Table to compare Declarations of Helsinki as finalised at 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, and 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Clause	Korea, October 2008	Brazil, October 2013	WMA comments/Faculty comments
1	No change	No change	
2	No change	No change	
3	Becomes clause 4	Old clause 4	
4	Becomes clause 3	Old clause 3	Expands the duty of physicians.
5	Number stays same	Loses part which states that 'Populations that are underrepresented in medical research should be provided appropriate access to participation in research' (See new clause 11)	
6	Becomes clause 9	Old clause 7	
7	Becomes clause 6	Old clause 9	
8	Becomes part of clause 16	Old clause 6	New text; In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests. Comment by WMA; There is an acknowledged internal inconsistency in the document but this paragraph is intended to be aspirational.

9	Becomes clause 7	Old clause 11	
10	No change	No change	Physicians **must** consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. (Formerly 'should')
11	Becomes clause 9	Old clause 13	
12	Becomes clause 21	Old clause 16	
13	Becomes clause 11	Takes missing part of old clause 5	
14	Becomes clause 22	Old clause 31	
15	Becomes clause 23	Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.	New paragraph. It reflects the obligation to ensure that subjects who are harmed will receive compensation and treatment. Faculty requested clarification on the definition of harm. Not stated in final version. Faculty challenged original wording of "adequate"; in final version it is "appropriate".
16	Becomes clause 12	Old clause 8 plus 21	
17	Becomes clause 20	Old clause 18	New text; Measures to minimise the risks must be implemented. The risks must always be monitored by the researcher throughout the trial. Faculty asked for clarification as to whether the 'researcher' was investigator or sponsor or both. Final wording is; Measures to minimise the

			risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher. So this is not clarified.
18	Becomes clause 17	Old clause 20	
19	Becomes clause 35	Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.	
20	Becomes clause 18	Old clause 17	Combines fair benefit and reasonable availability approaches. Captures several important principles with respect to vulnerable populations. Faculty wrote 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. Final wording is; Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group

			and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.
21	Becomes part of clause 16	Old clause 12	
22	Becomes clause 25	Old clause 14	Faculty suggested *"The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol."* This was incorporated. Also suggested *"The protocol must describe arrangements for post-study access by study subjects to interventions identified as clinically beneficial in the study."* Final wording is; In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.
23	Becomes clause 24	Old clause 15	Adds the issue of transparency of RECs. The issue of qualification of the REC and its members is now addressed, recommended by several commentators. Faculty suggested "*At the end of the study, the investigators must submit a final report to the committee containing a synopsis (methods and results) of*

			the clinical study report." Final wording is; After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions. Faculty also recommended a time-frame for the publication of the CSR. This is not addressed in the final version.
24	Becomes clause 26	Old clause 23	
25	Becomes clause 32	Old clause 22	
26	Becomes clause 27	Old clause 24, plus old clause 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."* Not incorporated.
27	Becomes clause 28	Old clause 26	
28	Becomes clause 29	Old clause 27	
29	Becomes clause 30	Old clause 28	
30	Becomes clause 36	Old clause 29	
31	Becomes clause 14	Old clause 34	
32	Becomes clause 33	Old clause 25	
33	Incorporated into clauses 26 and 34	Old clause 32	Faculty suggested the addition of text that encourages minimising the number of subjects exposed to placebo etc. to the smallest number required. Not incorporated.

34	Becomes clause 31	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 beneficial in the trial. This information must also be disclosed to participants during the informed consent process.	Clarifies and strengthens post-trial access issue.
35	Becomes clause 37	Old clause 19	
36		Old clause 30	Adds researchers and sponsors to those who have ethical obligations.
37		Old clause 35	Intended to clarify the intent of this paragraph. Strengthens requirement to make the intervention the object of subsequent research.

http://www.wma.net/en/30publications/10policies/b3/ 2013 Version

http://www.wma.net/en/30publications/10policies/b3/17c.pdf 2008 Version

http://www.wma.net/en/20activities/10ethics/10helsinki/15publicconsult/DoH-draft-for-public-consultation_annotated.pdf Annotated copy outlining changes.

Among the significant changes as described by the WMA are:

- Increased protection for vulnerable groups. The Declaration recognises that some research populations are disadvantaged or vulnerable and have an increased likelihood of incurring additional and greater harm than others.
- There is more protection for participants. In addition to strengthening protection from risks there is a new provision for compensation for subjects harmed as a result of participating in the research.
- There are expanded requirements for post-study arrangements. This requires that participants be advised prior to the study that they will be informed of the results and if needed have access to treatments determined in the study to be beneficial.

- There is also a more systematic approach to the use of placebos, strengthening the explicit ethical requirements essential for placebo use particularly where a known effective treatment is available.
- There has also been some reorganisation and restructuring of the document with the aim of improving its readability, while preserving its character and length.

One of the principles of the Declaration is that medical research involving the vulnerable or disadvantaged population can only be justified if the research is responsive to the health needs and priorities of this community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research. So the Declaration requires that research should be conducted only if the importance of the objective outweighs the inherent risks and burdens to the research subjects.