CHRIST
(DEEMED TO BE UNIVERSITY)
BANGALORE · INDIA

Research Conduct and Ethics Guidelines for Faculty and Departments

Research Conduct and Ethics Committee
(Institutional Review Board)

Human Participant Research

Centre for Research

Contents

Introduction

Guidelines for departments and faculty members to the process of applying for ethical clearance for human participant research is explained in the document. This guideline is based on Christ University Code of Research Conduct and Ethics issued on 13 May 2016. A copy of the full regulation is available in the Knowledge Pro account of every faculty member. It is strongly recommended that faculty members of the institution engaging in research read the regulation in full. In this document relevant extracts of the regulation that pertains to human participant research is cited. Guidelines are subject to changes based on amendments made to guiding regulations.

This document will cover the following topics

1. The Basis for the Research Conduct and Ethics Committee (Commonly referred to as Institutional Review Board)
2. The Functioning of the Research Conduct and Ethics Committee
3. Application Process for Review by RCEC or its sub committees
4. Application forms
5. List of training courses for ethics of human participant research

The Basis for the Research Conduct and Ethics Committee

The Research Conduct and Ethics Committee (RCEC) has its basis in the Christ University Code of Research Conduct and Ethics issued on 13 May 2016. Clause 5 (Research Ethics Guideline) and Clause 7 (Regulatory Authorities) are in particular relevant to this guideline.

Research Ethics Guidelines

The University is committed to follow good ethical practice, as a principle in itself and as a means to create public confidence in the research work of the University. The prescribed Regulatory Authority in this regard (Research Conduct & Ethics Committee – RCEC) will lay down specific Guidelines with reference to different disciplines of research duly reviewed from time to time in accordance with international practices and as guided by the Centre for Research of the University. Periodic review and approval of the Research Process for its conduct and ethical compliance by RCEC is mandatory and is done to ensure quality conduct and ethical propriety of the Research pursued at the University. General Guidelines for Research Ethics are as under:

a) Research must not cause harm to the participants in particular and to people in general.
b) Research should as far as possible make a positive contribution towards the welfare of people.
c) Researchers have a right, as well as a responsibility, to refrain from undertaking or continue undertaking any research that contravenes ethical guidelines, violates the integrity of research and/or compromises their autonomy in research, including design methodology, analysis and interpretation of findings and publication. If they feel that their rights are being violated, or that the study is unethical, they should make all possible efforts at making corrections. In the event of failure of remedial measures they should exercise their right to terminate the study or to opt out of it.
d) Research must respect and protect the rights and dignity of participants.
e) The benefits and risks of research should be fairly distributed among people.
f) All information and records provided by participants or obtained directly or indirectly on/about the participants are confidential. For revealing or sharing any information that may identify participants, permission of the participants is essential.
g) All research must take adequate precautions towards minimizing and mitigating risks if any involved in the research process or in the delivery of its output.
h) Research must not unnecessarily consume the time of participants or make them incur undue loss of resources and income. It should not expose them to risks due to participation in the research.
i) Covert research must not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance which cannot be uncovered in other ways are likely to be discovered.
j) The relationship within the research team, including student and junior members, should be based on the principle of non-exploitation.
k) Researchers have a responsibility towards the interests of those involved in or affected by their own work. They should make reasonable efforts to anticipate and to guard against possible misuse and undesirable or harmful consequences of research.
l) Researchers should take reasonable corrective steps when they come across misuse or misrepresentation of their own work.
m) Contribution of each member of the research team should be properly acknowledged.
n) The conduct of research must be fair, honest and transparent. It is desirable that the researchers are amenable to social and financial review of their research.
o) Researchers must ensure respect, protection and promotion of rights of participants. Criteria for the selection of participants of research should be fair, besides being scientific.
p) Researchers should declare and manage any real or potential conflicts of interest.
q) The principal researchers should delegate to the juniors, assistants, students and trainees only those responsibilities that they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision.
r) All members of the team on a research project have a right to know and document all aspects of research including ownership of the data. This will also apply to the participation of students doing their own research in a project team.

Extract of Clause 5 of Christ University Code of Research Conduct and Ethics issued on 13 May 2016

Regulatory Authorities

a) The Regulatory Authorities of the University as tabled herein will be responsible for overseeing the quality conduct of Research at the University including adherence to the requirements of this Regulation.
b) The Regulatory Authority concerned will record and document the proceedings of its review.
c) The RCEC may delegate the review of research that poses minimal risk to human participants to research committees at departmental or deanery level. Guidelines as to what form of research poses risk to human participants can be obtained from the Centre for Research of the University.
d) The Regulatory Authority will have powers to stop the Research if its directions are not acted upon by the Researchers.

