



CHRIST

(DEEMED TO BE UNIVERSITY)

BANGALORE | DELHI NCR | PUNE

**Guidelines for Departments, Faculty
members, Research Scholars and
Students**

Research Conduct and Ethics
Committee (Institutional Review Board)
Human Participant Research

Centre for Research

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1. Introduction

- 1.1. Guidelines for departments, faculty members, Research Scholars and students 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.
- 1.2. This document will cover the following topics
 - a. The Basis for the Research Conduct and Ethics Committee (Commonly referred to as Institutional Review Board)
 - b. The Functioning of the Research Conduct and Ethics Committee
 - c. Constitution of Department Research Ethics Committees (DREC)
 - d. Application Process for Review by RCEC and DREC
 - e. Application forms
 - f. Training courses on ethics of human participant research for Faculty and Student researchers

2. The Basis for the Research Conduct and Ethics Committee

- 2.1. 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.

Clause 5: 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.

Clause 7: 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.

3. Functions of the RCEC

- a. Functions as the University's Institutional Review Board (IRB) for all research involving human participants
- b. Uphold independence (free from undue influence) and competence (ability to evaluate research on ethical principles) as its two defining characteristics
- c. Safeguards the dignity, rights, safety and well-being of research participants, as per Clauses 5 and 6 of the Christ University Code of Research Conduct and Ethics

4. Composition and Appointment of Members

4.1. The Committee is composed of:

1. A Chairperson, drawn from an external pool of senior academicians, practitioners or researchers well versed in research ethics, with no stake in University research
2. A Member Secretary, is appointed by the Vice Chancellor, from among the faculty of the institution, and who conducts the business of the Committee
3. a senior advocate practising law or a retired Judge
4. a theologian or philosopher specialised in ethics
5. a social scientist / clinician / biomedical scientist
6. a representative of an NGO
7. a layperson from the community
8. two Professors/ Associate Professor

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

At least 50% of the Committee, including the Chairperson, shall be non-affiliated members with no institutional stake in the research under review.

All members of the RCEC, including the Chairperson, shall be appointed by the Vice Chancellor

5. Tenure

The term of RCEC membership shall be as follows:

- a. The tenure of the Chairperson shall be three (3) years, eligible for reappointment by the Vice Chancellor for one further term
- b. Internal (affiliated) members, a term of two (2) years, with no reappointment
- c. External (non-affiliated) members, a term of three (3) years, eligible for reappointment by the Vice Chancellor for one further term, subject to the member's continued willingness to serve.
- d. The Secretary will have a tenure of five (5) years, eligible for reappointment by the Vice Chancellor for one further term, subject to the member's continued willingness to serve.

The terms of all members shall be as specified above, unless otherwise modified at the discretion of the Vice Chancellor.

6. Meeting frequency

1. The Department Research Ethics Committees approved by the Head of the Department or Dean of the School will review all the proposals using human participants, by researchers associated with their department. This committee will convene each week and review applications that are received until then. The approvals or responses to those applications will be communicated within one week.
2. The RCEC full committee meets a minimum twice a year to review all significant research proposals and approval status of all applications submitted until one month prior to the meeting. Based on volume an RCEC subcommittee will review proposals flagged as greater than minimum risk by the Department Research Ethics Committees (DREC) within a period of two to three weeks. The RCEC will also review all major funded individual/collaborative projects (national or international funding) and all Interdisciplinary Projects involving researchers from different departments. Review may be expedited for urgent projects based on availability of quorum.
3. A minimum of five (5) members must be present for any RCEC meeting to be quorate, including both medical/technical and non-medical/non-technical members, with at least one

non-affiliated member present.

