Over regulation is stifling UK research

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Over regulation is stifling clinical research in the UK according to a group of leading academics. The researchers warn that patients are missing out on the benefits of new clinical trials because the burden of regulation hinders research.

Writing in this week's British Medical Journal (17th October) the academics from the Universities of Birmingham and Cambridge call for urgent changes in the way clinical research in the UK is administered.

Professor Paul Stewart who is Director of Research at the University of Birmingham's College of Medical and Dental Sciences comments: "Measures like the EU Clinical Trials directive that were set up with the laudable aim of providing greater safety for patients have actually had the unwanted effect of stifling research.

"The risks from clinical trials are lower than in everyday medicine but regulation is obstructing the very activity which it is meant to encourage: high-quality clinical research. Without reform, clinical research in the UK risks falling behind other countries where regulation is less oppressive."

The authors are particularly critical of the approvals process for clinical studies, which requires all trials to receive separate national approvals from both a central ethics committee and the Medicines and Healthcare Products Regulatory Agency (MHRA).

The authors also express major concerns about the double and triple jeopardy of numerous local obstacles which add months of delay even after national approval has been obtained. In addition, there is poor co-ordination, and often little understanding, between the NHS and University officers who are each required to sponsor academic research, but have differing rules from each other on key items such as indemnity.

Professor Stewart adds: "The approval process is both unnecessarily complex and time consuming. Getting approval from the MHRA may make sense when dealing with a novel drug but creates unnecessary bureaucracy when research involves drugs that are already licensed and therefore known to be safe."

The researchers suggest a four point plan to improve the situation:

1. A single and simple web based submission form for all research studies.

2. Automatic indemnity by the Department of Health's Research arm (NIHR) for all research protocols involving NHS patients.

3. A National and consistent Ethical review process.

4. MHRA to focus on its remit to ensure Medicines work and are safe

Professor Morris Brown, Professor of Clinical Pharmacology at the University of Cambridge adds: "As researchers, our patients' safety is always our primary concern. The extraordinary care devoted to participants in research means they are at much lower risk than the recipients of routine NHS care, and at the same time have access to treatments that are often not generally available.

Mindless regulation is halving the amount of research we can do and clearly works against the interest of the very patients it supposedly protects.

Research funders place great emphasis on translating science into new treatments. If their generous support is to be translated into productive research, rather than eaten away by hours of fruitless form-filling, then the leaders of these bodies cannot afford to turn a blind eye to the cancer within.

The regulatory burden must be simplified and be seen to support clinical research rather than close it down."

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Notes to Editors

The paper: The real threat to Clinical Research: Regulation, Regulation, Regulation is published in the British Medical Journal.