Extract of Clause 7 of Christ University Code of Research Conduct and Ethics issued on 13 May 2016

Functions of the RCEC

The RCEC is multidisciplinary and multisectoral in its composition. It fulfils the two critical characters of an Institutional Review Board: independence (free from undue influence) and Competence (Ability to evaluate research work from the point of ethical principles)

The Committee consists of a chairperson from an external pool of senior academicians, practitioners or researchers and well versed with ethics and with no stake in the University Research.

The Member Secretary is the director of research or a nominee of the director for research from among the faculty of the institution and he/she shall conduct the business of the committee. The membership of the RCEC is made up (a) a senior advocate practising law or a retired Judge (b) a theologian or philosopher specialised in ethics (**c)** a social scientist / a clinician/ a biomedical scientist (d) Representative of NGO (e) a layperson from the community (f) two senior professors nominated by the VC

Invitees: The RCEC can invite subject experts to review proposals for which additional competence is deemed to be required

Meeting frequency

The committee meets minimum twice a year to review significant research proposals flagged for review by the Centres and departments. The RCEC will review all major research projects, external grant projects and collaborative projects. In a case where a quicker review is required, the RCEC will convene or constitute a subcommittee of its members to expedite review. Any funded project must be reviewed by the RCEC.

The member secretary / centre for research will review the research proposals submitted to the centre for research for ethical review and classify them into three categories depending on their completeness and the risk involved. The three categories are: exemption from review, expedited review and full review. In some cases, like emergencies the proposals may be considered for accelerated review. (See explanations in a later section)

Delegated subcommittees

Considering a large number of research projects, theses, dissertations, and student projects involving human participants undertaken in the University and its campuses, the ethical review is delegated by the RCEC as follows:

1. Undergraduate and Masters theses/dissertations – Department level committee/s approved by the Head of the Department or Dean of the School will review projects involving human participants. If these committees are panels of teachers, then all the teachers must have mandatorily been trained in ethics. Any proposal that considers vulnerable groups as outlined in the Annexure must be escalated to the RCEC for review. Proposals that pose **more than minimum risk (**see criteria in a later section) should also be referred to the RCEC for review. All proposals will be reviewed only after they are approved by the departmental approval policies for methodological competence.

2. PhD Thesis – A subcommittee of the centre for research will review PhD proposals involving human participants, and human data. The PhD proposal must be submitted for review to the RCEC after the Research Advisory Committee (RAC) as per doctoral regulations has approved the proposal for methodological competence.

The RCEC will review all funded projects, major and minor research proposals, and collaborative faculty led research proposals involving human participants.

Review process

The RCEC will review every proposal involving human participants before the research is initiated. It is expected that the proposals submitted for ethical clearance have already been reviewed by appointed centres and committees of the University or processes set in place by external agencies for **its scientific rigor**. In case such a review has not been completed the RCEC must ensure it is done inviting relevant subject experts if necessary. However, in situations where the RCEC is not convinced about the scientific merits of the proposals, additional review may be sought from experts.

The committee will review the proposal for all aspects indicated in clause 5 and 6 of CHRIST University **Code for Research Conduct and Ethics**

Types of review

Normally there are three types of review:

Full review, Expedited review and Exempted review. In some cases, an accelerated review may be required or a continuous review may be suggested.

Full committee review of proposals

All research presenting with more than minimal risk, which do not qualify for exempted or expedited review projects that involve vulnerable populations and special groups shall be subjected to full review by all the members. (See criteria for expedited review in appendix)

Expedited review of proposals

A proposal is circulated for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case the proposal is sent to two members of the RCEC after scrutiny of eligibility for expedited review by the member secretary / Centre for research. In cases of national emergency, outbreak of disease, pandemics and so on, the review may be further accelerated **(accelerated review)**

(See criteria for expedited review in a later section)

Exempted Review

A proposal is exempted for review when there is no harm or risk of harm to the participants. The member secretary/ CFR records this and presents a list of exempt proposals during the periodic review of the RCEC

Continuous review

In some cases, the proposal may require reviews after a period based on the research proposal. In this case, the RCEC gives conditional approval.

Application for Ethical Review

All research involving human participants must be reviewed by the RCEC. **The researchers cannot by themselves decide** if the research is exempt from review. The RCEC will review all proposals and inform the researchers of the review status.

The application must be submitted to the centre for research in the prescribed application form duly signed by the researchers and all investigators.

The member secretary / CFR will inform the applicant of the status of the review within 48 hours of receiving the application. Approved applications are issued with a letter and reference number.

