## Project Information

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| **Ethics Review Details** | |
| Application number | Prefilled. |
| Project Title | Prefilled. |
| Application type | Prefilled. |
| Project Type | Prefilled. |
| Which of the following applies to this application? | I am applying for an exemption to Ethics Review  This project has previously been reviewed by an Ethics Committee external to JCU  This project is a clinical trial  None of these |
| Principal Investigator | Prefilled. |
| Academic group | --Please Select-- |
| Preferred contact number |  |
| Academic qualification(s) \* |  |
| Student/Staff? | Student  Staff |
| * Student   Does this project contribute to a qualification?  If Yes, which degree? \* | Undergraduate  Honours  Masters (Coursework)  Masters (Research)  PhD  Other Doctorate degree  Other |
| Role in project \* |  |
| Experience in your role \*  Experience in your role should outline previous experience, specifically in relation to your role in this project, or explain how you will be trained and supervised in your role. |  |
| Project duration: | Up to 6 months  1 year  2 years  3 years  5 years |
| If you are requesting more than 3 years, please justify why you will need more than 3 years and how you will have resources to cover this work \* |  |
| Detail any existing or potential conflicts of interest \*  Conflict of Interest should outline any actual or potential interest, including financial interest, other relationship, or affiliation, that may affect judgement and decisions regarding the well-being of animals involved or the ability to disseminate the results of the research. |  |
| **Aims and Background** | |
| State the background, aims and key research questions, any hypotheses to be tested and the significance of the research. \*  Please provide an overview of the project's background and its significance to the field of research, explaining how it aligns with existing literature and contributes to expanding knowledge. Provide references to support your response. |  |
| **Method** | |
| Outline the Proposed Methodology \*  Please refer to the Application Guidelines and the National Statement on Ethical Conduct in Human Research to assist you in completing these questions.  Include research design, details of data collection techniques, tasks participants will be asked to complete, the estimated time commitment involved, and how data will be analysed. |  |
| Are you recording moving images or photographing your participants? \*  If you are recording photo or video images that identify individuals please explain how this action adds to your data collection and validation of findings and ask participants also to sign the JCU Talent Release Form. | ☐ Yes ☐ No |
| * Yes   Explain why this is necessary in relation to the research aims of the project \* |  |
| **Research Sites and Locations**  If you require approval from the foreign government to conduct research in the designated country, you must submit any evidence of foreign ethics approvals or their equivalent.  If you require JCU Ethics approval prior to applying for foreign government approval, outline the requirements and how you will evidence the approval to the ethics office prior to the commencement of your project.  If no ethics approval is required in that country, provide evidence of this, such as an email from a collaborating institution or a reference from the country's government website. | |
| Identify the research locations and/or sites/locations where the research will be conducted \* |  |
| Outline how the locations will be appropriate to support the needs of the research, the physical and emotional needs, and the safety of both participants and the researchers \* |  |
| Is data to be collected from a country outside of Australia (for JCU-A applicants) or Singapore (for JCU-S applicants) \*  Examples include literature reviews, relevant conferences, discussions with colleagues, and research on websites that provide information on ways to address the 3Rs. | ☐ Yes ☐ No |
| * If Yes,   Which country or countries will be involved? \*  Have you received government approval to conduct research in that country? \*  🡪 If No, please explain. \* |  |
| ☐ Yes ☐ No |
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| **Dissemination of Results** | |
| Explain when, how, where and to whom results will be disseminated \* |  |
| Explain when, how, where and to whom results will be disseminated \* | Written summary of results  Copy of final manuscript (thesis, paper etc)  Verbal presentation (info session, debriefing etc)  Presented to all participants  Presented if requested  Presented to representative of participants (CEO, teachers of students)  Other |

