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**CLEARANCE NOº**

(office use only)

**Application Form for Ethical Clearance for**

**Research Involving Human Participants**

**For review by: Medical Research Ethics Committee (MREC)**

###### Behavioural & Social Sciences Ethical Review Committee (BSSERC)

 **For Staff and Student Research**

 **Refer to last page for website and other information, including mailing address**

 **Please tick boxes:**

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| **MREC** |  | **BSSERC** |  |

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| **Full Review** |  | **Expedited Review** |  |

**ALL QUESTIONS MUST BE ANSWERED**

* **minimum 12 point font**
* **define any acronyms and abbreviations used**

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| **Project Title:** |
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| **Principal Investigator:** |  |
| **Staff Noº/Student Noº:**(cross out if not relevant) |  |
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| **Co-Investigator/s:** |  |
| **Project Co-ordinator (or authorised contact)** |  |

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| **Supervisor/s:** (if applicable) |  |

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| **Schools/Departments:** |  |

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| --- | --- | --- | --- |
|  | **Telephone** | **Fax** | **Email** |
| **Contact details of Principal Investigator** |  |  |  |
| **Contact details of Project** **Co-ordinator or authorised contact** |  |  |  |

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| **Degree Enrolled (if student):** |  |
| **Funding Body:** |  |
| **If Project Funded - What year?**  **- Reference no. if available** |  |

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| **Project Location:** |  | **Project Duration:** |  |  |
| A. Is this submission identical or very similar to a previously approved protocol? YES/NO (circle) If **YES**, please provide clearance noº **and** indicate whether identical or very similar):*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **B. Does this submission hold other ethical clearance? YES/NO** **Note:** Copies from other **AHEC** registered ethics committeesmust be attached. (circle) |

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| **C. Are you applying for Expedited Review? YES/NO** **Note:** Please see UQ Guidelines page 10 for the conditions necessary to qualify for Expedited Review. (circle) |