All fields of the application form (see appendix) are expected to be filled by the applicants with clear explanations to all questions asked in the application form. In addition, they must attach:

1. A copy of the approved research proposal

2. Informed consent forms

3. Assent forms when applicable

4. Brochures, flyers, notices of the research

5. Brochures or information regarding recruitment of participants

A standard application from covers the following information:

1. The title with signature of the Principal Investigator and co investigators for Major research projects. Research scholars must affix their University Registration numbers, signature and Supervisor's signature and name.
2. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
3. Recent curriculum vitae of the Investigators indicating qualification and experience. For research involving the administration of educational training programmes, interventions and experiments, adequate competence in those areas must be demonstrated in the curriculum vita.
4. Procedures for recruitment of participants for projects that require participants for intervention research.
5. The inclusion and exclusion criteria of participants with screening procedures and tools used to screen the participants.
6. Accurate description of methods of the proposed research, including sample size (with justification), type of study design, intended intervention (if applicable), and other details if any. Invasive techniques if any must be reported clearly with the procedures outlined. If external facilities are used for procedures such as drawing human body samples, body scans and so on, clear agreements to be stated in the proposal.
7. Plan to withdraw or withhold standard interventions in the course of research.
8. Plan for statistical analysis of the study. The choice of the analysis and its appropriateness over other possible methods.
9. Procedure for seeking and obtaining informed consent with a sample of information sheet and informed consent forms in English and local languages. Assent forms in the case of minors and parental approvals for research must be submitted for research involving minors.
10. Safety of proposed intervention including psychological safety, to participants.
11. For research involving more than minimal risk, an account of management of such risk or injury.
12. Proposed compensation for incidental expenses. Plan for incentives if any.
13. An account of storage and maintenance of all data collected during the trial. Encryption details and adherence to storage of data as per international norms.
14. Online tools of data collection such as surveys, forms and video conferencing tools must be compliant with privacy norms and encryption procedures clearly stated
15. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
16. Statement of regulatory clearances where required. If IRB clearance obtained from a collaborating agency, then a copy of the approval to be attached.
17. Agreement to comply with National and International Good Clinical Practices (GCP) protocols for clinical trials. Agreement to comply with good standards of research.
18. Details of Funding agency/ Sponsors and fund allocation. Indicate the funding agency if a proposal is submitted prior to committed funding.
19. For international collaborative study details about foreign collaborators and documents for review. Approval and agreements from University approving authority.
20. A statement on conflict-of-interest (COI), if any.
21. A copy of the most recent completion of research ethics and compliance training course from among the courses recommended in the section on training.
22. Plans to upload data in open source, public repositories as advised by professional bodies must be stated by the researcher and any limitations to this stated as well.
23. Plans to ensure accurate translation of tools, spoken language skills in local languages and dialects of data collection requires

Decision Making Process

The RCEC will review all proposals submitted to them. The member secretary after the initial screening will send the proposal to RCEC members for review and based on broad consensus the Result of the review process intimated in writing to the applicant. The decision could be any one of the following:

1. Recommend
2. Reject
3. Suggested Modification and resubmit / or advise appropriate steps.

Reasons for number 2 and 3 will be given in writing to the applicant.

Training

As indicated earlier, researchers who work with human participants must mandatorily complete ethics courses. They may complete certification by any of the following:

1. CITI - Collaborative Institutional Training Institute (Paid course) (https://about.citiprogram.org/en/homepage/)
2. Research Ethics online training by Global Health Training Centre (Free course) (https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/)
3. Introduction to research ethics: Working with people by University of Leeds via FutureLearn platform (Free Course) (https://www.classcentral.com/course/research-ethics-an-introduction-12091)
4. Research Ethics Training Curriculum by FHI. (Free Course) (https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/RETCTraditional/intro.html)
5. NIH Research ethics (free course) (https://researchethics.od.nih.gov/CourseIndex.aspx)
6. Any other ethics course dealing with **human participant research w**ith approval from the centre for research. (Approval is needed because some courses on ethics are not related to human participant research)

Criteria for risk as given by National institute of Mental Health, USA

Criteria for minimum risk

Minimum risk to subjects/participants means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected.

