.

Questions initiated by an affirmative answer to QC14

**QD14a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD14b. Are there any duty of care, or duty of disclosure issues which might warrant the reporting of identified data to third parties?**

In Queensland, there are limited situations which constitute a duty of disclosure (eg suspected child abuse). However, there are ethical situations which may justify (and indeed legally override) the normal confidentiality provisions which apply to research. Generally these are based upon significant public interest, imminent predictable risk of injury or death, or the concealment of a crime.

Questions initiated by an affirmative answer to QC15

**QD15a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

Questions initiated by an affirmative answer to QC16

**QD16a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD16b. Are there any duty of care, or duty of disclosure issues that might warrant the reporting of identified data to third parties?**

In Queensland, there are limited situations which constitute a duty of disclosure (eg suspected child abuse). However, there are ethical situations which may justify (and indeed legally override) the normal confidentiality provisions which apply to research. Generally these are based upon significant public interest, imminent predictable risk of injury or death, or the concealment of a crime.

Questions initiated by an affirmative answer to QC17

**QD17a. Is prior warning given (ie is information about the risk – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD17b. Are there any duty of care, or duty of disclosure issues which might warrant the reporting of identified data to third parties?**

In Queensland, there are limited situations which constitute a duty of disclosure (eg suspected child abuse). However, there are ethical situations which may justify (and indeed legally override) the normal confidentiality provisions which apply to research. Generally these are based upon significant public interest, imminent predictable risk of injury or death, or the concealment of a crime.

Questions initiated by an affirmative answer to QC19

**QD19a. Is the observed activity innocuous – eg is the activity something which generally occurs in public that a reasonable person is unlikely to be concerned about having observed?**

The practicalities of conducting some kinds of human research involving “covert” observation (eg watching patterns of movement through a public space), make it difficult to obtain informed consent. Even though research involving such observation is disqualified from E1, it will still qualify for E2 unless the observed activity is in any way contentious or if it is to be recorded in an audio-visual form.

**QD19b. Will the “participants” be identifiable by the research team?**

Even if the participants will be identifiable, if the activity is innocuous, the project may qualify for E2.

Questions initiated by an affirmative answer to QC20

**QD20a. Have alternatives to deception been considered, and rejected because they would compromise the scientific validity of the research?**

The National Statement specifies that deception in research is only appropriate as long as there are no practical alternatives to achieving the research objectives.

**QD20b. The deception will not compound the risks associated with the research?**

Generally the presence of deception in research should not compound the risks associated with the research. If it does, such a project would be disqualified from E2.

**QD20c. Participants will be given adequate and prompt disclosure and debriefing?**

The National Statement requires that, following any deception, research participants be given a debriefing in relation to the deception.

**QD20d. Participants will be able to withdraw their data once the deception is disclosed?**

The National Statement requires that, having received a debriefing in relation to the deception, participants should be afforded the opportunity to withdraw their consent – in practice that means withdrawing their data from the research.

Questions initiated by an affirmative answer to QC21

**QD21a. Is appropriate consent obtained for access, use and storage?**

If appropriate prior consent is obtained, it is not necessary for the ethics committee to grant the research team special leave under the privacy legislation. Where such prior consent is not possible, the ethics committee may be able to grant the research team such leave, but this must be sought in the context of an application for full ethical clearance.

Questions initiated by an affirmative answer to QC22

**QD22a. Is prior warning given (ie is information about the testing and implications – in plain language – included in the informed consent materials)?**

Such a warning would normally be provided in the context of the recruitment materials and / or the informed consent mechanism.

**QD22b. Is appropriate counselling made available?**

Such counselling should be provided free-of-charge to the participant and by an appropriately qualified / experienced individual. In general, such counselling should not be provided by a member of the research team.

Questions initiated if the response to any earlier questions in Part D indicate that the project may not qualify for Expedited Ethical Review Level 2

**QD25. Are the risks associated with the research easily negated, minimised or managed? If yes, provide details (maximum of 200 words).**

The fact that the applicant is being asked to answer this question is an indication that there is an ethical issue or significant risk which has not yet been addressed. Indicate whether or not the risks associated with the research are easily negated, minimised or managed. Then, in 200 words or less, provide an outline of the measures which will be taken to address the risk.

