



PRESS RELEASE

Clinical trials: Not enough safeguards for EU Citizens

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There are grave concerns for individual liberties and autonomy as triologue negotiations between Council and Parliament on the Clinical trials Regulation are about to come to an end. The approach being considered by the EU is an affront to EU Citizens and the Medical professionals caring for them. Physicians are very concerned that not all safeguards have been established to ensure that ethical standards are respected and that patients' right to autonomy and self-determination are protected.

An ethics committee should always be composed of qualified persons that have the necessary skills to assess the clinical trial. This is an essential safeguard for individuals from over-bearing, zealous bureaucracies, whose actions will adversely affect Citizens of the EU. The definition introduced in the Regulation does not envisage this essential characteristic.

"While we highly welcome the inclusion of patients in the final decision process, we do not understand the logic of excluding professionals in the definition. Qualified persons provide ethics committees with the necessary expertise. This should be acknowledged." said Dr Katrín Fjeldsted, President of CPME. *"Furthermore, the definition should clearly state that an ethics committee has to be independent from the researcher, the sponsor and any other undue influence."* she continued.

Special derogations to informed consent have been introduced. These fail point blank to address the basic conditions under which informed consent may sometimes not be collected. Dr Margaret Mungherera, President of the WMA, condemned *"the disastrous removal of Patients' rights in the guise of unattainable and improbable patient autonomy. The EU direction will reduce Patient rights to a lesser standard than today - for dubious reasons with unclear motives which will leave citizens stripped of their rights and their dignity"*.

Ethical standards are enshrined in the WMA Declaration of Helsinki since 1964. If Council and Parliament will agree on these provisions, Europe will turn back the clock 50 years. This is certainly not what we want for European citizens.

The 2013 WMA Declaration of Helsinki is available [here](#)
The CPME Statements on clinical trials are available [here](#) and [here](#)

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