Criteria for greater than minimum risk

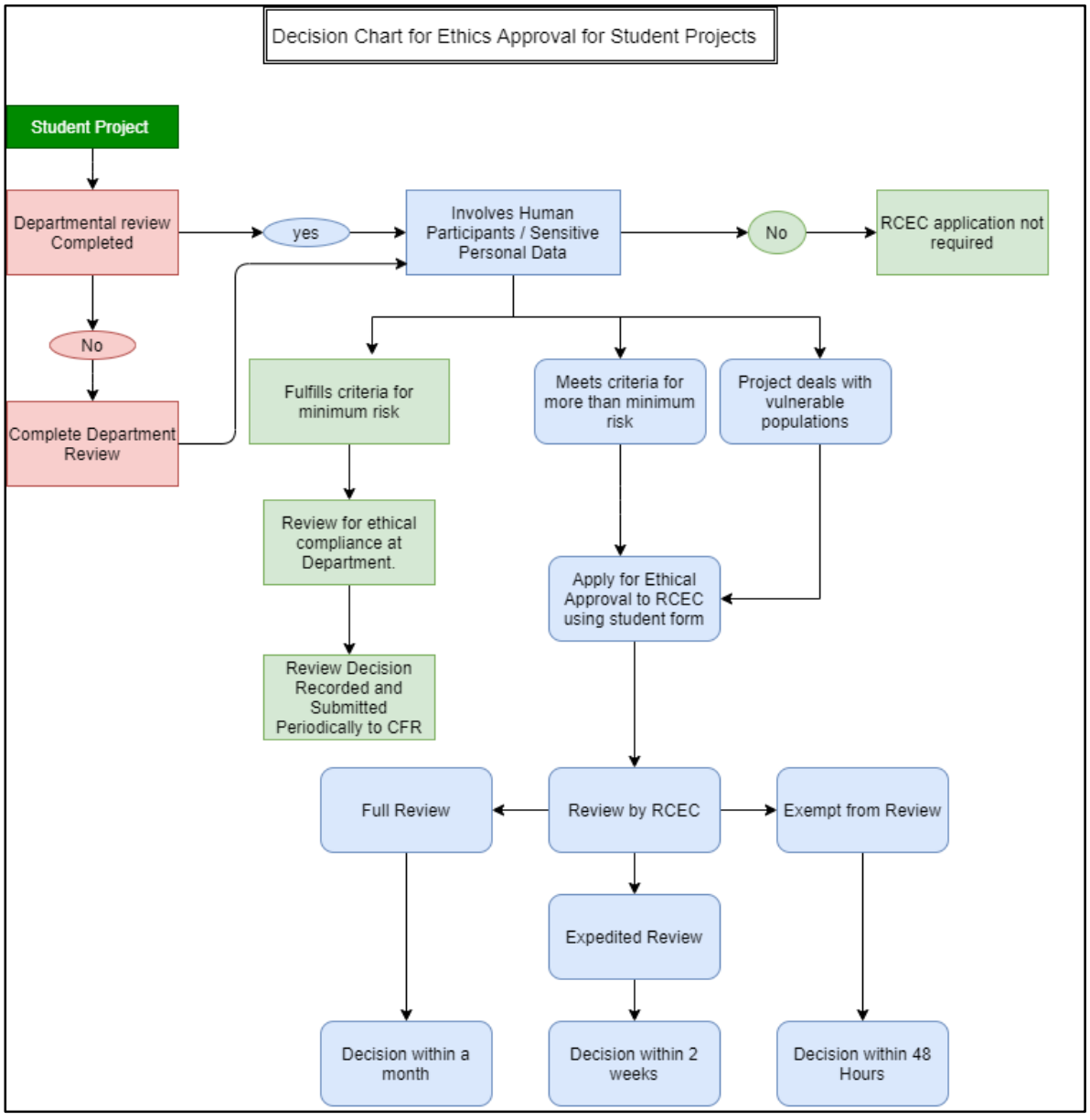
Greater than minimum risk to subjects/participants means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater. Studies that fall under this category will range in their probability of a moderate-severity event occurring as a result of study participation (and the level of safety monitoring will depend on that probability) but there are adequate surveillance and protections in place to identify adverse events promptly and to minimize harm.

Criteria for significantly greater than minimum risk

Significantly greater risk to subjects/participants means that there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events. Trials with significantly greater than minimal risk require adequate protections for foreseeable adverse events.