7. Scope of the Delegated Subcommittees

- 7.1. Considering a large number of research projects, theses, dissertations, and student projects involving human participants undertaken in the University and its campuses, some of the ethical review process is delegated to the DRECs. All the faculty members of the DRECs must obtain a certificate of training in ethics (see section on Training).
- 7.2. All applications for student or scholar projects, and faculty-led student projects are to be submitted to the parent DREC. Respective DRECs will review all submitted ethics applications from researchers for the following application categories:
- 7.3. Application categories
 1. Undergraduate and Postgraduate theses/dissertations – All projects with human participation that have been approved for methodological competence by the course faculty will be submitted for review and DREC will forward application after review to RCEC for certification . Any proposal that considers vulnerable groups and highly sensitive topics as outlined in the Annexure, and those that pose **greater than minimum risk** (see criteria in a later section) should also be referred to the RCEC for review.
 2. PhD Thesis – The PhD proposal must be submitted for review to the DREC after the Research Advisory Committee (RAC) as per doctoral regulations has approved the proposal for methodological competence. Any proposal that considers vulnerable groups and highly sensitive topics that may be greater **than minimum risk** (see criteria in a later section) should be referred to the RCEC for review.
 3. All faculty research proposals involving Human participant (less than minimal risk, minimal risk, and greater than minimal risk) should be directly submitted to RCEC for review and certification. However, Faculty-led student projects (curricular UG research) should be submitted to DREC for review, and DREC will forward application after review to RCEC for certification

8. Review process

1. The RCEC and DREC 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 appropriate supervisory entities (course faculty/RAC/Funding agency) for their scientific rigour. Applications with poor rigour will be asked to revise and resubmit, in which case the timeline will be suitably longer. However, in situations where the RCEC/DREC is not convinced about the scientific merits of the proposals, additional review may be sought from experts.
2. The committee review of the proposal covers all aspects indicated in clause 5 and 6 of CHRIST University Code for Research Conduct and Ethics.
3. The first stage of review at the department level aims to determine the scientific rigour, and subsequently classify the applications into three categories depending on the risk involved. The three categories are: (a) Exempt from review for proposals that are no risk, (b) Expedited review for proposals with minimum risk and (c) full review for proposals that have greater than minimum risk or significantly greater than minimal risk (See explanations in a later section).
4. Upon completion of the classification, DREC will review risk categories (a) and (b) using a review checklist. For those proposals meeting all the standards, the DREC will issue a letter of approval for the proposal and will forward that to the RCEC for the issuance of the certificate. The proposals classified into the third category of greater or significantly greater than minimum risk, will be forwarded to the RCEC for a full review, with an advisory letter for 'greater than minimal risk studies review'. RCEC will inform the researcher about the timeline of review, and upon completion of the review the decision will be intimated to the researcher and the respective DREC.
5. Researchers must report all Serious Adverse Events (SAEs) arising in the course of the research to the RCEC within 24 hours of becoming aware of the event, and must submit a report on the relatedness of the SAE to the research within 14 days.
6. All records and documentation of the RCEC and DREC shall be dated, filed and preserved, and shall be retained for a minimum of three (3) years after completion or

- termination of the study (five (5) years for studies involving regulatory clinical trials).
7. The RCEC shall be registered with the relevant regulatory authority (for example, the Central Drugs Standard Control Organisation, where the research falls within the ambit of the Drugs and Cosmetics Act) and shall make efforts to seek recognition or accreditation.

9. Types of review

Normally there are three modes of review: Exempted review, Expedited review and Full review. In some cases, a continuous review may be suggested.

1. Exempted Review

- a. A proposal is exempted from review when there is no harm or risk of harm to the participants. The
- b. The member secretary will record and present the list of exempt proposals during the periodic RCEC review.

2. Expedited review

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)

3. Full committee review

All research presented 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)

4. Continuing review

In some cases, the proposal may require reviews after a period based on the research proposal (studies with phases of research). In this case, the RCEC gives conditional approval.

10. Department Research Ethics Committee & Co-ordinator Roles

1. In order to manage research quality of proposals collecting and working on human data and review adherence to institutional policies on research ethics a Department Research Ethics Committee (DREC) has to be instituted to review all those projects. These projects may be student/scholar led, faculty-led or faculty-student(s) collaborative projects.
2. The DREC may have 3 to 6 faculty members (depending on department research volume) appointed for a 2 year term. The department research ethics review aims to be supportive to good quality research. All members must review the RCEC guidelines at this link- <https://christuniversity.in/view-pdf/research-conduct-and-ethics-guidelines-for-faculty-and-departments>
3. DREC member appointment may be decided based on the following **eligibility criteria**
 - a. At least 1 year of service in the university
 - b. Completion of the ethics course on SWAYAM
 - c. At least 3 publications in noted indexed journals
 - d. At least 1 Phd guidance / 1 application submitted for national / international external research grant
 - e. The whole committee should have at least 1 senior member (other than the coordinator), with more than 7 years of teaching and research experience at christ and major research project coordination experience, 1 mid-career member with more than 4 years of teaching and research experience at Christ, and 1 early-career member with at least 1 year of teaching and research in the university.

