

27 May 2024

Prof Vivekanand Jha,
George Institute for Global Health
308, Elegance Tower,
Jasola District Centre,
New Delhi - 110025

Sub: Project Number 07/2024, Titled: Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial - The Trauma Audit Filters

Dear Prof Jha,

Thank you for your application sent to us on 19 April 2024. The following documents were submitted for review:

- TGI_IEC_Application_Apr 24
- Study Proposal TERN protocol v1.0.0 dated 2024-03-28.
- Study_Synopsis_ 2024-03-28.
- CRF Data points_01.04.24_v1.0_TERN
- PICF_TERN English v1.0_020424
- TERN Assent_English v1.0_02042024
- Advanced-Trauma-Life-Support_guideline
- CV of investigator

The Executive Body of The George Institute Ethics Committee (TGIEC) considered the above application and did not approve the application in its present form.

The committee has sought the following clarifications before arriving at a decision-

1. The committee sought clarification whether the hospitals with specialised manpower to be involved in this project have the necessary infrastructure commensurate with the ATLS facility?
2. The committee wanted to know in case favourable outcome towards ATLS training is achieved after initial phases of trial whether the trial will be stopped to extend the outcome to the other study arms of the project? Would interim analysis involve capturing this information? The research team is advised to send in detailed randomisation and interim analysis plan.



3. The committee wanted to know how will other aspect be controlled, like non-functional equipment, type of nursing care provided, or other facilities provided towards the trauma patient during the intervention trial?

4. The committee directed that a more comprehensive statement for compensation policy is required within the project proposal keeping in mind various possibilities in the event of the death/injury/disability of a patient under care during the trial and sought clarification about the basic minimum compensation that should be in place.

The following members of the IEC were present in the meeting held on 04May 2024 and were involved in the discussion:

Sr No.	Members	Designation
1.	Dr O P Kalra	Chairman
2.	Dr Sona Khan	Member
3.	Dr C K Mukhopadhyay	Member
4.	Dr Jeyraj Pandian	Member
5.	Dr Dorothy Lall	Member
6.	Dr Renu Singh	Member
7.	Dr Pallab Maulik	Member Secretary

Yours Sincerely



Pallab K Maulik

Member Secretary

The George Institute Ethics Committee

The George Institute for Global Health