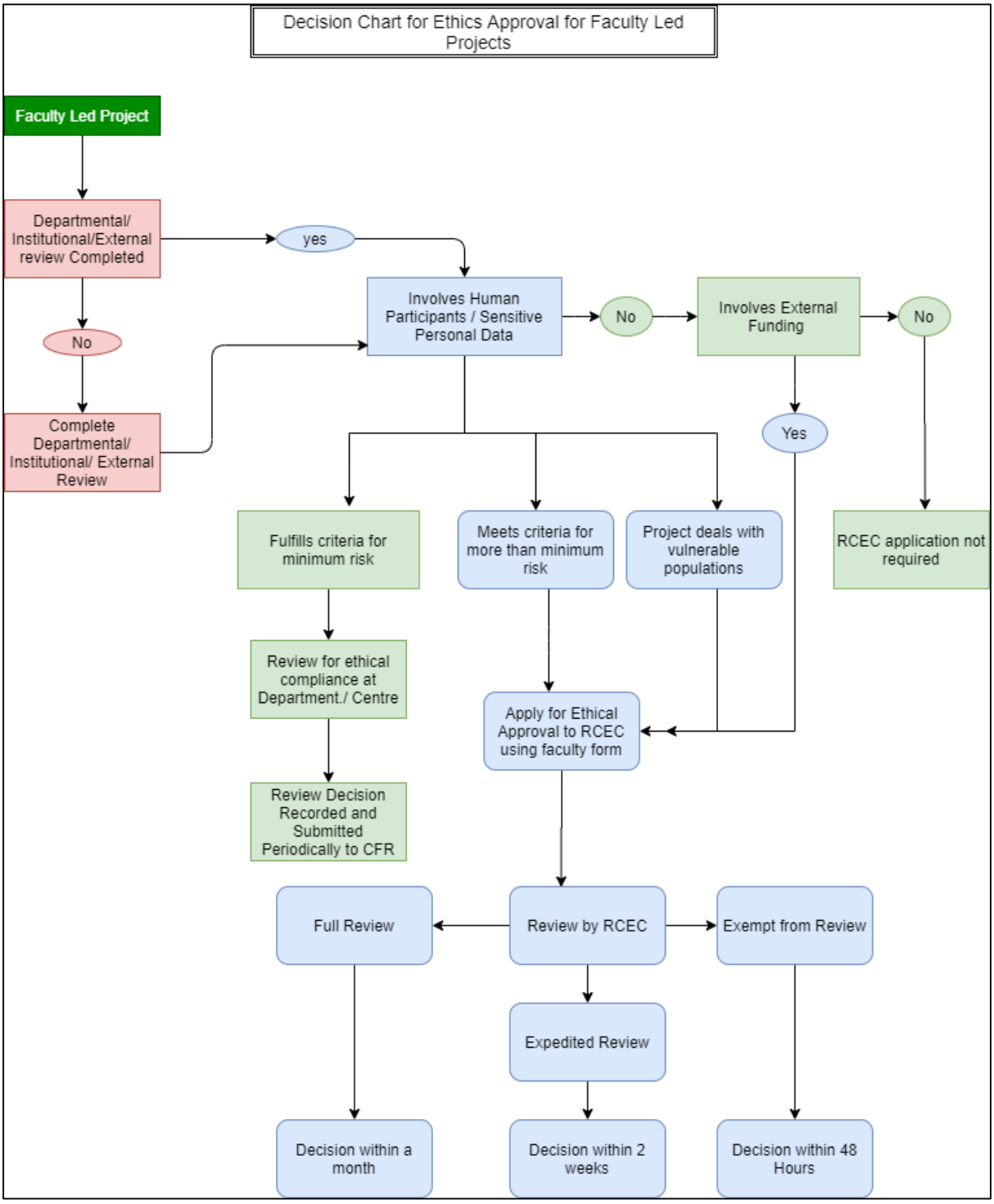
Decision Trees

1. Decision tree for student projects*



