

25 June 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 the clarifications submitted for your project, through your letter dated 14 June 2024, to the queries raised by the committee. These responses have now been reviewed by the committee.

The Executive Body of The George Institute Ethics Committee (TGIEC) considered the response and found them satisfactory. They have approved the project to proceed.

Would you please note -:

- Approval is valid for the project duration (01Oct24 till 30Sep29)
- You will be required to provide annual reports to the study's progress to the TGIEC.
- You are required to immediately report to TGIEC anything which might warrant review of ethical approval of the protocol including:
 - a) Serious or unexpected outcomes experienced by research participants (using the Serious Adverse Event proforma available from TGIEC;
 - b) Proposed changes in the protocol; and
 - c) Unforeseen events or new information (eg.from other studies) that might affect continued ethical acceptability of the project or may indicate the need for amendments to the protocol;
- Any modifications to the project must have prior written approval and be ratified by any other relevant Institutional Ethics Committee, as appropriate;



- If there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the appropriate monitoring organization;
- If the research project is discontinued before the expected date of completion, the researcher is required to inform TGIEC and other relevant institutions (and where possible, research participants), giving reasons. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins;
- Consent forms are to be retained within the archives of the Department /School /Unit/ Centre /Institute and made available to the Committee upon request.

The following members of the IEC were present in the meeting held on 04May24 and were involved in the approval process:

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 Maulik
Member Secretary
The George Institute Ethics Committee
The George Institute for Global Health