4. DREC can nominate one Co-ordinator who will co-ordinate the activities of the committee.
5. All members of the committee must complete the following course on the Swayam portal - **NIECer 102: Ethics Review of Health Research**
https://onlinecourses.swayam2.ac.in/aic22_ge22/preview and share the certificate with their department office.
6. The submitted application must include the following documents: (a) Study Proposal and all Annexures (Informed consent forms, Assent forms when applicable, Brochures, flyers, notices about the research study and/or recruitment of participants and Study tools, questionnaires and interview schedules) (b) Collaborative projects (faculty-student; faculty-faculty) must also include the signed Study Agreement (template provided). Incomplete proposals that do not fully state the procedures to be used in the project cannot be reviewed. (c) a filled IRB form. If the same project is collaborative and has been reviewed in another institution (national/international) - the ethics approval letter from that source may be included as well.
7. A DREC Review Checklist – will be used for review of submitted proposals. This checklist has two parts and will be used to determine (a) Complete articulation of all aspects of data gathering and use in the research study (b) If the proposal qualifies to be either - (a) **less than minimal risk**, (b) **no greater than minimal risk** and (c) **greater or significantly greater than minimal risk**.
8. In the event that a study is being conducted in multiple phases and the later phases can only be designed based on findings of the first phase, in this circumstance, the proposal is evaluated for a “**Continuing Review**” which requires the researcher to reapply for certification for subsequent phases.
9. The process framework:
 - a. Faculty researchers will forward their application (study agreement & proposal with all annexures, IRB form) to the RCEC directly, who will then arrange for the review.
 - b. PG and PhD researchers will forward their application (study agreement & proposal with all annexures, IRB form) to the Committee/Coordinator, who will then arrange for the review.
 - c. One/ two members will review the submitted application against the Review Checklist, and suggest recommendations for improving the proposal if essential elements are missing.
 - d. For the complete applications, after the review the DREC will issue (a) an approval for the proposal and (b) determine the risk level of the proposal. (template for approval certificate is provided)
 - e. The researcher will then upload the department approval certificate and the filled IRB form on the link (to be shared on the website along with the guidelines)
 - f. For all Minimum Risk and less than Minimum Risk projects the RCEC will issue the Ethics certificate within 7 working days. Approved applications are issued with a letter and reference number

11. Application for Ethical Review

1. All research involving human participants must be reviewed by the Department Committees/RCEC. The researchers cannot decide by themselves if the research is exempt from review. The Department Committees/RCEC will review all proposals and inform the researchers of the review status.
2. The application must be submitted to the DREC/RCEC in the prescribed application form duly signed by the researchers and all investigators. Next section details the submission process.
3. The DREC Co-ordinator/ Member Secretary will inform the applicant of the status of review within one/two weeks upon receipt of the application. Approved applications are issued with a letter and reference number by the RCEC only.
4. All fields of the Ethics 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:
 - a. A copy of the approved research proposal

- b. Informed consent forms
 - c. Assent forms when applicable
 - d. Brochures, flyers, notices about the research study and/or recruitment of participants
 - e. Study tools, questionnaires and interview schedules
5. The following links may be used by the respective designations to submit their forms. Incomplete applications will not be reviewed. [Note: Undergraduate research related applications must be filled and submitted by the Faculty mentor.
- A. Google form link for Faculty (Individual and Collaborative) Applications
 - B. Google form link for Faculty Mentor of UG projects
 - C. Google form link for PhD Scholar Applications
 - D. Google form link for Master's Student Applications

12. How to submit your Application

1. The PG, Scholar and Faculty application (for faculty-led student projects) submissions to the respective DREC will be made via email. The email addresses are unique for each DREC and are listed below. Incomplete applications will not be reviewed. [Note: Undergraduate research ethics applications must be filled and submitted by the Faculty mentor and all students listed as co-investigators on the application].
2. DRECs will forward applications that require further review to the RCEC at rcec@christuniversity.in.