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| **D. Is the project a Clinical Trial (eg, a trial of a drug, device, therapy, intervention, YES/NO** **treatment, etc) ? [refer to end of this form dealing with “clinical trials”]** (circle)If **YES**, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS:** |
| **1) Who are the participants or informants?:** eg, Children, University students, or other persons.  **Note:** Details of inclusion/exclusion criteria including approximate **number** (provide justification), age range, and  male/female ratios are required. |
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| **2) Special Groups**The *National Statement* has identified certain groups with specific ethical considerations. Researchers must take special care to protect the interests of these groups if they are in any way involved in the project. Those groups include: **pregnant women and the foetus** (Ch 4.1); **children and young people** (Ch 4.2); **people in dependent or unequal relationships** (Ch 4.3); **people highly dependent on medical care** (Ch 4.4); **people with cognitive impairment, intellectual disability, or mental illness** (Ch 4.5); **people involved in illegal activities** (Ch 4.6); **Aboriginal and Torres Strait Islander peoples** (Ch 4.7); **people in other countries** (Ch 4.8); **other cultural and ethnic groups**.In preparing your research project and application for ethical clearance, you should investigate thoroughly, through consultation with supervisors, colleagues in your school and other professional groups/organizations, how these special groups may or may not be represented in your research and if participation in this research could have a negative impact on members of any of these groups.**Note:** If participation of special groups is a focus of the research, the protocol can not qualify for expedited review (unless other current HREC clearance is held and a copy provided). |
| **2a) Aboriginal and Torres Strait Islanders Group**Specify the level of participation that Indigenous Australians will have in this research (as members of the research team, or as members of the group to be researched):  no participation some participation possible or likely focus of the research □ □ □**Please explain your choice:** |
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| If Indigenous Australians may be involved (2nd or 3rd response box above), what strategies will be used to address their needs and interests? [For guidance with this part of Q2a on indigenous and cultural issues, please refer to the NHMRC and AIATSIS codes of ethics for research with indigenous people. For further advice please contact the UQ Aboriginal and Torres Strait Islander Studies Unit.]**Please specify your strategies:** |
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| **2b) People in Australia belonging to other cultural or ethnic groups**Are there any ethical considerations that may arise as a result of collection from other cultural or ethnic groups in Australia? [for example, are there any particular customs, practices, or conditions which should be taken into account]: YES/NO |
| If YES, please provide details:Have you consulted anyone with knowledge to provide guidance? Who?: |
| **2c)** **People in overseas countries**Does your project involve data collection in an overseas country?: YES/NO |
| If YES, what ethical considerations may arise as a result of such data collection, which are different from those arising from data collection in a general Australian context? [for example, are there any particular **local** laws, customs, practices, or conditions which should be taken into account?]:Have you consulted anyone with knowledge to provide guidance? Who?: |
| **2d) Other Special Groups**Does your project involve any of the other special groups (listed above in the introduction to Q2)?: YES/NO If YES, please answer the following:Specify the group/s:What is the level of their participation: some participation possible or likely focus of the research □ □ |
| What strategies will be used to address their needs and interests?**Please specify your strategies:** |
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| **3a) Participant recruitment details: Please provide exact details of contact.** |
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| **3b) Does recruitment include disclosure of personal information (eg, mailing list, names, YES/NO****contact details, etc) from another party or organisation to the researchers?** **If YES, please provide details.****Note:** disclosure of personal information from another party or organisation to the researchers, even if merely for the purpose of seeking initial expression of interest in the project, must be authorised by each individual to whom the information relates (unless it is a completely public database with unrestricted access). Eg, Clinic X must not give to the researchers a mailing list of patients who might be potential participants for the project unless those patients have previously authorised such use and disclosure of their information to non-clinic parties. |
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| **4) In EVERY-DAY or LAY LANGUAGE please provide a summary of the project – including aims and benefit: This section MUST be completed in LAY LANGUAGE.** |
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| **5) Give details of the research plan:**  **Note:** The committee needs sufficient information to put into context the ethical considerations listed in later questions. **Note: This section should be completed in LAY LANGUAGE *as much as possible* so that it can be understood and appreciated by all Committee Members, including Lay Members.****Note: For application to the MREC – please keep response to a MAXIMUM of 2 pages.** |
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| **6) Give details of the ethical considerations attached to the proposed project:**  |
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| **7a) How will informed consent be obtained from participants or informants?** |
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| **7b) “Gatekeeper” Approvals**A “gatekeeper” or “permission-giver” is a person authorised to write a Letter of Authority and Recognition from an organisation of any type involved with the research, which gives permission to the researcher for access to the population **under the “gatekeeper’s” or “permission-giver’s” authority**. [For example, if you wish to conduct research in schools and the participants are the school teachers, then gatekeeper approval will need obtained from the relevant education authority (eg, Education Queensland) and the School Principals before you may approach those school teachers in recruitment.For example, if you wish to access staff from a private organisation, then similarly, gatekeeper approval will usually be required from senior personnel or an appropriate manager who is able to grant such access to approach that organisation’s staff in recruitment.] |
| 1. Are gatekeeper approval/s required for the research?: **YES/NO** |
|  |
| 2. If **YES**, who are the gatekeeper/s and how will their approvals be sought and obtained? (if gatekeeper approval/s have already been obtained, then please attach copy) |
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| **8) Provide details of procedures for establishing confidentiality and protecting privacy of participants or informants:** |
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| **9) Researchers must ensure that all data, particularly data containing personal information (ie, information that can identify the person), are secure both at the point of storage and during transit. Researchers must be aware of relevant legislation and guidelines governing privacy:- *Information Privacy Act* (Qld) 2009, *Privacy Act* (Cth) 1988, and Guidelines under S95 and S95A of the *Privacy Act* (Cth).** |
|  |
| **9a) Where will data be stored (eg, UQ office of researcher), and what measures will be taken to ensure security of data (eg, locked filing cabinets, computer hard-drive protected by password/encryption/de-identification of data, etc)?** |
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| **9b) Will data be stored on, or taken to, premises other than secure UQ premises (eg, researcher’s home)?: YES/NO****If YES, then what measures will be taken to ensure security of data at these premises?** |
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| **9c) What measures will be taken to ensure security of data during transit? (eg, if data is on hard-drive – protection by password/encryption/de-identification of data, etc).** |
|  |
| **9d) Will persons other than staff of the research team have access to the data?: YES/NO****If YES, then please specify these persons, state why these persons have access, and what provisions are in place to ensure the confidentiality of data by these persons.** |
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| **10) In what form will the data be collected:** Note:Tick the most appropriate box:  |
| **(i) Identified** 🞏 **(ii) Potentially Identifiable** 🞏 **(iii) De-Identified** 🞏(ie, not able to be re-identified)  |

