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Faculty of Pharmaceutical Medicine comments on the proposed changes to the Declaration of Helsinki – June 2013

Introduction

The Faculty of Pharmaceutical Medicine is a professional membership organisation and standard-setting body, with 1,450 members, who are practising pharmaceutical physicians or those with a professional interest in the speciality. It was founded in 1989, and is a Faculty of the Royal Colleges of Physicians of the UK.

Pharmaceutical medicine is a medical specialty concerned with the discovery, development, evaluation, licensing and monitoring of medicines and the medical aspects of their marketing. The Faculty's members work in diverse environments; from front line clinical trials, to pharmaceutical marketing and medicines regulation.

Our mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public. The Faculty seeks, through its activities, to bring about an improvement in the health of the public.

The Faculty supports the proposed updates to the Declaration and particularly welcomes the new clause 20 and clause 34. Our additions are highlighted in yellow below.

Comments on proposed changes

New Paragraph (last paragraph in general principles)

"Adequate compensation and treatment for subjects who are harmed as a result of participating in the research must be ensured."

We agree with the essence of this proposed addition, but we would like clarification on the definition of harm. We would recommend less ambiguous wording that reflects persistent or enduring harm (without need for proof of causality to the investigational product) from participation in the protocol.

Old paragraph 14

"The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol." ~~*The research protocol should discuss and justify the chosen study design.*~~*"*

We believe that the performance should be justified as well, so recommend omitting the second sentence and amend the first one.

"The protocol must describe arrangements for post-study access by study subjects to interventions identified as clinically beneficial in the study."

Addition for clarification

Old paragraph 15

"*At the end of the study, the investigators must submit a final report to the committee containing a ~~study's findings and conclusions~~ synopsis of the clinical study report."*

As the synopsis of the clinical study report (CSR) is the summary of the study findings and conclusion this would provide a good standard for EC reports as well and would increase transparency and consistency.

Old paragraph 17

"Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and the research cannot be carried out in a non-vulnerable population.

In addition, this population or community should stand to benefit from the knowledge, practices or interventions that result from the research.

Consideration should also be given to ensuring that the community receives a fair level of additional benefits."

The wording 'there is a reasonable likelihood that this population or community stands to benefit...' within was problematic in practice and it is appropriate to amend the wording in paragraph 1 of this paragraph.

While agreeing with the principles espoused in this revision, we are not clear on what constitutes 'additional' benefits and how this could work or be monitored in practice.

We believe that rather than "*research cannot be carried out in a non-vulnerable population*", it is more appropriate to add that any information discovered from studying these populations will add clearly (pre)defined potential benefit to that population. This ensures that research must have a purpose that will help that particular population, rather than just confirming what is already known in a similar demographic sample.

New second part of paragraph 18

"Measures to minimise the risks must be implemented. The risks must always be monitored by the researcher throughout the trial."

We would like clarification as to who the 'researcher' precisely is. Is it the sponsor or the investigator or both? If it is both then this should be stated as such

Old paragraph 32

"Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo or no treatment is necessary to determine the efficacy or safety of an intervention...

...and the patients who receive any intervention less effective than the best proven one, placebo or no treatment will not be subject to any additional risks of serious or irreversible harm as a result of not receiving the best proven intervention."

We would suggest the addition of text that encourages minimising the number of subjects exposed to placebo etc. to the smallest number required.

Old paragraph 33

"In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as clinically beneficial in the study."

Added for clarification