## Collaborators and Funding

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| **Internal Collaborators**  Use this section where members of the project team are students or staff of JCU. | |
| Role on the team \*  This should outline the tasks and responsibilities of the person in this project. |  |
| Select Team Member \* |  |
| Student/Staff \* | Student  Staff |
| Org Unit Affiliation \* |  |
| Preferred contact number \* |  |
| Academic qualification(s) \* |  |
| Does this project contribute to a qualification? \* |  |
| Role in project \* |  |
| Experience in the role \*  Experience in the role should outline previous experience, specifically in relation to the role in this project, or explain how this person will be trained and supervised in the role. |  |

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| **External Collaborators**  Use this section where members of the project team are external to JCU. | |
| Role on the team \* |  |
| Name \* |  |
| Organisation \* |  |
| Email \* |  |
| Preferred contact number \* |  |
| Academic qualification(s) \* |  |
| Role in project \* |  |
| Experience in the role \* |  |

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| **Ethics Advisor**  If you would like an Ethics Advisor to review your application, please add them here | |
| Choose Ethics Advisor |  |

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| **Funding**  If your funding is not listed in GECO you are required to provide details.  Create a separate entry for each type of Funding and/or Funding Body. If your project is self-funded, leave the Funding Body section blank.  Provide an approximate value that includes all cash contributions.  In-kind funds or support is the donation or provision of goods or services other than cash contributions. E.g. office space, stationary, software etc.  Details of what support will be provided in the funding should be provided in the Description | |
| Do you have a Grant for this project that has been approved in GECO? | Yes  No |
| * If Yes   Select the funding record this application relates to \* |  |
| Please indicate any additional sources of funding or resources for this project |  |
| * If No |  |
| The most significant source of funding/resources for this research will be \* |  |
| What is the status of the funding application? \* | Approved  Pending  Not Applicable |
| Funding Body |  |
| Funding Scheme |  |
| Description of funding support \* |  |
| Approximate Value \* |  |
| Start Date |  |
| End Date |  |
| Please indicate any additional sources of funding or resources for this project |  |

## Participants

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| **Participant Details**  The Description should include the inclusion/exclusion criteria and details of the sex/gender and age range, experimental/control groups, and sampling strategy. Please explain the reason behind any proposed or expected imbalances in sex or age and outline what measures will be put in place to prevent bias, or explain how bias is not of concern to the design of the study in the results.  **Aboriginal and Torres Strait Islander research**  This is understood as research that concerns or impacts Aboriginal and Torres Strait Islander peoples in any of the following ways:   * The research is about Aboriginal and Torres Strait Islander peoples, societies, culture and/or knowledge, Aboriginal and Torres Strait Islander policies or experience * The target population is Aboriginal and Torres Strait Islander individuals, groups, communities or societies * The target population is not explicitly Aboriginal and Torres Strait Islander individuals or communities but the research population includes a significant number of Aboriginal and Torres Strait Islander people * Aboriginal and/or Torres Strait Islander people have been incidentally recruited and researchers wish to do separate analysis of Indigenous-specific data * There are Aboriginal and Torres Strait Islander individuals or communities contributing to the research * There is new or pre-existing data related to Aboriginal and Torres Strait Islander peoples being used in the research * The research concerns Aboriginal and Torres Strait Islander peoples’ lands or waters (AIATSIS Code)   **Children and Underage Participants**  If the research involves participants under the age of 18 years, please upload the document to this application, of an Australian working with children approval (Blue Card if working in Queensland), or a Singapore Police Certificate of Clearance or other working with children approval if working in another country. | |
| Describe the target group(s) who will be recruited into this research. \* |  |
| How many total participants do you need to meet your project aims? \* |  |
| How many of the total participants will be JCU students? \* |  |
| Does the research involve participants under the age of 18 years old? \* | ☐ Yes ☐ No |
| * If Yes,   provide details |  |
| Is the research Aboriginal and Torres Strait Islander research? \* | Yes  No |
| * If Yes | Provide details below |
| **Aboriginal and Torres Strait Islander Research**  In addition to the National Statement, research involving Aboriginal or Torres Strait Islander peoples or communities needs to demonstrate the six values below. Before beginning to plan your research, please ensure that you read the following documents, [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders](https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities), 2018 and [Keeping your Research on Track II](https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii), 2018 and allow these documents to guide your research planning and design and discussions. See also the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research, and its guide. | |
| Please outline how your research will demonstrate the value of Spirit and **Integrity** |  |
| Please outline how your research will demonstrate **Cultural Continuity** |  |
| Please outline how your research will demonstrate **Equity** |  |
| Please outline how your research will demonstrate **Reciprocity** |  |
| Please outline how your research will demonstrate **Respect** |  |
| Please outline how your research will demonstrate **Responsibility** |  |
| Please outline how your research will demonstrate **Engagement** |  |

