Comments from a contributor who wishes to remain anonymous

To whom it concerns,

The Directorate General for Health and Food Safety, DG SANTE, seeks the views of stakeholders and other interested parties on the document regarding "Risk proportionate approaches in clinical trials" which has been developed in preparation for the implementation for the Clinical Trials Regulation (EU) No 536/2014.

My background is I am a consultant psychiatrist, post doctoral researcher in clinical neuroscience, and Principal Investigator of a clinical trial on risk reducing treatment for patients with paedophilic disorder, a study called [redacted].

With this e-mail I want to suggest a complement to the document "Risk proportionate...".

My suggestion is to state that the risk of a clinical trial must not only be measured in relation to the participating research subjects themselves, but also in relation to third party. The absence of clear instructions as on how to design a study involving research subjects that might be at risk of hurting third party makes it very difficult to do high quality research on patients with, for example:
- high risk of aggressive behavior (intermittent aggressive disorder)
- rape behavior
- homocidal tendencies
- paraphilic disorders
- impulse control disorders (pyromania, cleptomania, ...)
- ...

And, as well:
- patients with infectious diseases that are contagious
- pregnant women (3rd party = the fetus)
- nursing women
- patients with very low degree of functioning (so low that the caregivers around them in fact are the ones that will be the victims if the treatment fails): dementia, autism, intensive care treated patients

Since there are no guidelines in ICH-GCP or Declaration of Helsinki on how to assess the risk for 3rd party, the researcher is left with a very difficult task in designing a study for the patient populations mentioned above (when is it OK to use placebo for example, does 3rd party ever has the right of a veto?), the ethic review boards have difficulties in assessing the risks, and also the editors of the journals. My personal belief is that this is a contributing factor why so little research using RCT design is done for these patient populations. It is so difficult that it is easier to not make research. Which of course is very bad for the patients (and in the long run the 3rd party).

It would be a very helpful thing if the document "Risk proportionate..." (as well as ICH-GCP and Declaration of Helsinki) could give some clear instructions as on how to view the role of 3rd party.

Best wishes

[redacted]
[redacted]
[redacted]