SN	Name of the Department / School	Group Email Address
1	Business and Management (BBA)	drec.bba.bkc@christuniversity.in
2	Business and Management (MBA)	drec.mba.bkc@christuniversity.in
3	Civil Engineering	drec.civil.bkc@christuniversity.in
4	Mechanical Engineering	drec.mech.bkc@christuniversity.in
5	AI, ML & Data Science	drec.aiml.bkc@christuniversity.in
6	CSE	drec.csc.bkc@christuniversity.in
7	S and H	drec.sh.bkc@christuniversity.in
8	ECE	drec.ece.bkc@christuniversity.in
9	EEE	drec.eee.bkc@christuniversity.in
10	SOA	drec.architecture.bkc@christuniversity.in
11	Business and Management (BGR)	drec.sbm.brc@christuniversity.in

12	Media Studies (BGR)	drec.mediastudies.brc@christuniversity.in
13	Economics (BGR)	drec.economics.brc@christuniversity.in
14	Psychology (BGR)	drec.psy.brc@christuniversity.in
15	Liberal Arts (BGR)	drec.liberalarts.brc@christuniversity.in
16	International Studies, Political Science and History (BGR)	drec.iph.brc@christuniversity.in
17	English and Cultural Studies (BGR)	drec.english.brc@christuniversity.in
18	Commerce (YPR)	drec.commerce.byc@christuniversity.in
19	Economics (YPR)	drec.economics.byc@christuniversity.in
20	Business and Management (YPR)	drec.sbm.byc@christuniversity.in
21	Computer Science (YPR)	drec.computerscience.byc@christuniversity.in
22	Mathematics (YPR)	drec.mathematics.byc@christuniversity.in
23	Statistics & Data Science (YPR)	drec.statistics.byc@christuniversity.in
24	Professional Studies (YPR)	drec.professionalstudies.byc@christuniversity.in
25	English and Cultural Studies (YPR)	drec.english.byc@christuniversity.in
26	Languages (YPR)	drec.languages.byc@christuniversity.in
27	Psychology (YPR)	drec.psy.byc@christuniversity.in
28	Media Studies (YPR)	drec.mediastudies.byc@christuniversity.in
29	School of Law	drec.law.bcc@christuniversity.in
30	Business and Management (BBA)	drec.bba.bcc@christuniversity.in
31	Business and Management (MBA)	drec.mba.bcc@christuniversity.in

32	Commerce	drec.commerce.bcc@christuniversity.in
33	Professional Studies	drec.professionalstudies.bcc@christuniversity.in
34	Hotel Management (BHM)	drec.bhm.bcc@christuniversity.in
35	English and Cultural Studies	drec.english.bcc@christuniversity.in
36	Chemistry	drec.chemistry.bcc@christuniversity.in
37	Computer Science	drec.computerscience.bcc@christuniversity.in
38	Life Sciences	drec.lifesciences.bcc@christuniversity.in
39	Mathematics	drec.mathematics.bcc@christuniversity.in
40	Physics & Electronics	drec.physics.bcc@christuniversity.in
41	Statistics & Data Science	drec.statistics.bcc@christuniversity.in
42	Social Work	drec.socialwork.bcc@christuniversity.in
43	School of Education	drec.education.bcc@christuniversity.in
44	School of Psychological Sciences	drec.psy.bcc@christuniversity.in
45	Economics	drec.economics.bcc@christuniversity.in
46	International Studies, Political Science and History	drec.iph.bcc@christuniversity.in
47	Media Studies	drec.mediastudies.bcc@christuniversity.in
48	Sociology	drec.sociology.bcc@christuniversity.in
49	School of Sciences (NCR)	drec.sciences.ncr@christuniversity.in
50	School of Business and Management (NCR)	drec.sbm.ncr@christuniversity.in
51	Department of Psychology (NCR)	drec.psychology.ncr@christuniversity.in