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| **Recruitment**  Additionally, include details of external organisations, third parties, social media to be used, websites or public documents | |
| Describe the process for recruiting participants, including how they will be identified, selected, and invited to participate and how you will access their contact details. \* |  |

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| **Consent**  When describing the process of obtaining informed consent, include the method (e.g. written, verbal) and process for each part of the research project.  For the future use of data obtained in this project, will you be asking for:   * Specific consent - use of the data is limited to this project only * Extended consent - the use of data or tissue in future research projects that are:   + (i) an extension of, or closely related to, the original project; or   + (ii) in the same general area of research (for example, genealogical, ethnographical,epidemiological, or chronic illness research) * Unspecified - the use of data or tissue in any future research   Examples of ensuring informed consent   * Provide translations of information sheets and consent forms * Use an interpreter * Seek parental/guardian consent for children * Ensure your research is undertaken in a culturally sensitive manner * Ensure participants understand their participation is voluntary | |
| Will any part of the research require a waiver of consent or will it use an opt-out consent process? \* | Yes  No |
| * If Yes,   justify this choice based on the criteria outlined in the application guideline. \* |  |

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| **Reimbursement/Incentives**  Note that while participants may, in certain circumstances, be paid or reimbursed for their inconvenience and time, any payments or inducements that are offered must not be disproportionate to the time involved such that it might encourage participants to take risks. | |
| Will the participants be offered any reimbursement of costs, incentives or other rewards to participate in the research? \* | ☐ Yes ☐ No |
| * If Yes,   Describe how much, from what source, and in what form the payment/incentive will take. \* |  |

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| **Dependent/Unequal Relationships and Coercion**  Note that while participants may, in certain circumstances, be paid or reimbursed for their inconvenience and time, any payments or inducements that are offered must not be disproportionate to the time involved such that it might encourage participants to take risks. | |
| Does a dependent or unequal relationship exist between any participant and researcher, particularly those involved in recruitment and consent? \* | ☐ Yes ☐ No |
| * If Yes,   Describe the unequal relationships identified \*  Explain the steps to be taken by the researchers to ensure that the participant’s participation is purely voluntary and not influenced by the relationship in any way. \* |  |
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| **English as a Second Language or with a Low Literacy Level**  Describe how you will ensure that participants, whose first language is not English or who have low literacy level will be able to provide informed consent. | |
| Describe how you will ensure that these participants will be able to provide informed consent. \* |  |

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| **Discontinuing Participation or Withdrawing Consent**  Note the implications for anonymous surveys where potential participants need to be informed that if they withdraw, their data cannot be identified to be deleted. | |
| Identify up to what point of the data collection participants are able to withdraw the information they have provided. \* |  |
| Describe how, as part of the informed consent process, participants will be advised that they have the right to withdraw. \* |  |

