NANYANG TECHNOLOGICAL UNIVERSITY SINGAPORE

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IRB 360 NEWSLETTER

Connecting Research with Ethics

When Do You Need to Submit a Study Amendment?

When **changes** need to be made to an IRB-approved study.

Changes To:

- Study Objectives / Methodology
- Informed Consent Forms (ICFs)
- Study Team Members
- Recruitment Target Numbers
- Advertisement Materials *etc…*

ERMP Guide for Amendments

For faster approvals:

- **NEVER** delete documents that were previously approved.
- Complete the 'Amendment' cover note; Ensure the ERMP form is updated to align with the proposed changes.
- Provide revised documents in both their 'Clean' and 'Tracked Change' versions – *e.g. Survey (Clean); Survey (Tracked); ICF (Clean); ICF (Tracked) ...*
- Upload revised documents to their corresponding tabs – *e.g. 'Informed Consent' tab for ICFs.*
- Practice version no. & dating in your document's footer, and file naming. *It makes tracking easier.*

When Do You Need to Submit an IRB Continuing Review?

Annually for the reporting of recruitment numbers to the IRB.

Post-approval Requirement:

- To ensure continued validity of ethics approval; and
- To assure the protection of study subjects' rights, safety, and welfare.

ERMP Guide for Continuing Reviews

Expert Tips:

- Common ERMP Mistake: Selecting "Project Closure" instead of "Continuation Review" from the 'Workflow' button.
- If the form is greyed out *(i.e. locked / cannot edit),* select "Check-out" from the 'Action' button.
- Answer **ALL** sections and questions in the "Continuation Review" tab.
- Prevent lapses in IRB validity by submitting at least 4 weeks prior to the anniversary date of the original approval.

Stay tuned for our next newsletter to learn more!

To subscribe to our mailing list and for further queries, please write to **IRB@ntu.edu.sg**

Brought to you by:
Research Integrity and Ethics Office (RIEO)

Refer to our website for more information on **IRB Guidelines** here.