52	School of Commerce, Finance and Accountancy (NCR)	drec.scfa.ncr@christuniversity.in
53	School of Humanities and Performing Arts (NCR)	drec.hpa.ncr@christuniversity.in
54	School of Law (NCR)	drec.law.ncr@christuniversity.in
55	School of Social Sciences (NCR)	drec.socialsciences.ncr@christuniversity.in
56	Pune Lavasa Campus	drec.plc@christuniversity.in

3. Faculty research projects - direct submissions to RCEC for review and certification rcec@christuniversity.in.
4. A standard application form should comprise the following information:
 - a. 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.
 - b. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
 - c. 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.
 - d. Procedures for recruitment of participants for projects that require participants for intervention research.
 - e. The inclusion and exclusion criteria of participants with screening procedures and tools used to screen the participants.
 - f. 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.
 - g. Plan to withdraw or withhold standard interventions in the course of research.
 - h. Plan for statistical analysis of the study. The choice of the analysis and its appropriateness over other possible methods.
 - i. 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.
 - j. Safety of proposed intervention including psychological safety, to participants.
 - k. For research involving more than minimal risk, an account of management of such risk or injury.
 - l. Proposed compensation for incidental expenses. Plan for incentives if any. In addition to compensation for incidental expenses, the application must include a plan for compensation for any physical or psychological injury or harm to participants, distinct from reimbursement of incidental expenses, for consideration and approval by the RCEC.
 - m. 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.
 - n. Online tools of data collection such as surveys, forms and video conferencing tools must be compliant with privacy norms and encryption procedures clearly stated

- o. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
- p. Statement of regulatory clearances where required. If IRB clearance obtained from a collaborating agency, then a copy of the approval to be attached.
- q. Agreement to comply with National and International Good Clinical Practices (GCP) protocols for clinical trials. Agreement to comply with good standards of research.
- r. Details of Funding agency/ Sponsors and fund allocation. Indicate the funding agency if a proposal is submitted prior to committed funding.
- s. For international collaborative study details about foreign collaborators and documents for review. Approval and agreements from University approving authority.
- t. A statement on conflict-of-interest (COI), if any.
- u. A copy of the most recent completion of research ethics and compliance training course from among the courses recommended in the section on training.
- v. 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.
- w. Plans to ensure accurate translation of tools, spoken language skills in local languages and dialects of data collection required.

13. Decision Making Process

1. The DREC will review all the submitted applications. The DREC coordinator will complete the initial screening of applications each week and will invite at least 2 DREC members for a review meeting. Each application will be discussed and will be either approved or sent back to applicant to either (a) revise and resubmit based on comments or (b) add more documents. Each review meeting minutes with a list of applications reviewed and key points discussed are to be compiled regularly and periodically shared with RCEC.
2. The approval letter will be sent to the applicant by email. This letter will also be forwarded to RCEC (rcec@christuniversity.in) for the issuance of the certificate.
3. The decision of the RCEC full committee on any proposal referred to it shall be one of the following: (i) approved, with or without suggestions or comments; (ii) revision required, with minor modifications, for approval by the Member Secretary or through expedited review; (iii) revision required, with major modifications, to be resubmitted for reconsideration by the full committee; or (iv) not approved, including termination or revoking of permission where applicable. Reasons must be recorded in each case and communicated to the researcher.

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

1. 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.
2. 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.
3. 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.