## Research Data Management

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| **Rata and Information Management**  Human research data must be managed using the Research Data JCU platform and according to JCU’s Research Data Management policies and procedures.  Data include hard copies, electronic files and forms. Note the difference between data being anonymous (no identifying information collected) and confidential (identifying information collected, but kept secret).  **Minimum period for which data will be retained** The Code for the Responsible Conduct of Research and Research Data JCU give the following guidance:   * In general, the minimum recommended period for retention of research data is 5 years from the date of publication. * Research data that results in a patent must be retained for a minimum of 7 years * For most clinical trials, data should be retained for a minimum of 15 years, and longer if necessary. * If the research work has community or heritage value, research data should be kept permanently, preferably within a national collection.   **Open Data** Many funding bodies and journals require that wherever possible, de-identified data from human research be shared with other researchers.  If there is a chance the data will be shared/made publicly available and used by other researchers in their projects in the future, please ensure that there are the appropriate statements on the Participant Information Sheet and Consent Form. | |
| I have completed a Research Data Management Plan (RDMP) If yes, please upload the RDMP in the attachment section \*  What species, strain/breed, sex, age etc are you asking to use? |  |
| Indicate how the data, materials and records will be kept to protect the confidentiality, privacy or identities of participants and their data  Provide the reason this (these) animal(s) have been chosen. | Data will be entirely anonymous  Data and records will be coded and non-identifiable  Data and records will be coded and re-identifiable  Some or all of the retained data and records will include personally identifying information  Other |
| In what form(s) will data be collected and stored? \*  e.g. electronic, hard copy, recordings, etc |  |
| Where will data, materials and records be stored during and after completion of the project and how will it be secured? \*  Refer to JCU Research Data’s advice on data storage and compliant data storage options. |  |
| Who will be responsible for the security of, and access to confidential data and records, including consent forms, collected in the course of the research? \* |  |
| Indicate the minimum period for which data will be retained \* | Indefinitely  5 years post-publication  7 years post-publication  15 years post-publication  Other |
| Is there any reason NOT to share the de-identified or anonymous data from this project via a research data database such as Research Data Australia for use by other researchers? \* |  |

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| **Privacy**  Please see the Guidelines Approved under Section 95a of the [Privacy Act](https://www.legislation.gov.au/C2004A03712/latest/text)1988 produced by NHMRC.  Please give attention to privacy implications and compliance with legislative requirements including the [Privacy Act](https://www.legislation.gov.au/C2004A03712/latest/text)(Australia),[Information Privacy Act](https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2009-014)(Queensland) or the[Personal Data Protection Act](https://sso.agc.gov.sg/Act/PDPA2012)(Singapore). | |
| Does this project involve gaining access to medical (including epidemiological) information from a Commonwealth agency? (Applicable to Australia only) \* | Yes  No |
| * If Yes,   Which Commonwealth Agency?  Note: this is for Commonwealth Agencies only, and not government agencies at a state/territory level |  |
| Does this information require the disclosure of identifiable personal information? \*  For the HREC to approve this project, they need to assess the privacy provisions according to the relevant legislative requirements | Yes  No |
| * If Yes,   What type of information will you be accessing? |  |
| Will you obtain informed consent from ALL individuals to whom the information is related?   * + If No, explain why you are not obtaining consent \* |  |
| What is the number or range of records required for the research? | Yes  No |
| Does this project involve the collection, use or disclosure of personal health information from a Private Sector organisation, for the purpose of: \* | Research relevant to public health or safety?  The compilation or analysis of statistics relevant to public health or safety?  The management, funding or monitoring of a health service?  None of the above |
| Which Private Sector organisation(s)? \* |  |
| For this project, was it impracticable for consent to be obtained from the individuals to whom the information is related? | Yes  No |
| Was identifiable data required? \*  i.e. the purpose of the proposed project could not be achieved using de-identified information   * If Yes,   What is the reason that identifiable data is required? \*  For the HREC to approve this project, they need to assess the privacy provisions according to the relevant legislative requirements | Yes  No |