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| **11) In what form will the data be stored and/or accessed:** Note: Tick the most appropriate box:  |
| **(i) Identified** 🞏 **(ii) Potentially Identifiable** 🞏 **(iii) De-Identified** 🞏(ie, not able to be re-identified) |

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| **12) Give details of how feedback will be available to participants or informants:** |
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**13) Does the project involve any of the following possibilities? Answer YES or NO. If YES, give details.**

a) The trial or use of any medicine, drug, or other substance

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| 1. Answer YES or NO. If YES, provide details:  |
| 2. Does this project require the submission of a Clinical Trial Notification/Clinical Trial Exemption (CTN/CTX) Form to the Therapeutic Goods Administration (TGA)? [Refer to the TGA website for further information]:  |

b) The trial of any device

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| 1. Answer YES or NO. If YES, provide details:  |
| 2. Does this project require the submission of a Clinical Trial Notification/Clinical Trial Exemption (CTN/CTX) Form to the Therapeutic Goods Administration (TGA)? [Refer to the TGA website for further information]:  |

c) The trial of any intervention, therapy, or treatment (whether medical, behavioural, physical, or other)

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d) Any invasive procedures (eg, blood sampling)

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e) Any diagnostic scans carried-out for the purposes of the project (including, *but not limited to*: MRI, NMR,

 CT/CAT, X-Rays, etc).

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| 1. If YES, please list. |
| 2. Does your project involve the use of MRI? YES/NONOTE: If using MRI at a hospital site (i.e. a facility with emergency services available on site during testing), you MUST have at least one staff who has current CPR certification and must have undertaken an emergency evacuation drill at least once a year.If using MRI at non-hospital sites, (e.g. UQ St Lucia Campus), you MUST have 2 staff who both have current CPR certification and they must have undertaken an emergency evacuation drill at least once a year.Does your project fulfil these mandatory conditions? YES/NOIf NO, outline reasons for submitting your application without these conditions in place. |
| 3. Does your project involve exposure to ionising radiation? YES/NONOTE: If YES, the protocol MUST comply with the Queensland *Radiation Safety Act (1999)* and *Radiation Safety Regulation (2010)*.  The legislation requires compliance with the Australian Radiation Protection and Nuclear Safety Agency’s *Code of Practice for the Exposure of Humans to Ionising Radiation for research Purposes (ARPANSA 2005)* (<http://www.arpansa.gov.au/pubs/rps/rps8.pdf>) and you MUST consult with the University Radiation Protection Adviser before submission.Does your project meet the guidelines of the Code of Practice? YES/NOHas the project been reviewed by the University Radiation Protection Adviser before ethics submission? YES/NO |

f) The possibility of physical stress/distress, or discomfort

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| 1. to the participants:2. to the researchers/data collectors: |

g) The possibility of psychological/mental stress/distress, or discomfort

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| 1. to the participants:2. to the researchers/data collectors: |

h) Deception of/or withholding information from, participant at **ANY** stage of the project

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i) Access, by the investigators, to data held by a Commonwealth Department or Agency (Please also specify the

 number of records to be accessed)

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j) Access, by the investigators, to data held by other bodies or people (Please also specify the number of records to

 be accessed)

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k) Access to data (eg, medical records), by other bodies or people not the investigators.