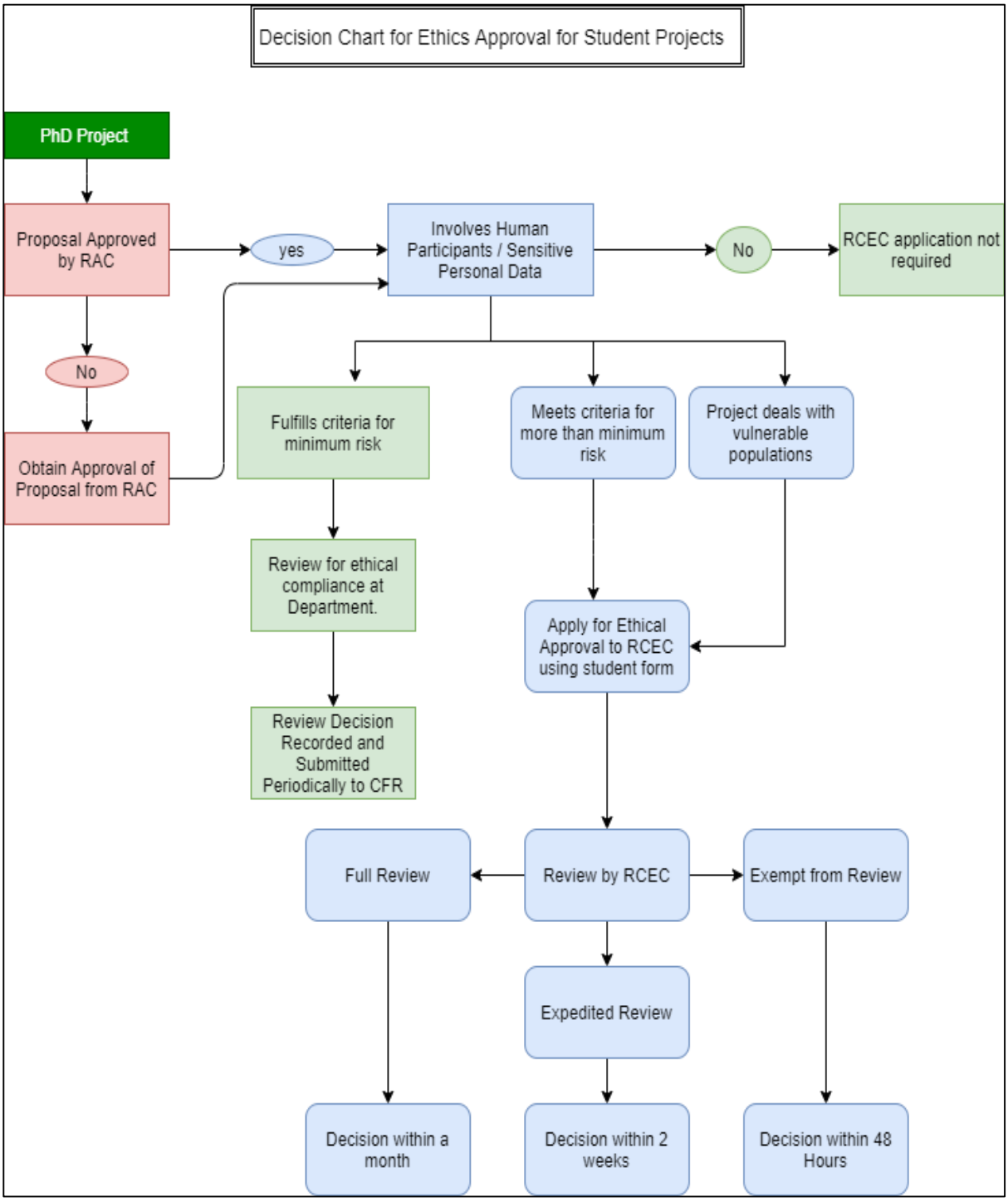
*Student projects without supervisory support will not be considered

