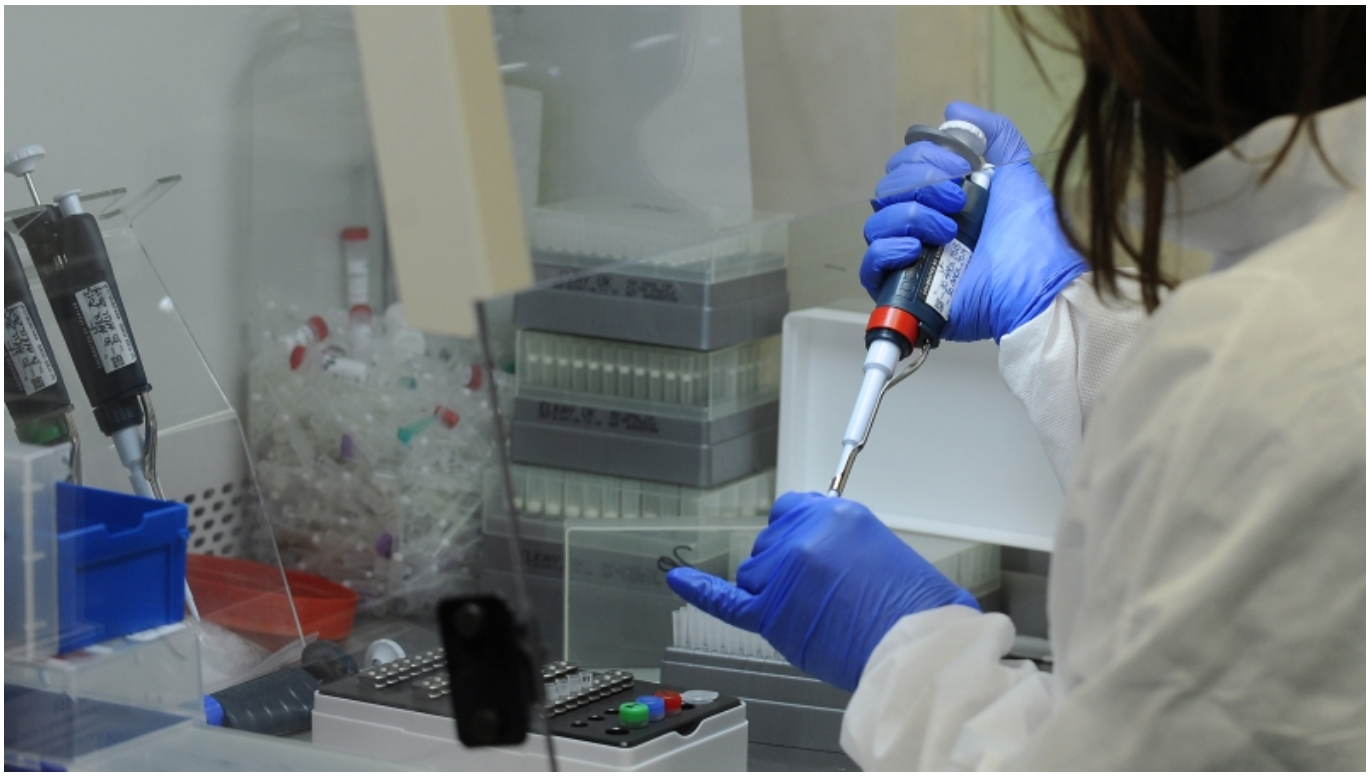
Published on *The Parliament Magazine* (https://www.theparliamentmagazine.eu)

PM+: EU 'substantially weakens' informed consent in clinical trials regulation

Written by Katrin Fjeldsted on 23 April 2014 in Opinion Plus
Opinion Plus

As the clinical trials regulation reaches implementation, Katrin Fjeldsted highlights the importance of both 'informed consent' and 'medical ethics'.



On 14 April 2014, the council of the European Union approved the agreement reached in December of last year with the European parliament. This means the text is now adopted and will directly apply in the 28 member states.

We welcome several positive developments such as the inclusion of ethics committees and their binding decision on the approval of the clinical trials protocol. Regrettably though, we have serious concerns that the ethical principle of informed consent has been substantially weakened.

The newly adopted regulation introduces special derogations to informed consent, whereby a subject consenting to participate in a clinical trial would be asked in parallel "to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes" (article 28.2.a). "Simplified means for informed consent" are also made possible in certain situations (article 30).

When agreeing to take part in a research project, one should be informed of the risks and benefits of the project, as well as of the potential alternatives. It is very improbable that this will be the case with a broad or a simplified consent. There are of course some situations where informed consent may be impossible or impracticable to obtain, where it might even undermine the results of the research project. In these specific cases, derogations do exist, but they are subject to strict safeguards and governance mechanisms.

> "When agreeing to take part in a research project, one should be informed of the risks and benefits of the project, as well as of the potential alternatives"

As such, an independent research ethics committee has to give its green light. In the adopted clinical trials regulation, it seems the derogation is becoming the rule, without any clear guarantee that a strict governance structure - such as an ethical review - would oversee the whole process.

Not only are these provisions in breach of medical ethics, they also are completely unsound in terms of data protection. It is very doubtful that the broad or simplified consent introduced in the regulation are consistent with the concept of purpose limitation. In data protection, the concept of purpose limitation guarantees that the processing of the data does not exceed the purpose for which the data was collected. On the other hand, a certain level of flexibility is sometimes needed for the further processing of data.

This is undoubtedly the case for medical research: health data are of real added value for research. However, this further processing is only allowed under the caveat that strong safeguards are in place, ensuring fair processing and preventing any undue impact on the data subjects. The clinical trials regulation fails to ensure that. It is unclear how the privacy of the data subjects will be ensured, since there is no clear obligation in the text to anonymise or at least pseudonymise the data.

Is informed consent such an unsustainable burden that one should be authorised to easily overlook and circumvent? Certainly not. As medical doctors, we are ethically obliged to do what is best for the patients we treat.

Informed consent is one of the major achievements of the 20th century in making ethical research acceptable. It forms an integral part of the world medical association's declaration of Helsinki and is the backbone principle protecting autonomy and self-determination of patients.

As the regulation is now undergoing the implementation process, we will continue to oppose any attempt to weaken informed consent and medical ethics in general. We will also pay particular attention to the data protection regulation which contains a section on medical research.

In this context, we do hope the European legislator will find an acceptable and balanced solution that does guarantee research to advance in an ethically sound framework. This is a matter of reliability and credibility of medical research.

About the author

Katrin Fjeldsted is president of the standing committee of European doctors

Tags
Health [1]

Research and Innovation [2]

Categories

Health and social care [3]

Science, technology and research [4]

CompanionVacher's Quarterly The European Union and Public Affairs Directory

Dods events

Westminster BriefingDigital Health & Care ScotlandMEP AwardsThe Skills SummitScottish Public Service AwardsPublic Sector Procurement SummitPublic Sector ICT SummitCyber Security SummitCyber Security 2017Training Journal Awards

Partnership events

The Health and Care Innovation ExpoCivil Service LiveCivil Service AwardsChief Nursing Officer for England's SummitWomen into LeadershipThe Youth Justice ConventionSocitm Spring ConferenceNHSCC Annual Members' EventDods at Party Conference

---

Links
[1] https://www.theparliamentmagazine.eu/tags/health
[2] https://www.theparliamentmagazine.eu/tags/research-and-innovation
[3] https://www.theparliamentmagazine.eu/categories/health-and-social-care
[4] https://www.theparliamentmagazine.eu/categories/science-technology-and-research