**QD26. Has the research already been approved by another HREC? Or are the procedures to be used in the research listed in the *GU Register of Approved Procedures*? Or is the application a renewal application? Provide details (maximum of 200 words).**

Research which would not otherwise qualify for expedited ethical review, may qualify on the following grounds:

- the project has already been approved by another HREC – you should provide a copy of the outcome letter / certificate, and the approval should preferably be from the primary or host site for the research;
- the procedures in the research have already been approved for inclusion in the *GU Register of Approved Procedures*; or
- the application is a renewal application (ie seeking to extend the clearance beyond 3 years, and / or make major changes to the project design).

## **PART E – PROJECT DETAILS**

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In responding to this section of the Checklist you will provide some brief information about the specifics of your project.

**QE1. Provide a brief project description, including the question / objective(s) of the research and what participants will experience / undertake (maximum of 1,000 words).**

This question must be answered whether you are seeking E1 or E2.

**QE2. List the relevant qualifications, experiences and /or skills of the research team which equip them to conduct this research (maximum of 200 words).**

Depending upon the nature of the research, this question may only require a very brief overview of the relevant experience, training or supervision which will enable the research team to conduct the proposed research.

**QE3. Provide details in relation to the potential participant pool: target participant group, identification of potential participants, initial contact method, and recruitment method (maximum of 300 words).**

Ensure that the response to this question provides the detail of each element of the recruitment process:

- target participant group – what are the demographics or features of the potential participants group;
- how will potential participants be identified and their contact details (if needed) obtained – contact via third party lists can raise significant ethical and legal privacy issues – and in such cases it may be preferable for the initial contact to be conducted via the third party; and
- how will the actual recruitment of the participants be conducted.

Depending upon the nature of the research, your response to this question may also include an overview of your sampling / screening technique to manage risk issues.

**QE4. Provide details in relation to the data collection: method, location, duration and analysis (maximum of 500 words).**

The response to this question should provide a succinct overview of the data collection procedures for the research.

**QE5. Provide details of the appropriate informed consent procedure, and attach a copy of the informed consent package to the Checklist (maximum of 200 words).**

The response to this question should provide a summary of the informed consent procedure, including an indication of whether the standard process will be used (a written information sheet and the completion of a consent form, or a questionnaire coversheet with consent being indicated by the return of the completed questionnaire) or an appropriate alternative informed consent mechanism. A copy of the actual informed consent package must be provided.

**QE6. Provide details of how the results of the research will be report / disseminated, including the appropriate provision of results to participants. If appropriate / required, please also provide details of any planned debriefing of participants (maximum of 200 words).**

Ethical research will include an appropriate mechanism to report results (if only aggregated results) back to the participants. The research may also involve other reporting, including academic publication. In some cases it will be appropriate or necessary to provide participants with debriefing of their results (eg because their particular results are likely to be a source of significant concern to the participant and / or raise significant issues of ethical concern).

**QE7. Provide details of the anticipated duration of the data collection / human research phase of the project.**

The maximum duration for a clearance is 3 years from the commencement date.

## **PART F – DECLARATIONS**

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All of the required signatures in this part must be provided before this application can be processed.

**F1. The Chief Investigator for this project is to sign the form and indicate the level of ethical clearance being sought.**

This section also includes questions relating to whether or not the research is associated with a student project, whether the research is funded, and whether the research team has a potential conflict of interest associated with their conduct of this research. The responses to these questions are used for the interface between the research ethics and other systems and for institutional governance purposes.

**QF2. The relevant Head of School or Centre Director for this project is to sign the form.**

The authorising officer must indicate whether or not the scientific merit and research safety of the project have been considered, and whether or not there is any need for further review of these matters. Whilst the GU HREC will make its own determination, it will be guided by the recommendation of the authorising officer.

A member of the research or supervisory team cannot be an authorising officer for a project.

## **Submitting your Checklist**

Before you submit your Checklist do not forget to:

**Have you fully completed every section of the form?**

**Have you attached a copy of your informed consent mechanism, that companies with Booklet 22 of the Griffith University Research Ethics Manual?**

**Have you provided the details of any data collection instrument (eg some sample questions that give a sense of the most ethically intrusive or sensitive line of questioning)?**

**Have you provided copies of any required agreements or approvals from other bodies, or an assurance that these approvals will be obtained prior to the commencement of this research?**

**Have you included all other relevant attachments to accompany this application?**

The signed hard copy of your Checklist with the various attachments should be sent to:

**Manager, Research Ethics  
Expedited Ethical Review  
Office for Research  
Bray Centre, Nathan Campus  
Griffith University**