2. Decision tree for faculty Led Projects*

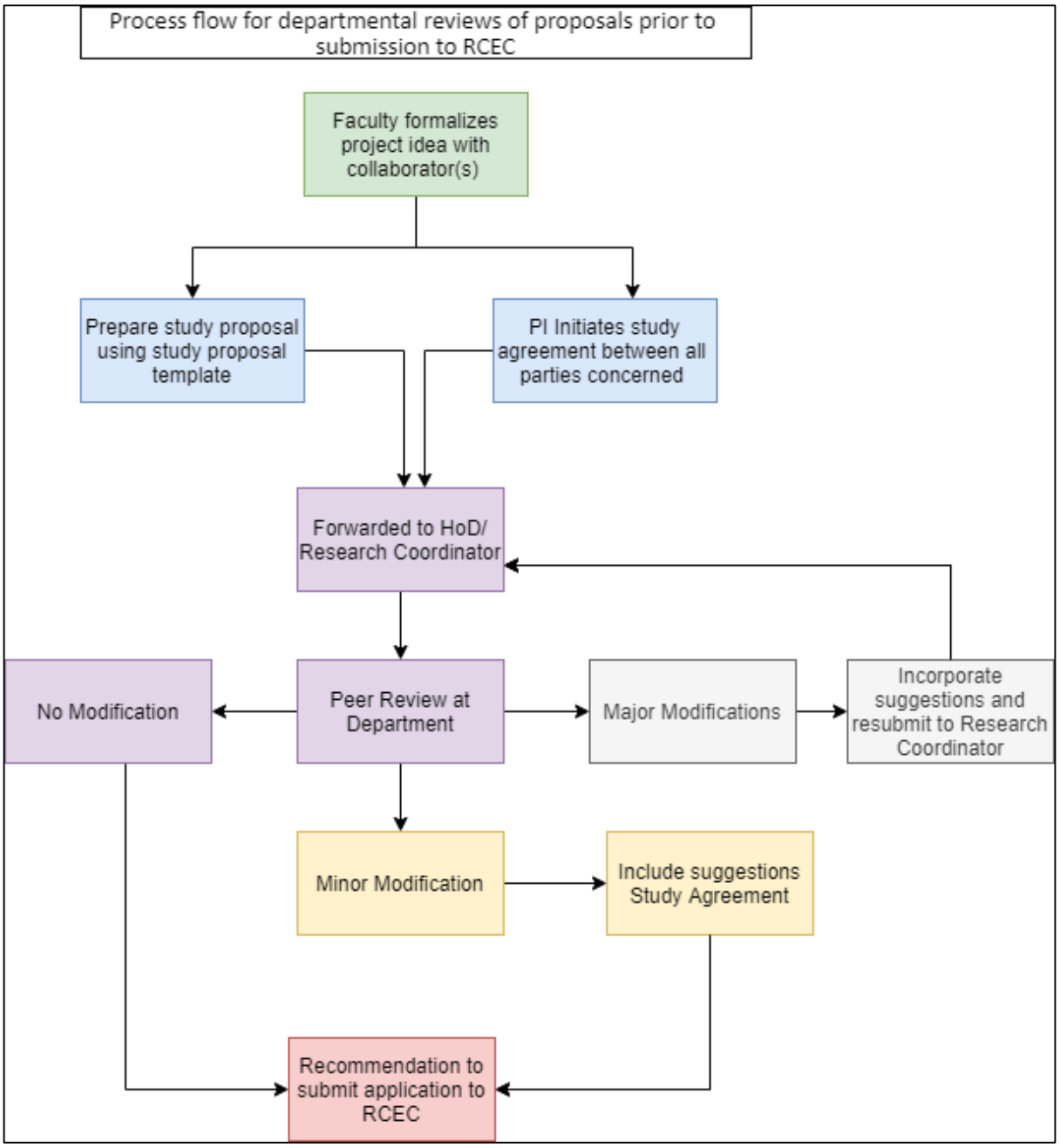


* See Appendix 1 for Process framework for faculty led collaborative research projects, Appendix 2 for proposal review checklist and Appendix 3 for Collaborative Study Agreement Template

3. Decision tree for PhD Projects



4. Process flow for departmental reviews of proposals prior to submission to RCEC



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 RCEC – Research Ethics Application Form 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

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

Appendix- 1

Process Framework for Faculty led collaborative research projects

CHRIST faculty are encouraged to conduct intramural or extramural collaborative research with other faculty. These projects may involve students as research interns, project fellows in an extracurricular manner.

After the concerned CHRIST Faculty has formalized the project idea with a Collaborator (Faculty/Researcher) a project proposal needs to be prepared. (Study Proposal Template – to be drafted)

Following this, the Principal Investigators (PI) can initiate a study agreement between all involved parties that covers issues of roles and responsibilities, data use and publications/patents. (Study Agreement Template).

The Faculty-PI (CHRIST Deemed to be University) will forward a copy of this agreement along with the draft proposal, to the parent department HOD and research coordinator. The proposal will be reviewed by a designated member of the Department Research Committee. Subsequently, a recommendation to proceed with the ethics review will be made (provided the institutional regulations [CU Regulations for Code of Research Conduct and Ethics] have been adhered to). If there are violations, a request for resubmission and amendment will be shared with the PIs. With the approved proposal, the CHRIST Faculty (PI) can initiate the submission for ethics approval by filling out the Ethics Review Form [available here].

Proposal Review Checklist (PRC)

1. Collaboration objectives and aims are clearly defined.
   Acceptable / Not Acceptable
   Reason:

2. Topic idea is relevant to the expertise of both PIs. Yes / No
   Comments:

3. There is proper use of institutional framework and proposal submitted is a clear and complete document (Format - Aims, Objectives, Introduction & Review, Methods, Data – Tools/Collection/Storage, Analysis & Interpretation, Ethical Considerations)

4. Methodology is relevant to the title.
   Comments:

5. Data Collection - well planned; Sample is appropriate and accessible. Yes / No
   Comments:

6. Informed Consent, ethical procedures and data collection instruments are aligned to the sample characteristics. Yes / No
   Comments:

7. Data Analysis plan appears aligned to the study objectives and the analysis process has been detailed in the proposal. Yes / No
   Comments:

8. Research Expenditure issues are anticipated and explained clearly. Yes / No
   Comments:

9. Timeline of the project is clear and effective. Yes / No
   Comments:

10. Data sharing and access between collaborators is detailed in Study Agreement. Yes / No
    Comments:

11. Is there a well-defined plan for publications in Study Agreement? Yes / No
    Comments:

12. Is there a plan to explore possibility for filing a patent application? Yes / No
    Comments:

13. Are student researchers part of the project? Yes / No
    Comments:

14. Are the student roles clearly defined for the project work and for publications? Yes / No
    Comments:

Recommendation about modifications required (if any):

Reviewer Name: Review Date:

Signature:

No Modifications: Researcher can go ahead and submit the IRB form with the required annexures (Proposal, Tools, Study Agreement and Informed Consent copy)

Minor Modifications: The suggestions from this report can be incorporated into the Proposal/Study Agreement. Subsequently, the researcher can go ahead and submit the IRB form with the required annexures (PRC Report, modified Proposal, Tools, Study Agreement and Informed Consent copy)

Major Modifications: The suggestions from this report can be incorporated into the Proposal/Study Agreement. The researcher can resubmit this for a second review to the Research Co-ordinator.