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l) Use of questionnaires, interviews, or focus groups with questions or topics which are sensitive, have

 potential to cause distress, or may reveal illegal activity

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| **14) Please Indicate What You Think Is The Level Of Risk For Prospective Participants Against The Scale Below:** *Tick the most appropriate box. (Refer to the UQ Guidelines)* |
|  |  | **Extreme Risk**  |
|  |  | **High Risk** |
|  |  | **Some Risk** |
|  |  | **Minimal Risk** |
|  |  | No Foreseeable Added Risk Above the Risks of Everyday Living |

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| **15) Please provide details to assist the committee as to why you indicated the level of risk to prospective participants or informants in the question above (Question 14):** |
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| **16) How has the possibility of withdrawal from the project been addressed?:**  **Note:** Ensure that details and effects of withdrawal without prejudice AT ANY TIME have been considered and explained. Refer to the NHMRC’s *National Statement* section 2.2.19 – 2.2.20. |
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| **17) Please note that this section must be completed for funded research or the application will not be**  **processed.** |
| **17 a) Is this project receiving financial support to conduct the research? YES/NO**  (circle) |
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| **17 b) If Yes, from what source(s)?** |
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| **17 c) Who will be administering the budget?** |
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| **17 d) Please provide details of the budget distribution. (Or attach a copy of the budget statement.)** |
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| **17 e) Provide details of any other “in kind” support for the project or direct or indirect payment to any investigator:** |
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| **17 f) Please provide details of participant reimbursement for their involvement in the Project, if any:** **Note:** This could be cash payment, food vouchers, free services, or movie passes, etc. |
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| **18) In undertaking this research do any “conflict of interest” issues arise?**  **If YES,** please provide details. **Note:** Conflict of Interest may arise, for example, because a researcher, or someone close to the researcher, stands to benefit financially from the research or the carrying out of the project or because inconsistent or incompatible obligations exist.  Refer to section 5.4 of the NHMRC’s *National Statement*: |
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| **19) Is the project a multi-centre or site project?** **If YES**, provide the name of the principal ethics committee. Please provide copies of any conditions or requirements placed by other AHEC registered Human Ethics Committees: **Note:** The Principal Ethics Committee is the Institutional Ethics Committee where the budget is to be administered. |
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| **20a) Some projects may involve permits from National Parks & Wildlife in relation to collection of data and Native Title issues. How have you addressed this issue?:** (Refer to the UQ Guidelines) |
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| **20b) Does the project require biosafety clearance? YES/NO** (circle) |
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**ATTACHMENTS:**

**1) Participant Consent Form Yes/No**

**Note:** for examples of what should be included in a consent form, please consult page 12 of the UQ Guidelines for Ethical Review of Research Involving Humans. Also refer to “Checklist” below.

**2) Participant Information Sheet Yes/No**

**Note:** for External Use - forms should be released on letterhead and contain University Ethical Paragraph.

Refer to UQ Guidelines and Ethics website, and “Checklist” below.

**3) Questionnaire** (if applicable) **Yes/No**

**4) Indemnity Agreement** (primarily for clinical trials and contract work) **Yes/No**

**5) CTN/CTX [Clinical Trial Notification/Clinical Trial Exemption] Form** **Yes/No**

(primarily for clinical trials)

**6) Gatekeepers or Permission-Givers Yes/No**

**Note:** A “gatekeeper” or “permission-giver” is a person authorised to write a letter of Authority and Recognition from an organisation of any type involved with the research, which gives permission to the researcher for access to the population under the “gatekeeper’s” or “permission-giver’s” authority.

**7) Bibliographic References Yes/No**

**8) Other - please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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### DECLARATION

We/I, the undersigned researcher(s) have read the University of Queensland’s Guidelines for Ethical Review of Research Involving Humans and the NHMRC’s *National Statement on Ethical Conduct in Human Research*, and agree to abide by them in the conduct of this research. It is understood that this includes the reporting and monitoring roles associated with the approval by the University of Queensland.

### Signature of Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date: / /**

**Signature of Supervisor** (if applicable)**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: / /**

**An original plus 15 copies should be submitted to the:**

**Ethics Coordinator**

**UQ Research & Innovation**

**Cumbrae-Stewart Building (72)**

**THE UNIVERSITY OF QUEENSLAND QLD 4072**

**Ph: (07) 3365 3924**

**Fax: (07) 3365 4455**

**Email:** humanethics@research.uq.edu.au

**ADDITIONAL INFORMATION**

Application information, including the UQ Guidelines, can be found on our website:

 <http://www.uq.edu.au/research/integrity-compliance/human-ethics>

The NHMRC’s *National Statement* can be found on the following website: <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

