Protocol for Project Amendment and Termination

WorkFREE

ERC - 2018 - StG - 805425

Introduction

WorkFREE's primary ethical commitment is to do no harm. To this end, we have established a *Risk Assessment and Management Plan* and deploy this alongside our living *Risk Register*. The strategies contained in the *Plan* limit the chances that WorkFREE will cause harm to participants, partners or staff. However, complexity dictates that we can never fully eliminate the risk of harm; it is also true that some harms are decisively outweighed by their associated benefits[1]. It is therefore our task to make a constant, situated assessment of how to respond ethically at any given moment and in collaboration with partners and participants. The WorkFREE *Unexpected Findings Policy* is designed to help with this task, and it equips staff with processual tools necessary to assess and address unanticipated harms discovered in the course of research. The present document aims to add to that Policy in the event that widespread harms are identified which occur *as a result of WorkFREE actions and interventions.* It outlines a process by which staff and partners can:

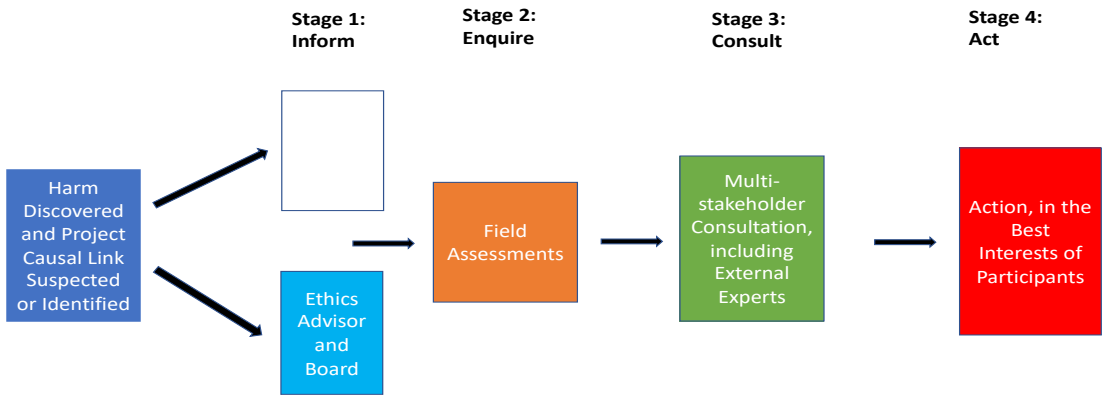
i) Establish causality around harm;

ii) Decide upon appropriate remedial action and rapidly take it; and

iii) If necessary, potentially amend or terminate the WorkFREE social experiment, initiating corresponding modifications to the project as a whole.

Process

As will be the case with any unexpected finding, staff will begin following the *Unexpected Findings Policy.* However, if it emerges or is suspected that the harm in question is widespread and caused by the project itself, then staff will initiate the following process, which will supersede the *Unexpected Findings Policy*:



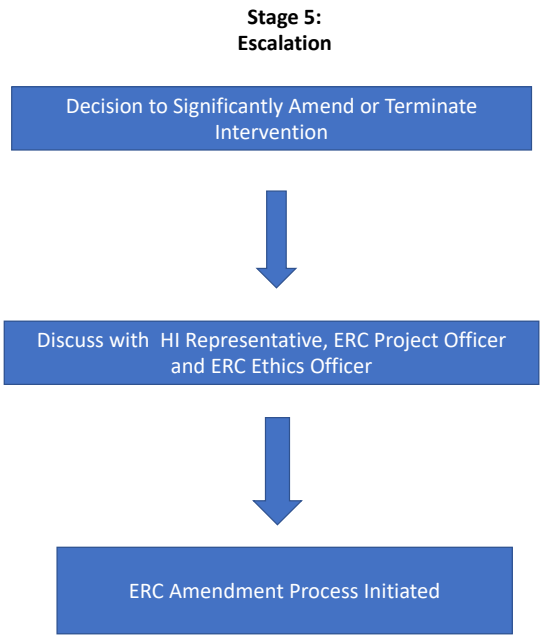
Consultation and Decision-Making Process

[1] The most frequently cited example here is that of the vaccination injection: no-one can deny that injections are uncomfortable and even distressing, especially for young children, but the benefits of immunity are widely deemed to far outweigh the costs of receiving the injection.

First, staff will immediately inform the Research Manager and the PI, as one would at Stage 2 of the *Unexpected Findings Policy*. Staff will also inform the Ethics Advisor and Ethics Board, such that they log the harm under investigation and initiate formal oversight of this process. The PI, Research Manager, Ethics Advisor and Ethics Board will work together in leading Stages 3 and 4 of this process. These will involve further, on-the-ground investigations into the extent of the harm and its causality, alongside consultations with partners, participants and potentially external experts to determine which remedial action to take in the best interests of participants. These enquiries and the process of action determination will be guided by the reflection questions contained within the *Unexpected Findings Policy*.

It is important to emphasise that although we may expect full collaboration between the PI, Research Manager and Ethics Advisor and Board, the ultimate sovereign body once this protocol has been activated is the Ethics Board, on which the Ethics Advisor sits. This is so as to protect against any conflict of interest, however unlikely, and is why it is vital that staff inform the Ethics Advisor and Board alongside the PI and Research Manager. Any steps taken at Stages 3 and 4 of this process will be agreed between the PI, Research Manager, Ethics Advisor and Ethics Board. However, should there be any disagreement, the decision of the Ethics Board will be final.

In case it becomes clear that a major amendment, pause or termination of the WorkFREE intervention is required, then Stage 5 of this process will be initiated, as per the diagram below. This will be communicated by the PI and Ethics Advisor (or, in the extremely unlikely event of conflict, by the Ethics Advisor) to the HI and ERC:



Any amendments will be legally binding and all contracts will be modified to reflect them.