Policy governing the use of human subjects in 3ie funded studies

Scope and definitions

This policy applies to 3ie-funded studies which involve interaction with human subjects. ‘3ie-funded studies’ are all studies receiving financial support, in whole or in part, from 3ie. ‘Interaction’ is any form of communication or other interpersonal contact between any member of the study team and a human subject. A ‘human subject’ is a living individual from whom private information is collected either through interaction with the individual from other sources. ‘Private information’ is any individually identifiable data.

Principles

Research involving human participants must comply with the following principles:

· be relevant to the needs and interests of the community in which the research is conducted

· have a valid scientific methodology

· ensure research participants are well informed on the purpose of the research and how the research results will be disseminated and have consented to participate, where applicable

· ensure that the confidentiality of private information is maintained, unless explicit permission has been obtained to the contrary (an example would be using a quote from qualitative fieldwork).

Policies

· Approval for the study must be obtained from all relevant ethical or institutional review boards prior to the commencement of any interaction with human subjects.

· Subjects must not be exposed to any risk that can practicably be avoided without impairing the research design.

· Investigators shall respect the privacy of subjects. They shall protect confidential information given to them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

· Subjects shall not be induced to participate by means or in circumstances that might affect their ability to decide freely.
- It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time and without prejudice to their legitimate interests. Subjects who indicate a desire to withdraw shall be allowed to do so promptly.

- If investigators detect an adverse change in the health or behaviour of a subject that may be attributable to a study, or if they identify new risks that may result from subject participation in that study, they shall immediately exercise judgment as to whether to suspend the study immediately. They should then refer the case to the relevant review board (where there is such) and 3ie for their view. A decision by 3ie to suspend the study on such grounds is binding.

- An investigator shall disclose to a subject, upon request, the source of support for the research.