Information concerning clinical trials and the CTN/CTX schemes can be found on the TGA website:

<http://www.tga.gov.au/index.htm>

Information regarding biosafety can be found on the following website:

<http://www.uq.edu.au/ohs/uq-edu-au-ohs-biosafety>

Aboriginal and Torres Strait Islander Studies Unit website: <http://www.atsis.uq.edu.au/> (which includes links to sites including the Australian Institute of Aboriginal and Torres Strait Islander Studies Unit under Cool Sites). Enquiries to the Aboriginal and Torres Strait Islander Studies Unit can be made on: 3365 6714 (ext 56714).

Full Review of applications may take a minimum of eight weeks from the time of submission. Expedited Review and Amendments may take a minimum of three weeks.

**NHMRC**: National Health and Medical Research Council

**AHEC**: Australian Human Ethics Committee

**HREC**: Human Research Ethics Committee and, for the purposes of this application, means an AHEC registered committee

Applications to MREC

Please note that medical research includes epidemiological research (Privacy Act 1988).

**Audits**

Please note that the Committee reserves the right to visit the research site and view materials at any time, and to conduct a full audit of the project.

**Last Update 25/08/2015**

**Submission of Research Protocols for Human Ethical Clearance**

**APPLICATION CHECKLIST**

This checklist is supplied for use as an additional means of ensuring all aspects of the proposed study have been considered and adequately detailed before submission to a reviewing Committee. A copy should be attached to the original application form for the reviewing Committee to support your submission.

Project Title:

Principal Investigator:

**Participant Information Sheet** (PIS)

|  |  |  |  |
| --- | --- | --- | --- |
|  | YES | NO | IF NO, WHY? |
| 1. Version for each participant group *(if applicable)* |  |  |  |
| 2. On letter-headed paper  *(if applicable)* |  |  |  |
| 3. Full title of project |  |  |  |
| 4. Lay title of project  *(if applicable)* |  |  |  |
| 5. Names, positions, & affiliations of all investigators |  |  |  |
| 6. Clear purpose of study |  |  |  |
| 7. Non-technical language - appropriate lay language and length for PIS |  |  |  |
| 8. Details of participation/ procedures |  |  |  |
| 9. Duration of participation |  |  |  |
| 10. Location for participation |  |  |  |
| 11. Risks outlined  *(% explanation needed?)* |  |  |  |
| 12 Benefits to participants |  |  |  |
| 1. What support if something goes

 wrong |  |  |  |
| 14. Statement that participation is  entirely voluntary and that participants are free to withdraw without penalty |  |  |  |
| 15. Assurance of confidentiality |  |  |  |
| 16. Access to results |  |  |  |
| 17. Debriefing |  |  |  |
| 18. Reimbursement to participants (*if* *any*) |  |  |  |
| 19. Contact details for further  questions  |  |  |  |
| 20. Ethical Clearance Paragraph *(refer below)* |  |  |  |

**University of Queensland Ethical Clearance Paragraph**

The following paragraph is to be incorporated into all Participant Information Sheets given to participants in human research:

"*This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with project staff (contactable on .......................), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on 3365 3924.*”

**Participant Consent Form** (PCF)

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| --- | --- | --- | --- |
|  | YES | NO | IF NO, WHY? |
| 1. Version for each participant group *(if applicable)* |  |  |  |
| 2. Full title of project |  |  |  |
| 1. Lay title of project

*(if applicable)* |  |  |  |
| 4. Names, positions, & affiliations of all investigators |  |  |  |
| 5. Provision of space for full name of participant |  |  |  |
| 6. Written declaration ofinformed consent, eg,“*I have read/“I understand…*” |  |  |  |
| 7. Freedom to withdrawwithout penalty |  |  |  |
| 8. Assurance of confidentiality |  |  |  |
| 9. Provision for signature ofparticipant and date |  |  |  |
| 10. Provision for signature of  parent/guardian, relationship to  Participant, and date (*if* *applicable*) |  |  |  |

**Is your trial a Clinical Trial?**

Please tick the applicable box/s for each question.

