



**CENTRE FOR RESEARCH**

CHRIST (Deemed to be University)

Application for Ethics Clearance/ Approval from Research Conduct and Ethics Committee (RCEC) for Projects

<b>APPLICANT DETAILS</b>			
Name of the Faculty			
Emp No			
Title of Research			
Name of the Co-investigator			
Discipline / Affiliating Department			
<b>BASIC INFORMATION</b>			
Has your proposal been reviewed by the departmental research committee?	Yes	No	
Proposed Project Duration:	Start date (of data collection):		
	Anticipated end date (of project):		
Suitability:	Does your research involve any of the vulnerable populations in Annexure 1	Yes	No
	If yes state the group:		
	Does your research involve potentially highly sensitive topics listed in Annexure 2	Yes	No

	If yes state the topic:		
	Is your research a clinical trial or human intervention study?	<b>Yes</b>	<b>No</b>
<b>SUMMARY OF RESEARCH</b>			
<p>Your application is more likely to be approved quickly if you provide the ethics reviewers with enough detail so that they can make an informed judgement about the research without having to ask for further details. You should:</p> <ol style="list-style-type: none"> <li>1. provide sufficient information about all aspects of the research - use appropriate language accessible to a lay/ non-specialist person</li> <li>2. ensure consistency across all documentation - pay attention to detail in the answers to your questions</li> <li>3. consider any potential risks posed by the research and state how you intend to mitigate these risks</li> </ol> <p>(please note: research which may present a risk and/or presents potentially contentious issues may be undertaken providing these risks have been justified with appropriate steps put in place to mitigate and manage them)</p>			
<p><b>Aims and Objectives:</b>  (In this section you should provide a summary of the aims and objectives of the planned research. It should be in sufficient detail for the ethics reviewer to understand what the research will involve. Please remember that the ethics reviewer may not be an expert in your field so use language comprehensible to a lay person. You may also wish to include the scientific justification and background for the research.)</p>			
<p><b>Methods/ Methodology:</b> (In this section you should provide a summary of the methods of the planned research, including how the research will be analyzed. It should be in sufficient detail for the ethics reviewer to understand. Please remember that the ethics reviewer may not be an expert in your field so use language comprehensible to a lay person.)</p>			

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**Personal Safety:** (You should include information on how you will decide who the potential participants will be. If potentially vulnerable participants will be involved in your research, you should justify why the research needs to be done using this participant group.)

Does your research raise any issues of personal safety for you or other researchers involved in the project?	Yes	No
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If yes: Explain the issues of personal safety raised and how these issues will be managed

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**PARTICIPANTS**

**Potential participants:**

You should include information on how you will decide who the potential participants will be. If potentially vulnerable participants will be involved in your research, you should justify why the research needs to be done using this participant group.

How will you identify potential participants?

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<p><b>Recruiting Participants:</b> You should include details of how participants will initially be contacted, a summary of the information that they will be given and how they will indicate their initial interest in becoming involved (consent procedures should be covered in the next question)</p>			
<p>How will the potential participants be approached and recruited?</p>			
<p><b>Consent:</b> You should detail how you will give participants enough information so that they can make an informed decision about whether to take part in the research. The information should be understandable and free from complex terminology, with steps taken to ensure it is appropriate for the project’s participants (e.g. by explaining research to children through the use of images and text). There should be an appropriate mechanism for documenting consent (e.g. a consent form or implied consent through the completion and return of a questionnaire). You should also consider whether the participants have the competence to give consent and that they are not subject to inducements. There are some research projects where it is not always possible or desirable to obtain informed consent (e.g. observational research or covert research); this may be acceptable provided it can be justified</p>			
<p>Will informed consent be taken from the participants?</p>	<p>Yes</p>	<p>No</p>	
<p>If yes: How do you plan to obtain informed consent? (i.e. the proposed process)</p>			
<p>If no: Please explain and justify why you will not be obtaining informed consent?</p>			
<p><b>Payment:</b> A factor that may cloud the judgement of a potential participant when deciding whether or not to participate in research is whether money or payments in kind (e.g. gift vouchers) will be offered. It is reasonable for expenses and compensation of time to be offered</p>			