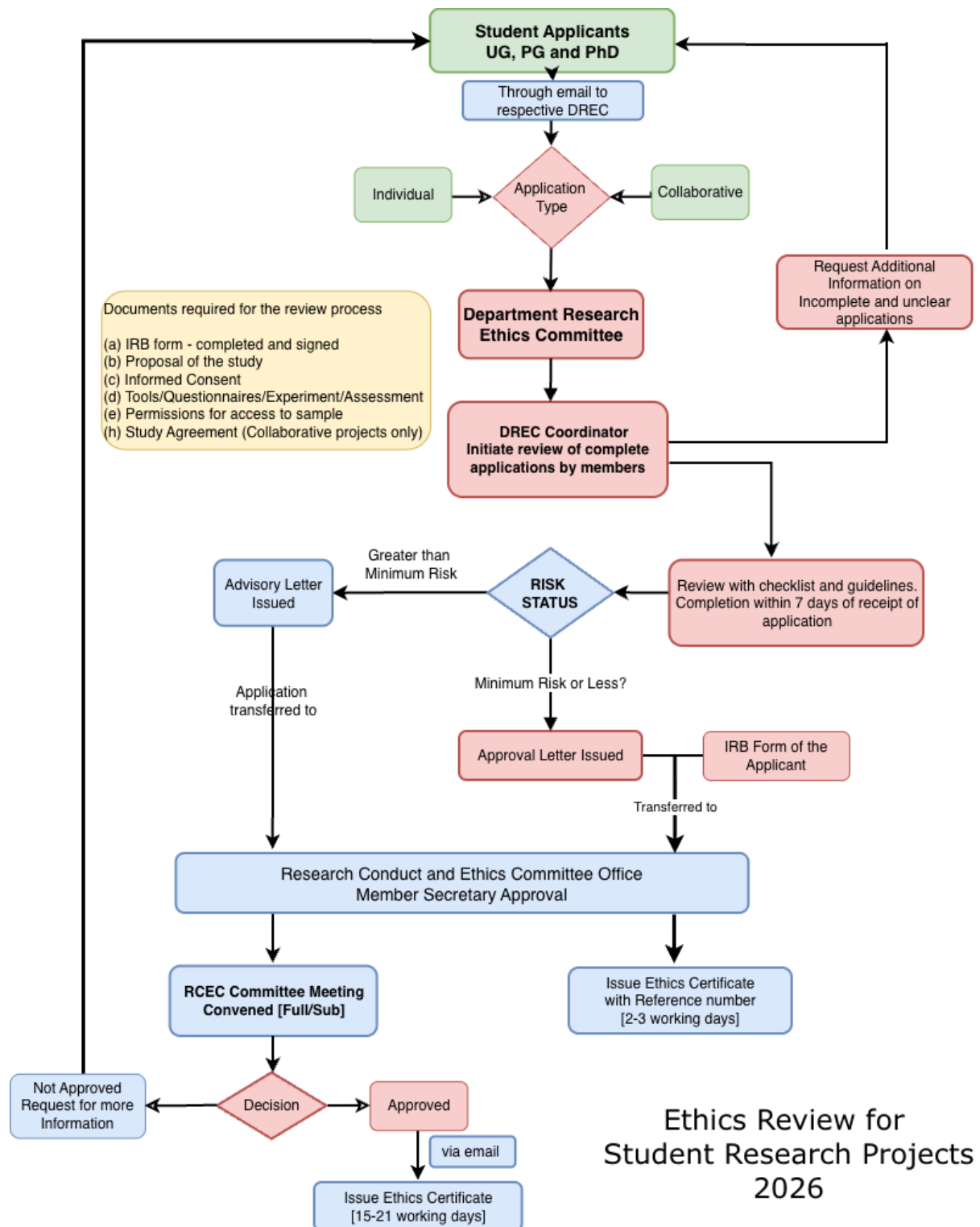
15. Training Resources

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

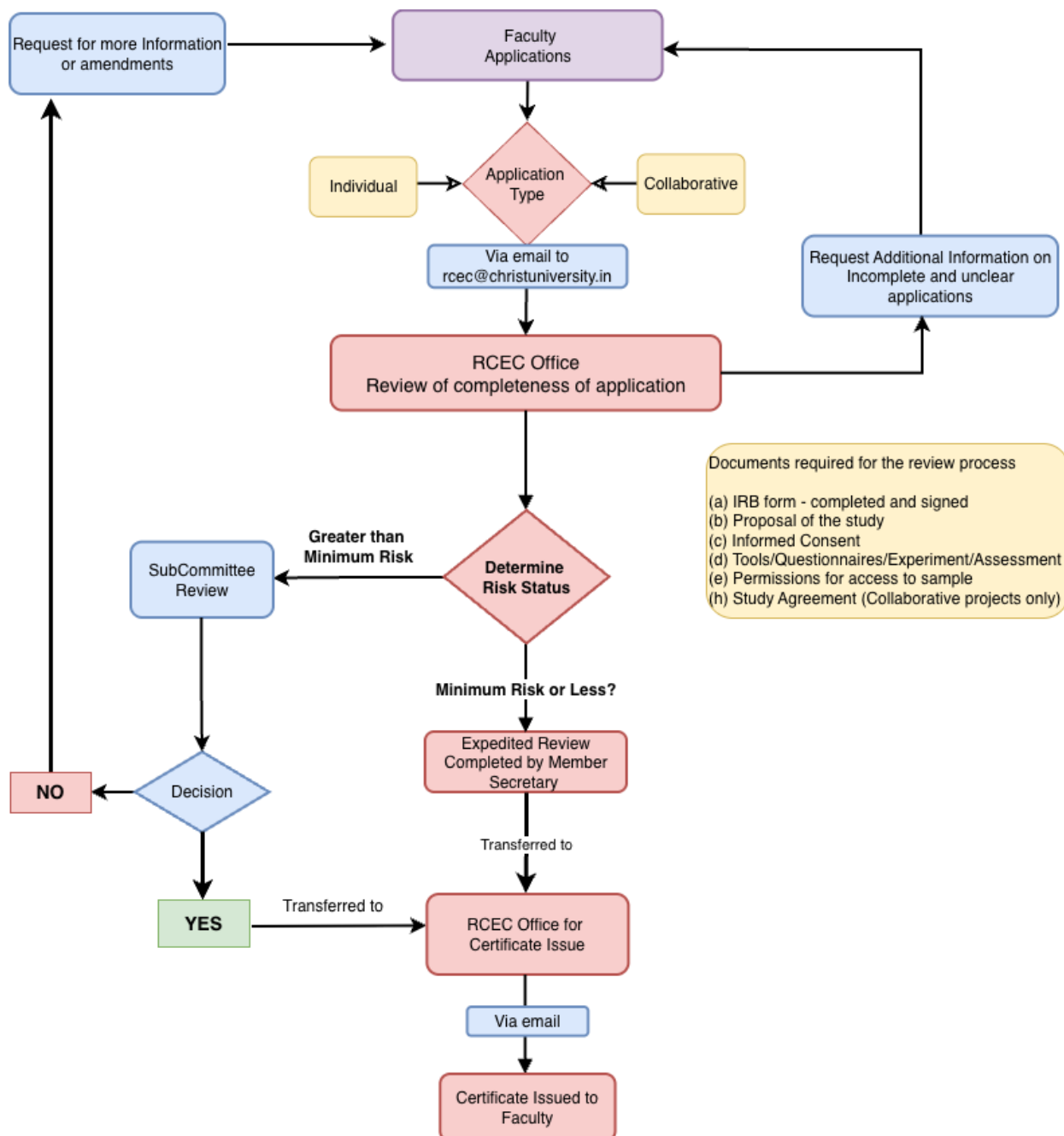
1. CITI - Collaborative Institutional Training Institute (Paid course) (<https://about.citiprogram.org/en/homepage/>)
2. Research Ethics online training by Global Health Training Centre (Free course) (<https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>)
3. Introduction to research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

16. Process Flow for Ethics Review

1. Decision tree for student projects*



2. Decision tree for faculty Led Projects*



Ethics Review of Faculty Research Projects 2026

17. Potentially Vulnerable Participants

This includes, but is not restricted to:

1. People whose competence to exercise informed consent is in doubt, such as:
 - a. infants and children under 18 years of age
 - b. people who lack mental capacity
 - c. people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate
 - d. people who may have only a basic or elementary knowledge of the language in which the research is conducted
2. People who may socially not be in a position to exercise unfettered informed consent, such as:
 - a. 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)
 - b. 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:
 - i. people with disabilities
 2. people who are frail or in poor health
 - ii. relatives and friends of participants considered to be vulnerable
 - iii. people who feel that participation will result in access to better treatment and/or support for them or others
 - iv. people who anticipate any other perceived benefits of participation
 - v. people who, by participating in research, can obtain perceived and/or real benefits to which they otherwise would not have access