* **Is UQ the Principal Investigator of this trial?**

If you ticked **YES**, please proceed with completing this form.

If not, this trial will not fall under the University’s protections and you do not need to complete this form.

**The Definition of a Clinical Trial for the purposes of the Clinical Trial Protection is:**

**A study or research involving humans:**

* to test a drug, or a surgical, therapeutic, preventative or diagnostic procedure or device where the nature of the study or research is such that it requires the investigator or an assistant to be a registered medical practitioner or other registered qualified health service provider; or
* requiring any invasive procedure (see below definition) to be undertaken by a registered medical practitioner or other registered qualified health service provider.
* Not applicable

**An invasive procedure means** (for the purpose of this definition) any procedure involving:

* penetration of the skin (other than taking of blood samples);
* biopsy or any taking of or extraction of tissue samples; or
* penetration of the bodily orifices (other than ears or mouth) or insertion of diagnostic or other device within the bodily orifices (other than ears or mouth).
* Not applicable

However, research or study involving humans where the research or study:

* involves evaluating outcomes of established health care management or treatment relating to the condition or illness from which the participants are suffering; or
* only involves the participants completing questionnaires or interviews.

will **not** be deemed to be a **clinical trial** for protection purposes.

**Clinical Trials Required Information**

If your trial is a **Clinical Trial** then please complete the required details on **Page 2** and **include this form with your Ethics Office submission.**

**Does your Clinical Trial need to be Specifically Declared?**

18. Will your trial:

1. Involve research subjects who are either pregnant or breastfeeding (this extends to the unborn fetus of a pregnant research subject and the breastfed infant or baby of a research subject)? Yes 🞏 No 🞏
2. Be undertaken in the USA or Canada? Yes 🞏 No 🞏

**If you ticked yes to a. and/or b.**, your Clinical Trial will need to be specifically declared to the University’s Clinical Trials Protection Provider before protection can be provided.

**If you ticked no to a. and b.**, your Clinical Trial will be automatically included under the University’s Clinical Trials Protection, upon Ethics Office approval.

**Amendments**

Any amendments that change the answers provided on this form must be emailed to insurance@uq.edu.au

**ETHICS OFFICE INSTRUCTIONS ONLY**If Question 18 a and/or b has been ticked yes, then please scan and send **this form and a copy of the Patient Information Sheet and Patient Consent Form** to insurance@uq.edu.au

If Question 18 a. and b. are both ticked ‘no’ then please scan and send **this form only** to insurance@uq.edu.au

**Clinical Trials Required Information – ALL SECTIONS MUST BE COMPLETED**

|  |  |
| --- | --- |
| Ethics Approval Number: |  |
| 1. | **Ethics Approval**Which institution that granted ethics approval? |  |
| 2. | **Principal Investigator**Principal Investigator’s Details.  | **Name:** |  | **Position:** |  |
| **Email:** |  | **Phone:** |  |
| 3. | **School / Department**Who is the School /Department conducting the trial |  |
| 4. | **Clinical Trial Title & Description**Provide the trial name and a brief description (short paragraph). |  |
| 5. | **Sponsor** (if applicable)What is the name of sponsor, their insurer and policy limits? |  |
| 6. | I**ndemnity** Is an indemnity provided by the sponsor? |  |
| 7. | **Granting Body** (if applicable)Who is the granting body for the non-sponsored trial? |  |
| 8. | **Target Participant Numbers**What is the number of participants anticipated to be involved in the trial during the next 12 months? |  |
| 9. | **Target Participants for Whole Trial Period**What is the number of participants anticipated being involved in the whole trial? |  |
| 10. | **Number of Sites**What is the total number of sites? |  |
| 11.  | **Invasive Nature of Trial**Provide details of any invasive procedures to be used during the trial. |  |
| 12. | **Start Date** What is the start date of the trial? |  |
| 13. | **End Date**What is the expected end date of the trial? |  |
| 14. | **Name of Drug** |  |
| 15. | **Dosage of Drug** |  |
| 16. | **Trial - Full Description**(including references to risk events) |  |
| 17. | **Comments** |  |

I declare this document is true and correct to the best of my knowledge:

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**Signature - Chief Investigator Date**