RCEC – Research Ethics Application Form

<p>but any payments made to individuals to enable them to participate in research activities must not be so large as to induce them to take risks beyond those that would usually be part of their established life-style.</p>		
<p>Will financial/in kind payments be offered to participants?</p>	<p>Yes</p>	<p>No</p>
<p>If yes: Please provide details and justification for this payment</p>		
<p>What is the potential for physical and/or psychological harm/distress to the participants? You should outline the steps that will be put in place to minimize any potential for physical and/or psychological harm/distress to participants mentioned above.</p>		
<p>How will this be managed to ensure appropriate protection and well-being of the participants?</p>		
<p><b>DATA</b></p>		
<p>Data Confidentiality Information relating to the extent to which a participant's data will remain confidential should be disclosed to the participant as part of the process of seeking informed consent. Researchers should take care not to promise participants a level of confidentiality and/or anonymity which they may later find they are unable to meet without jeopardising the research itself, and should think carefully in advance about their plans for the analysis, publication and dissemination of the research findings - complete confidentiality/anonymity is often very difficult to ensure. It is good practice to consider possible future uses of the research data as well as the immediate project</p>		
<p>What measures will be put in place to ensure confidentiality of personal data, where appropriate?</p>		

<p><b>Data Storage:</b> The ethics reviewer may need to know: - Who will have control of, and act as the custodian for, the data generated by the project? - Where the analysis of the data from the project will take place and who will analyse the data? - Whether any encryption or other anonymization will be used and at what stage? - Who will have access to the data generated by the project? - Is it likely that the data will be made available for use in future research projects? - When (if ever) will the data be destroyed? - If your research is externally funded and if so has it met the requirements of the funder with regards to data storage and management? If you are planning to record activities on audio or video media you will need participants' permission to do so. You must ensure that there is a clear understanding with participants as to how these recorded media will be used, stored and (if appropriate) destroyed.</p>			
<p>How and where will the data be stored, used and (if appropriate) destroyed?</p>			
<b>SUPPORTING DOCUMENTATION</b>			
<p>Information &amp; Consent: Are the following supporting documents relevant to your project?</p>			
Participant information Sheet(s)	Yes	No	
Consent Form(s)	Yes	No	
<p>Additional documentation: If any other supporting documentation (such as a complete research proposal, a letter of support from a research partner or a covering letter) is relevant to your application, list it here and attach a copy with the application.</p>			
1.	2.	3.	4.
<b>DECLARATION</b>			
<p>I confirm my responsibility to deliver the research project in accordance with Christ University's Regulations pertaining to 'Code of Research Conduct and Ethics', Academic Integrity Policies, General Regulations and Departmental Policies.</p>			
<p>In signing this research ethics application form I am conforming that:</p>			
<ol style="list-style-type: none"> <li>1. The form is accurate to the best of my knowledge and belief.</li> <li>2. The project will abide by the University's Code of research conduct and ethics:</li> <li>3. There is no potential material interest that may, or may appear to, impair the independence and objectivity of researchers conducting this project.</li> <li>4. Subject to the project being approved, I undertake to adhere to any ethics conditions that may be set.</li> </ol>			

5. I undertake to inform the ethics reviewers of significant changes to the protocol (by contacting my academic department's research coordinator/ HOD and my supervisor in the first instance).
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data,
7. I understand that the project, including research records and data, may be subject to inspection for audit purposes, if required in future.
8. I understand that personal data about me as a researcher in this form will be held by those involved in the ethics review procedure (constituted under the center for research)

SIGNATURE

Investigator:

ANNEXURE - 1

Potentially Vulnerable Participants

This includes, but is not restricted to:

A. People whose competence to exercise informed consent is in doubt, such as:

1. infants and children under 18 years of age
2. people who lack mental capacity
3. people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate
4. people who may have only a basic or elementary knowledge of the language in which the research is conducted

B. People who may socially not be in a position to exercise unfettered informed consent, such as:

1. people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organizational employees)
2. family members of the researcher(s) iii. in general, people who appear to feel they have no real choice on whether or not to participate

C. People whose circumstances may unduly influence their decisions to consent, such as:

1. people with disabilities
2. people who are frail or in poor health
3. relatives and friends of participants considered to be vulnerable
4. people who feel that participation will result in access to better treatment and/or support for them or others
5. people who anticipate any other perceived benefits of participation
6. people who, by participating in research, can obtain perceived and/or real benefits to which they otherwise would not have access

## ANNEXURE - 2

Highly Sensitive Topics This includes, but is not restricted to:

- 'race', caste or ethnicity
- political opinion
- religious, spiritual or other beliefs
- physical or mental health conditions
- sexuality
- abuse (child, adult)
- nudity and the body
- criminal activities
- political asylum
- conflict situations
- personal violence