

Speaker Abstracts

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Guidelines for ethics committees in HIC

Infecting a healthy volunteer even for the benefit of others rightly causes concern. This exceeds the expected/accepted level of research risk ("minimal risk") and as there is clearly no benefit to the volunteer, it seems to contravene a central tenet of medicine – "First do no harm"

So how should these studies be reviewed and judged?

Oxford A Research Ethics Committee frames its review using the following principles below, recognising two important caveats:-

- "one size won't fit all" as the major risk in these studies is the infection itself which will vary, depending on the infecting agent and
- these studies will be conducted in many different locations under differing circumstances so, while the principles and questions provide an overarching structure for review (and design), there may be local considerations that need to be taken into account.

Particular important principles to frame review of this type of research

1. There should be a clear research question and purpose.
2. The research team should be equipped to complete the study.
3. The research should incorporate patient and participant views.
4. Benefits, harms and burdens of the study should be properly addressed.
5. The choice and recruitment of participants must be justified, safe and fair.
6. Participants should be offered a fair choice (Informed consent) and understand what they are agreeing to.
7. There should be fair payments for participation.

Consequent considerations will be discussed in the presentation.

<http://www.reviewingresearch.com/human-challenge-studies/>

