	Original	Suggestions/ Changes	Final
15	Adequate compensation and treatment for subjects who are harmed as a result of participating in the research must be ensured.	Appropriate ~~adequate compensation and~~ treatment for subjects who are harmed as a result of participating in the research must be ensured.	Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.
20	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, ~~and if there is a reasonable likelihood that~~ this population or community should stand~~s~~ to benefit from the knowledge, practices or interventions that result from the ~~results of the~~ research. Consideration should also be given to ensuring that the community receives a fair level of additional benefits.	Omit entire sentence beginning with "Consideration…" Delete "disadvantaged"	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 nonvulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.
22	The protocol must describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study.	The protocol must describe arrangements for post-study access by study subjects to interventions identified as safe and beneficial in the study, if available to sponsor and investigator, and have required local regulatory approval.	The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol. 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, 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.
23	At the end of the study, the investigators must submit a final report to the committee containing a summary of the study's findings and conclusions.	At the end of the study, if not available on ClinicalTrials.gov, or another trial registry, the investigators should submit a final report to the committee containing a summary of the study's findings and conclusions when it becomes available.	The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as

			applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. 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.
33	The use of placebo~~,~~ or no ~~treatment~~intervention~~,~~ is acceptable in studies where no ~~current~~ proven intervention exists; or Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, 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 risk~~s~~ of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option.	… will not be subject to ~~additional~~ foreseeable risk~~s~~ of ~~serious or~~ irreversible harm as a result of not receiving the best proven intervention. ~~Extreme~~ Careful consideration must be taken to avoid abuse of this option.	The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances: Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or 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 intervention 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 intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option.

34	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 study. This information should also be disclosed to participants during the informed consent process. All study participants should be informed about the outcome of the study. ~~At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.~~	In ~~advance of~~ planning a clinical trial, sponsors, researchers and host country governments should when possible make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the study. This information should also be disclosed to participants during the informed consent process. All study participants should have the opportunity to be informed about the outcome of the study.	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.