## Risk

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| 1. **Contentious or Controversial Topics**   Based on this risk assessment, assign a risk category in F. For each selection where you have identified a potential risk, consider how you will:   1. Gauge the risk – consider the likelihood and severity of any risk. 2. Remove the risk – can you remove the risk by changing your project’s methods? 3. Minimise the risk – If the risk can’t be removed, can it be minimised by a change to the methods? 4. Manage the risk/harm – can any remaining risk or harm be managed by putting in place a monitoring program to detect and institute measures to deal with any harm?   Please note that selections from the checklist can be used as a guide in determining whether your project is lower or higher risk research, and so whether it can qualify for an exemption or low-risk review. | |
| Are any of the following topics covered in part or in whole in your project? \* | Research about parenting issues  Research investigating sensitive personal issues  Research investigating sensitive cultural issues  Explorations of grief, death or serious/traumatic loss  Depression, mood states, anxiety  Gambling  Eating disorders  Illicit drug use  Substance abuse  Self-reporting of criminal behaviour  A psychological disorder  Suicide  Gender identity  Sexuality  Race or ethnic identity  Any disease or health problem  Fertility  Termination of pregnancy  None of the Above |

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| Research procedures/practices Use of JCU Students Personal Information  Please contact the JCU Privacy Officer to get permission to use student data and upload the approval email to this application. | |
| Are any of the following procedures/practices to be used in your project? \* | Use of students’ personal information from a JCU system without specific consent from the students.  Use of personal data obtained from Commonwealth or State Government Department/Agency  Use of personal information from a non-government organisation  Does your research require a waiver of consent?  Deception of participants  Concealing the purposes of the research  Use of human biospecimens in laboratory-based research  Genomic research  Covert observation  Audio or visual recording without consent  Recruitment of a third party or agency  Withholding from one group specific treatments or methods of learning, from which they may “benefit” (e.g. in medicine or teaching)  Psychological interventions or treatments  Administration of physical stimulation  Physically invasive procedures  Potentially painful procedures  Administration of drugs  Administration of other substances  Exposure to ionising radiation  Tissue sampling or blood taking  Collecting body fluid  Use of medical records where participants can be identified or linked  Genetic testing/DNA Extraction  A clinical trial or drug trial  None of the Above |

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| Participant groups: Ethical considerations specific to participants in research Please note that the selections from the checklist can be used as a guide in determining whether your project is lower or higher risk research, and whether it qualifies for an exemption or low-risk review. | |
| Does your project specifically target participants from any of the following groups? \* | Patients, staff, data, facilities or sites in a Queensland health facility. If 'Yes', please submit your application to the HREC of that facility  People suffering from mental ill-health  People suffering from physical ill-health or disability  People highly dependent on medical care who may be unable to give consent  Children or young people  People whose ability to give consent is impaired  People in jail/prison or detention  People unable to give free informed consent because of difficulties in understanding the information provided eg. Language difficulties  People with a cognitive impairment, an intellectual disability or mental illness  People who may be involved in illegal activities  People in dependent or unequal relationships eg. Lecturer/student, doctor/patient, teacher/pupil & professional/client  Members of a socially and/or culturally identifiable group with special social/cultural/ethnic or religious beliefs or political vulnerabilities  Women who are pregnant and the human foetus  Participants are identifiable in the final report when specific consent for release has not been given  None of the Above |

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| 1. **Risks to researchers**   Please note that the selections from the checklist can be used as a guide in determining whether your project is lower or higher risk research, and whether it qualifies for an exemption or low-risk review. | |
| Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots)? \*   * If Yes,   Risk minimisation and/or Management Strategy \* | Yes  No |
| Are there any potential risks to non-participants in the research, such as the participant’s family members and social community? e.g. effects of biography on family and friends or infectious disease risk to the community) \*   * If Yes,   Risk minimisation and/or Management Strategy \* | Yes  No |

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| 1. **Research overseas**   Please note that the selections from the checklist can be used as a guide in determining whether your project is lower or higher risk research, and whether it qualifies for an exemption or low-risk review. | |
| Research being undertaking in a politically unstable area \*   * If Yes,   Risk minimisation and/or Management Strategy \* | Yes  No |
| Research involves sensitive cultural / social / political / ethinic/ economie or religious issues \*   * If Yes,   Risk minimisation and/or Management Strategy \* | Yes  No |
| Where criticism of the government and institutions may be a risk to participants and/or researchers \*   * If Yes,   Risk minimisation and/or Management Strategy \* | Yes  No |

