Does My Thesis or Research Project Need to Be Submitted for Review?

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- Under the Human Subjects Research Act:
  - For human subjects research, the principal investigator shall prepare a research protocol and obtain approval from the Institutional Review Board (IRB) before conducting the research. (Article 5, Paragraph 1, Human Subjects Research Act)
  - What is human subjects research? Research involving obtaining, investigating, analyzing, or using human specimens or an individual's biological behavior, physiological, psychological, genetic, or medical information. (Article 4, Subparagraph 1, Human Subjects Research Act)
- What is human research? Under the scope of the National Science Council (Executive Yuan) Pilot Program for Research Ethics Review of Funded Research Projects: "Human research under this Program refers to systematic investigation or knowledge-seeking activities in a professional discipline concerning individuals or groups, conducted through observation, intervention, or interaction, or through the use of personal data whose identifying links have been removed without the individual's consent." Although this is not mandated by law, we recommend submitting your protocol to this Committee for review before the research begins.
- To protect research participants and promote academic research, projects subject to any of the following should be submitted to the IRB and carried out only after approval: the Human Subjects Research Act; requirements of funding agencies (e.g., Ministry of Health and Welfare, National Science and Technology Council, Ministry of Education); Ministry of Education requirements for degree theses; or requirements of data providers (e.g., Health and Welfare Data Science Center, Ministry of Health and Welfare) or journals.

My research project (including a thesis) was completed without review, and a journal now requires proof of approval. Can I apply for review retroactively or ask the Committee to issue an approval certificate?

- This Committee can only review protocols that have not yet been carried out, so that it can assess risks, consider relevant research ethics issues, and work with the principal investigator on any necessary revisions.
- An approval certificate can be issued only after review is completed, and the principal investigator must conduct the research in accordance with the approved documents.
- Once the research has been completed, its risks have already occurred, and retrospective review is not possible. Please apply for review before the research begins (before recruiting participants or making contact with them).



Common Questions About Submitting for Review

Common Questions About Submitting for Review – 1

- How to submit a new application
  - Please submit new applications through the Human Research Protocol Management System: https://eirb.fju.edu.tw/index_login.php
- Eligibility for a system account
  - Accounts are currently available only to principal investigators, who must be full-time faculty members.
- Human research ethics training hours
  - Principal investigators: 8 hours within the past 3 years; research team members: 6 hours within the past 5 years, counted backward from the date the new application is submitted.
  - Under this Committee's SOP, courses from the Center for Taiwan Academic Research Ethics Education (AREE) may count for a maximum of 2 hours.

Common Questions About Submitting for Review – 2

- Do I need to submit paper documents?
  - Starting from Academic Year 112 (2023–2024), new applications and amendment applications are submitted through the Human Research Protocol Management System.
    - ➢ User manual for new applications: https://reurl.cc/M607n3
    - ➢ User manual for amendment applications: https://reurl.cc/kM154b
  - For progress reports, final reports, suspensions, terminations, and protocol deviations, please first email the electronic files to the Committee's mailbox, **and submit the paper copies after they have been confirmed.**

Common Questions About Submitting for Review – 3

- Review timelines (initial review and re-review)
  - Exempt review: 7 working days, excluding holidays. Reviewers: 1.
  - Expedited review: 10 working days, excluding holidays. Reviewers: 2.
  - Standard review: initial review 10 working days, excluding holidays. Reviewers: 2.

  ★ In addition to review by 2 members, standard review applications must be discussed at the full IRB meeting. Completion of review and issuance of the approval certificate therefore depend on the meeting schedule.

  IRB meeting dates are announced on the Committee's website: https://reurl.cc/myaReY
- Response time for review comments
  - Responses to review comments are due within 5 working days, excluding holidays, and no later than 2 months.

Common Questions About Submitting for Review – 4

- Can the project title be changed after IRB approval?
  - A different title is treated as a different project. The title of a project reviewed and approved by the Fu Jen Catholic University IRB therefore cannot be changed. To change the title, please submit a new application.
- Can a student serve as principal investigator?
  - No. The principal investigator must be a full-time faculty member or researcher of the University.
- Can on-campus projects be reviewed elsewhere?
  - No. Under the regulations, full-time faculty members may submit their projects only to the University's IRB.

Common Questions About Submitting for Review – 5

- Human research ethics training courses
  - On-campus human research ethics workshops are held every January, March, May, July, September, and November. Dates and course details are announced on the Human Research Ethics Committee website one month in advance.
  - Off-campus courses: see the courses announced on the Committee's website, or check the websites of other IRBs for course offerings.
  - Website: http://irb.rdo.fju.edu.tw/
- Online courses
  - Taiwan Clinical Trial Education and Training Center: https://www.ccttt.org.tw/mooc/index.php
  - Chung Shan Medical University: https://irbsystem.csh.org.tw/public_html/ProSystem/app/registration/SignGCRC.html?loadTime=1750229191623
  - China Medical University: https://edu.cmuhctc.tw/qa-online-course