Neurobiological Stress Markers in Tsunami Survivors: A Commentary

The Background

On 26 December 2004, an earthquake of surface wave magnitude of 9.0 on the Richter scale occurred off the West coast of Northern Sumatra. The tsunami hit more than two thirds of Sri Lanka’s coastline, causing catastrophic destruction and loss of lives, with more than 35,000 deaths or missing in Sri Lanka. Government response was quick and the Center for National Operations was put in place within the first week to coordinate the relief work.

In Matara on the southern tip of Sri Lanka, a wave less than 1 metre tall was followed 10 minutes later by a second wave up to 10 metres in height, causing almost 2,000 deaths. (In the aftermath of the tsunami, scientists from diverse disciplines came to conduct research.

The Event

Investigators from a renowned university in a developed country in Asia were collecting blood samples from tsunami survivors living in temporary shelters in the Matara district. The objective of their project was to identify biological markers of stress, using proteomic analysis in the samples collected from these survivors. A local health official, an epidemiologist, confiscated the blood samples as the investigators had failed to produce any document that permitted them to carry out research or collect blood samples in Sri Lanka. The matter was then referred to the Ministry of Health in Colombo.

The investigators did not have a research protocol. They had not sought or received ethical clearance from any of the local ethics committees. They, however, promised to forward a copy of the protocol to the Ministry of Health.
During the course of further inquiry, they could not produce any documentary evidence of ethical approval from the sponsoring country either, although they claimed to have such clearance.

In the meantime, the investigators identified a local collaborator and an institution (a Non Governmental Organisation) and applied for ethical approval from an Ethics Review Committee (ERC) in a prestigious Sri Lankan university. The founder and the head of this NGO was the chair of this ERC and a close relative of the local collaborator. Documents pertaining to the ethical approval of the sponsoring country were submitted to the local ERC. The approval was in fact obtained in 2003 (a year before the Asian tsunami) and they did not provide any documents about ERC approval for a collaborative study to be carried out in Sri Lanka. They were granted ethical clearance after an expedited review. Although continuation of the research project was not approved by the Ministry of Health, there is evidence that sample collection was carried out even after the refusal.

Even before the tsunami, there was a publication with data obtained from Sri Lanka. It reported having obtained ethical clearance from their university but none from a committee in Sri Lanka. Nor was there mention of a local collaborator. It collected blood samples from 54 Sinhalese persons and reported on two novel FUT3 alleles responsible for “Lewis null phenotypes” in Sri Lanka.6

**Ethical Issues**

The investigators were clearly violating the privacy of survivors by collecting blood without fully disclosing their intention. Survivors living in temporary shelters after this large and complex disaster were a vulnerable group. They may have been deceived about the blood collection (therapeutic misconception) as there were several health care teams that were treating them. Investigators sought neither their own nor local ERC approval prior to the research and did not obtain consent for research.

Retrospectively applying for approval, the investigators submitted an old ethical approval from the sponsoring country, given for a completely different research in the host country. They tried to gain undue influence, which may have occurred by enlisting a close relative of the local ERC chairperson as their local collaborator. Further they enlisted the NGO that was founded and led by the chairperson of the ERC as their local collaborating institution.

The local ERC received a research proposal from a team of investigators that included a close relative of the chairperson. ERC should have detected the relationship and conflict of interest associated with it because of the collaborating
local NGO and the name of the collaborator (the chairperson and the local collaborator have the same surname). According to the information available the chairperson did not disclose voluntarily his conflict of interest and did not withdraw from the ERC when they deliberated the proposal. The ERC granted approval after expedited review in a letter signed by the chairperson. The local ERC did not justify the reasons for expedited review.

**Discussion**

The post-disaster research in developing countries without strong biomedical research infrastructure is beset with serious ethical issues that have not received adequate attention from the international research fraternity. Empirical evidence gathered from a global review of post-disaster research and establishment of normative guidelines is needed with clear criteria for expedited review. In that, there should be specific safeguards built in for developing countries as survivors in such countries may be doubly vulnerable. This is due to multiple reasons such as: poor infrastructure, poor access to basic human needs such as food, water, shelter, pre-existing conflicts, inadequate protection of human rights, and disharmony, and sub-optimal human development among survivors such as poor health and education.

In a disaster situation, preferably a single central ERC should be put in place to review research protocols in each developing country and adequate capacity should be developed into these committees. Although international collaborative research is to be encouraged, North-South collaborations need careful scrutiny by each ERC because of imbalance in research capacity, funding and publication between the two collaborating institutions. High risk post-disaster research may be submitted for prior ERC approval with a mechanism built in for modification after accordingly. This will encourage researchers to conduct more research in post-disaster situations to fill the barren landscape of post-disaster interventions with benefit to future survivors.

**Acknowledgements**

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Annexure-1

The *Journal of Traumatic Stress* published a special section titled “The ethics of disaster research” addressing ethical issues related to conducting research after disasters and terrorist attacks, based on a meeting organised by the New York Academy of Medicine and the US National Institute of Mental health. The guidance given below is based on their recommendations.7

Guidance for Post-Disaster Research

1. Competent research participant gives informed consent
2. Capacity assessment tools should be utilised if needed
3. Disaster affected populations should not be necessarily considered vulnerable
4. Specific research proposals should be scrutinised for novel nature of research and risk benefit ratio
5. Additional research is needed in the risks and benefits in the participation in disaster-related research
6. Representatives of the community should be consulted before planning and implementation of research.
7. Informed consent procedure should clear all therapeutic misconceptions
8. Explanation about the research should be done in a safe and controlled environment
9. Confidentiality and privacy of the participants must be ensured
10. Research staff should be trained and supported
11. Participants should be informed about the research findings
12. Coordination among researchers should minimise redundant research and participant burden.

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Notes


5. Sumathipala et al., 2006


**References**