Appendix 2

Proposal Review of Faculty led collaborative research projects, Department of Psychology

Dear Researcher

Thank you for submitting the proposal for review and the report is appended below. Kindly review and if there are queries, please do address it in the proposal document. After you make the required modifications, you may prepare the IRB form and submit the

Proposal Review Checklist (PRC)

1. Collaboration objectives and aims are clearly defined.
   Acceptable / Not Acceptable
   Reason:

2. Topic idea is relevant to the expertise of both PIs. Yes / No
   Comments:

3. There is proper use of institutional framework and proposal submitted is a clear and complete document (Format - Aims, Objectives, Introduction & Review, Methods, Data – Tools/Collection/Storage, Analysis & Interpretation, Ethical Considerations)

4. Methodology is relevant to the title.
   Comments:

5. Data Collection - well planned; Sample is appropriate and accessible. Yes / No
   Comments:

6. Informed Consent, ethical procedures and data collection instruments are aligned to the sample characteristics. Yes / No
   Comments:

7. Data Analysis plan appears aligned to the study objectives and the analysis process has been detailed in the proposal. Yes / No
   Comments:

8. Research Expenditure issues are anticipated and explained clearly. Yes / No
   Comments:

9. Timeline of the project is clear and effective. Yes / No
   Comments:

10. Data sharing and access between collaborators is detailed in Study Agreement. Yes / No
    Comments:

11. Is there a well-defined plan for publications in Study Agreement? Yes / No
    Comments:

12. Is there a plan to explore possibility for filing a patent application? Yes / No
    Comments:

13. Are student researchers part of the project? Yes / No
    Comments:

14. Are the student roles clearly defined for the project work and for publications? Yes / No
    Comments:

Recommendation about modifications required (if any):

Reviewer Name: Review Date:

Signature:

No Modifications: Researcher can go ahead and submit the IRB form with the required annexures (Proposal, Tools, Study Agreement and Informed Consent copy)

Minor Modifications: The suggestions from this report can be incorporated into the Proposal/Study Agreement. Subsequently, the researcher can go ahead and submit the IRB form with the required annexures (PRC Report, modified Proposal, Tools, Study Agreement and Informed Consent copy)

Major Modifications: The suggestions from this report can be incorporated into the Proposal/Study Agreement. The researcher can resubmit this for a second review to the Research Co-ordinator.

Appendix 3

Collaborative study agreement

Collaborative Research Study Agreement (X Pages)

This is a study agreement for a research project with the following aims:

Title of the project:

Investigators and institutional affiliation

Department of XX Other Institution

(1) Person 1 ,Designation
(2) Person 2, Designation

Department of Psychology, Christ (Deemed to be University), Bangalore, India

Brief outline of project: (250-300 word abstract that includes some details on sample and site of data collection) [if available attach the Study Proposal separately]

Roles and Responsibilities of all parties involved in the project (list all members of this project)

Name	Role
CHRIST	
	Principal Investigator (Project design, supervision)
	Co-Investigator (Domain expertise eg. Statistical analysis)
	Project/Research Fellow (Data Collection, curation & analysis)
[Other Institution]	
	Principal Investigator
	Research Intern (Data Collection & Curation)

Personnel assistance in the project (Describe the expectations, honoraria and quantum of work): Research Interns etc.
Project Data use and Analysis (Indicate where data will be stored, who has access, how it will be shared, and who is responsible for analysis)
Publication and Authorships (Indicate who has primary responsibilities for publication, expectations of how many manuscripts, terms for authorship)
Additional Information (if any)

This Agreement shall continue in force until either (i) the completion of the Study as mutually agreed upon by the parties; or (ii) _____ months from the date set forth above. However, either party may terminate this Agreement before the agreed date after framing a mutually acceptable course of action vis-a-vis data and publications.

All researchers participating in this study agree to abide by this agreement:

Names:	Signatures:
XXXXXXXXXX	_____
XXXX XXXXX	_____
XXXXXXXXXXXXX	_____
XXXXXXXXXXXXX	_____

For Office Use:
Reviewed by:
Signature:

Sources

The following documents were used in the creation of the current guideline

Ethical Guidelines for biomedical research involving human participants, NIMHANS

Ethical Guidelines for Biomedical Research on Human Participants – ICMR 2006

British Psychological Society - IRB Review documents

CITI Training - Institutional IRB- Structure and functions

APA: IRBs and IRBs and Psychological Science: Ensuring a Collaborative Relationship

Global Health Training ethics online course

(https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring.shtml)

Centre for Research

rcec@christuniversity.in