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| 1. **Risk Category**   Please note that the selections from the checklist can be used as a guide in determining whether your project is lower or higher risk research, and whether it qualifies for an exemption or low-risk review. | |
| * Assess your project’s overall risk category \* | Lower risk research  Research in which the only foreseeable risk is no more than one of discomfort which includes, for example, minor side-effects of medication, the discomfort of measuring blood pressure or the anxiety induced by an interview. Proposals will be reviewed by the HREC's Executive.  Higher risk research  Research in which the risk for participants or others is more serious than discomfort which includes the risk of harms such as psychological stress or distress, limited disclosure, social, and reputational damage or other harms. Proposals will be reviewed by the full HREC at their scheduled meeting. |

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| **Other Risk** | |
| Potential other risk that is not stated above |  |
| Risk minimisation and/or Management Strategy |  |
| **Potential Benefits**  Please give your assessment of how the potential benefits to the participants or contributions to the general body of knowledge would justify any risks. Even if the risk is negligible, the research must bring some benefit to be considered ethical. | |
| Outline the potential benefits of the research e.g. for the participants, the community, human knowledge etc \* |  |
| Risk-Benefit Statement \* |  |

## Exemption Questions

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| **Exemption Request Details**  **Ensure you upload any and all relevant documents that support your request for exemption.**  **Surveys** For surveys, include   * a copy of the survey questions * recruitment material used to attract participants   **Teaching** You must upload a copy of the subject outline, practical class manual or other document detailing the activity  **Lower Risk Research** Lower risk research describes research in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research. Research in this category is considered higher risk research and carries risk of harm.  **Publicly Available Data** Examples include mandatory reporting information from registries such as births, deaths and marriages coronial investigations or reports information from statistical agencies such as the Australian Bureau of Statistics | |
| Do you plan to use information about people without their consent \* |  |
| For your research to qualify for an exemption it must carry lower risk to participants and/or the community. Explain how your research meets this criteria. \* |  |
| Provide a brief description of your research \* |  |
| What will the outcomes of the research be used for? \* |  |
| The institution can exempt certain human research from ethics review if it satisfies one or more of the following criteria. Please select the most relevant criteria from the following options that apply to your research. \* | involve the use of collections of information or data from which all personal  identifiers have been removed prior to being received by the researchers.  restricted to anonymous surveys where the outcomes or documentation are unlikely to cause distress to the participants.  restricted to observation of public behaviour where the participants will not be identified and the outcomes or documentation are unlikely to cause distress to the participants.  being conducted as a part of a teaching or educational training program, where the activity is for training purposes only and where any outcomes or documentation are for program use only and will not be published in any way.  involve only information that is publicly available through a mechanism set out by legislation or regulation that is protected by law. |

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| **Collaborating Organisations**  Include Organisations that are involved in the project e.g. Pharmaceutical companies, third parties involved in recruitment etc. Individuals involved in the project should be entered in the External Collaborator section. | |
| Organisation \* |  |
| Description of collaborating efforts |  |

## Clinical T-External Approval

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| **Project Details**  Provide a brief description of the activity you plan to undertake and the impact on the participants. Include justification if applying for an exemption. | |
| Description of the project \* |  |
| Reviewing committee \* |  |
| Provide a brief description of your research \* |  |
| External approval number \* |  |
| How many total participants do you intend to recruit? \* |  |

## Attachments and Comments

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| **Attachments**  Please upload documentation that assists or supports the answers provided in the form. Examples include   * reasons for exemption * approval by another Ethics committee * diagrams, tables, pictures * monitoring sheets or welfare checklists   Mandatory training certificate is required. | |
| Upload file |  |
| Document type \* |  |
| Version |  |
| File name description \* |  |

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| **Comments**  You can add comments to a proposal here by typing in the comment and clicking on Add   * To delete a comment, click on Delete in the Actions column. | |
| Upload file |  |
| Document type \* |  |
| Version |  |
| File name description \* |  |