

IRB 360 NEWSLETTER ISSUE 2023/06

Connecting Research with Ethics

What are **AMENDMENTS?**

Should there be any modifications to your IRB-approved protocols, PIs and study teams are required to submit an amendment to the IRB for review and approval before effecting the change.





Any deviations from an approved protocol without prior approval are considered Non-Compliances/Protocol deviations. If the study is under the scope of the Human Biomedical Research Act (HBRA), such deviations are considered contraventions and reportable to the relevant authorities.

EXCEPTIONS to the Amendment Requirement

To ease the burden on Pls, the requirements for amendments recently been relaxed. The following now do not require an Amendment submission:



Correction of typographical and/or grammatical errors that do not change the overall meaning of the text.



Changes to colour palette (or artistic design) of recruitment materials – e.g. flyer's background colour.

This info is now available on our IRB Guidelines webpage.

Tips for faster **APPROVALS** of your Amendments in ERMP

- Delete previously approved changes in 'Amendment' tab.
- Answer compulsory questions i, ii, iii in 'Amendment' tab.
- Update the relevant tabs that are affected by the change, e.g. increase in target sample size → reflect the new target number in 'Human Subjects Information' tab.
- Attach relevant files of the changes requested, e.g. additional personnel → attach his/her brief CV and CITI training.
- Upload new files of the current amendment into the Amendment tab ONLY (no need to attach the same files again in another tab): Track changes or yellow highlight the changes in the files.
- Do **NOT** delete previously approved documents.
- Refresh CITI training requirements if expired.





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.sq

Brought to you by:

Research Integrity and Ethics Office (RIEO)

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