

Anise Gold-Watts  
Norges miljø- og biovitenskapelige universitet (NMBU)  
[Anise.gold-watts@nmbu.no](mailto:Anise.gold-watts@nmbu.no)

Our ref.: 2017/169

Your ref.:

Date: 30 June 2017

## **Ethical evaluation of Project SHINE (2017/169)**

The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH) is an independent advisory committee providing guidance and advice on research ethics. Statements from NESH are advisory, and both researchers and research institutions must ensure that the research is being conducted in accordance with recognized ethical norms and values.

On 12 June 2017 NESH received a request for a review from Anise Gold-Watts at Norges miljø- og biovitenskapelige universitet (NMBU) concerning Project SHINE (Sanitation and Hygiene INnovation in Education), a school and community-based research pilot intervention to improve water and hygiene in Sri Puram/rural India. The request is based on the assessment of Personvernombudet at Norsk senter for forskningsdata (NSD) that certain components of the project – including the study design, consent procedures and observation tools – require ethical review from NESH. The request and submitted material has been reviewed by NESH in a meeting on 14 June 2017.

### **Background**

The original Project SHINE intervention was conducted with Maasai pastoralist between May and November 2014 in the Ngorongoro Conservation Area in Tanzania. The aim of Project SHINE is to develop sustainable strategies for water, sanitation and hygiene (WASH)-associated health challenges. The overall goal of this research project is to adapt, implement and evaluate

Project SHINE in the rural Indian context in order to reduce diarrheal disease among students in Vellore, India.

According to the project description, the school-based intervention focuses on knowledge sharing and mutual learning that encourages youth to develop culturally relevant tools and strategies to improve health, self-esteem, self-efficacy, social cohesion and connectedness. The study design of the intervention will be a three group, non-equivalent control group study with a design that includes a pretest-posttest with one follow-up. The study include both qualitative and quantitative methods, and the study is comprised of two phases: Phase 1 consists of a base line assessment and formative research to help identify barriers to performing WASH-associated behavior; Phase 2 consist of the intervention, implementation and evaluation of Project SHINE, and the process evaluation will include interviews, focus groups, surveys, attendance logs and teacher diaries.

According to Personvernombudet (NSD) the recommendation for an ethical assessment from NESH concerns only the data collection in phase 2 – more specifically concerning the design of the *intervention*, the requirement for informed *consent*, and the method of *observation*:

- 1) NSD would like NESH to consider if there can be ethical implications with providing some students with (better) education about sanitation/hygiene.
- 2) NSD would appreciate advice form NESH on how the project leader can ensure that they obtain valid consents from parents who may suffer from illiteracy and do not attend the information meetings.
- 3) NSD want NESH to assess whether observing students in the latrine area is justifiable.

NESH will restrict the evaluation to these three questions, albeit in a different order.

## **Ethical evaluation**

The advisory statement from NESH is based on the [Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology](#) (2016).

### **1) Consent**

According to the project description the recruitment will first have to be approved by the school principal who invites specific classes to participate. Each individual student and parent/caretaker will be informed of the consent process, and the parents/caregivers will receive a Project SHINE information sheet and an invitation to a Project SHINE information meeting. Originally, the project intended to follow a *passive* consent procedure from the parents/caretakers arguing that Project SHINE is a low-risk educational intervention. However, NSD has advised an *active* consent from all parents/caretakers in the study arguing for an alternative consent procedure also involving follow-up phone calls to parents who either haven't returned the information sheet *or* couldn't attend the information meeting *or* may suffer from illiteracy.

According to the NESH *Guidelines*, researchers collecting personal data have an obligation to inform research subjects (guideline 8). In the letter of request, it is outlined in detail how the procedures for active consent can be fulfilled in a responsible way, also involving personal phone calls. NESH considers it both advisable and possible to obtain active consent in this project according to this approach.

Thus, NESH is not convinced that it is «unethical» to require active consent, as suggested in the request based on the argument that lack of consent from the parents/caretakers would exclude students from the beneficial effects the intervention could have on their health. This health benefit is clearly important in terms of public health, but in terms of research ethics it is not a sufficient reason to abstain from obtaining consent.

However, if (in singular cases) it is impossible to obtain active consent (due to distances, illiteracy, season work etc.) NESH is convinced that the project will manage these challenges in a responsible way. NESH therefore has no further comments to the procedures for obtaining active consent.

## **2) *Intervention***

Concerning the intervention, NSD would like NESH to consider if there can be ethical implications with providing some students with (better) education about sanitation/hygiene. Given that the project design is based not on deprivation of goods but on providing information and (better) education, NESH does not consider this discrimination in the design as unethical. Further, it is clearly stated in the project description that all students in both control groups will be given the SHINE curriculum, so that they can implement the intervention after the research study period. NESH considers this to be in accordance with responsible conduct of research, including the obligation to report the results back to all the participants (Guideline 46). Consequently, NESH does not consider it unethical, in this project, to provide some students with (presumed better) education about sanitation/hygiene. However, it would be preferable to have some kind research board monitoring the possible occurrence of diarrheal diseases in the control groups with permission to provide a better intervention.

## **3) *Observation***

NSD also wants NESH to assess whether observing students in the latrine area is justifiable. Initially, NESH had some remarks concerning this observation. For instance, in the school observation checklist (1.8), it is suggested that the teacher should «find a spot to observe without being seen» – thus indicating «stalking» or «spying» rather than observation based on free and informed consent. Also, in the parent information and consent letter, parents are expected to consent to «photographs/video to be taken of my child» without clarifying whether this also involved pictures being taken in the more private and intimate settings of the latrine area. NESH would agree with NSD that some of these formulations and proposed practices could be challenging.

However, based on the letter of request, NESH is of the understanding that the research team, after careful consideration, has decided to withdraw the School Observation Tool and Handwashing Form. It would still be able to observe the school facilities and infrastructure, but with little risk of observing students in the latrine area directly. NESH supports this judgement and has no further comments on this issue.

## Conclusion

NESH share the view of NSD concerning the need for *active* consent and advice the research group to follow the procedures already outlined. As for the two other questions, concerning the *intervention* and the *observation*, NESH find the approach to be ethically justifiable and in accordance with good research practice.

For NESH,

Bjørn Hvinden  
Chair of Committee

Vidar Enebakk  
Director of Committee

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- Norsk senter for forskningsdata (NSD)