18. Highly Sensitive Population

This includes, but is not restricted to:

- a. Being whose competence to exercise informed consent is in doubt, such as:
 - i. infants and children under 18 years of age
 - ii. people who lack mental capacity
 - iii. people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate
 - iv. people who may have only a basic or elementary knowledge of the language in which the research is conducted
 - v. Animals
- b. People who may socially not be in a position to exercise unfettered informed consent, such as:
 - i. 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)
 - ii. 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:
 - i. people with disabilities
 - ii. people who are frail or in poor health
 - iii. relatives and friends of participants considered to be vulnerable
 - iv. people who feel that participation will result in access to better treatment and/or support for them or others
 - v. people who anticipate any other perceived benefits of participation
 - vi. people who, by participating in research, can obtain perceived and/or real benefits to which they otherwise would not have access

19. Highly Sensitive Topics

This includes, but is not restricted to:

- a. race, caste or ethnicity
- b. political opinion
- c. religious, spiritual or other beliefs
- d. physical or mental health conditions
- e. sexuality
- f. Gender
- g. abuse (child, adult)
- h. nudity and the body
- i. criminal activities
- j. political asylum
- k. conflict situations
- l. personal violence
- m. any medical (physical or psychological diagnosis) information
- n. any financial information
- o. Past or present trauma



(Dr Anil Joseph Pinto)
Registrar

Amended as on 17 August 2026

Appendix- 1

- A. Collaborative Faculty Research Projects
 - 1. 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.
 - 2. 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)
 - 3. 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).
 - 4. The Faculty-PI (CHRIST Deemed to be University) will forward a copy of this agreement along with the draft proposal, to the ethics review committee. The committee will review and approve (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.

Appendix- 2

A. Proposal Review Checklist of for research projects

SN	Review Criterion	Response	Comments / Reason
1	Collaboration objectives and aims are clearly defined.	☐ Acceptable ☐ Not Acceptable	
2	Topic idea is relevant to the expertise of both PIs.	☐ Yes ☐ No	
3	There is proper use of the institutional framework and the proposal submitted is a clear and complete document covering: Aims, Objectives, Introduction & Review, Methods, Data – Tools/Collection/Storage, Analysis & Interpretation, and Ethical Considerations.	☐ Yes ☐ No	
4	Methodology is relevant to the title.	☐ Yes ☐ No	
5	Data collection is well planned; sample is appropriate and accessible.	☐ Yes ☐ No	
6	Informed Consent, ethical procedures and data collection instruments are aligned to the sample characteristics.	☐ Yes ☐ No	
7	Data Analysis plan appears aligned to the study objectives and the analysis process has been detailed in the proposal.	☐ Yes ☐ No	
8	Research expenditure issues are anticipated and explained clearly.	☐ Yes ☐ No	
9	Timeline of the project is clear and effective.	☐ Yes ☐ No	
10	Data sharing and access between collaborators is detailed in the Study Agreement.	☐ Yes ☐ No	
11	Is there a well-defined plan for publications in the Study Agreement?	☐ Yes ☐ No	

12	Is there a plan to explore the possibility of filing a patent application?	☐ Yes ☐ No	
13	Are student researchers part of the project?	☐ Yes ☐ No	
14	Are the student roles clearly defined for the project work and for publications?	☐ Yes ☐ No	

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.

20. Appendix 3

Template for 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]

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)

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

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:

Signatur

es:

XXXXXXXXXXXXX

XXXX XXXXX

XXXXXXXXXXXXXXXXX

XXXXXXXXXXXXXXXXX

For Office Use:
Reviewed by:
Signature:

21. Sources

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

- a. Ethical Guidelines for biomedical research involving human participants, NIMHANS
Ethical Guidelines for Biomedical Research on Human Participants – ICMR 2006
- b. British Psychological Society - IRB Review documents CITI Training - Institutional IRB-
Structure and functions
- c. APA: IRBs and IRBs and Psychological Science: Ensuring a Collaborative Relationship
Global Health Training ethics online course
- d. (<https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring.shtml>)

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