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On 13 June 2013, the CPME Executive Committee adopted the "CPME Response to the WMA public consultation on the draft revised text of the Declaration of Helsinki"

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The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues[1].

CPME is grateful to the WMA for the opportunity given to comment on the draft revised text of the *"WMA Declaration of Helsinki on ethical principles for medical research involving human subjects"*.

CPME highly welcomes the general approach of creating categories by introducing headings in the Declaration. It indeed improves the readability of the text and facilitates its understanding.

Among all the changes proposed by the WMA Declaration of Helsinki WG, CPME especially welcomes the reinforcement of the provisions regarding vulnerable groups and the introduction of compensation for harmed subjects in the text. Providing for high protection schemes and damage compensation mechanism are prerequisites to the safe conduct of trials worldwide. The subjects undergoing clinical trials should always benefit from the highest protection frameworks. If these are not guaranteed, patients might be reluctant to participate in trials, hence this would in the long run be detrimental to medical research.

Additionally, CPME strongly supports the inclusion of the example of biobanks in the paragraph related to possible consent exemptions when using identifiable human and material data (old para. 25; new para. 32). We believe that the derogations to informed consent in the context of research should be exceptional and strictly supervised. In any case, the involvement of an ethics committee is absolutely crucial.

CPME fully endorses the changes introduced and would invite the WMA to consider the following suggestions:

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.
More information about CPME's activities can be found under www.cpme.eu

	WMA version	CPME amending proposal
8	In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.	In medical research involving human subjects, the health and well-being of the individual research subject must take precedence over all other interests.

Justification: The health and well-being of research subjects should be considered together in this paragraph.

22	The design and performance of each research study involving human subjects must be clearly described in a research protocol. The research protocol should discuss and justify the chosen study design. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol must describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study.	The design and performance of each research study involving human subjects must be clearly described in a research protocol. The research protocol should discuss and justify the chosen study design. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and information regarding provisions for treating and~~/or~~ compensating subjects who are harmed as a consequence of participation in the research study. The protocol must describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study.

Justification: This amendment is consistent with the newly introduced paragraph n°15 ("Adequate compensation and treatment for subjects who are harmed as a result of participating in the research must be ensured"), to which CPME fully adheres. Subjects who are harmed during a trial should benefit both from adequate treatment and compensation.

29	When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.	When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent ~~should~~ must be respected.

Justification: Stronger wording.