Health Research as a Public Good

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April 13, 2012

*Participant in the activities of the IOM Forum on Drug Discovery, Development, and Translation.

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The arrangements for the regulation and governance of health research in the United Kingdom (UK) have evolved, piecemeal, over the past 30 years, and much is now enshrined in UK and European Union (EU) legislation. Each individual measure was introduced with the best of intentions, but the law of unintended consequences has meant that the regulatory and governance framework for health research is now dysfunctional, uncoordinated, and no longer “fit for purpose.” The EU directive regulating clinical trials places unnecessary and unreasonable burdens on investigators; there are at least a dozen bodies involved in granting ethical approval for health research; and each National Health Service (NHS) hospital involved in a study insists on re-examining the ethical, legal, and financial arrangements that have already been largely scrutinised by one (and often more) of the relevant ethics committees.

The goal of health research—encompassing experimental medicine, clinical trials, and epidemiology—is to improve and sustain the public’s health. Whether involving healthy volunteers, patients, or the public more widely, the Academy of Medical Sciences (2011) has enunciated four fundamental principles (see Box 1) that should underpin the regulatory environment for health research.

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<th>BOX 1</th>
<th>Guiding Principles for the Regulation and Governance of Health Research</th>
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<tr>
<td>1</td>
<td>Safeguard the well-being of research participants</td>
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<tr>
<td>2</td>
<td>Facilitate high-quality health research for public benefit</td>
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<tr>
<td>3</td>
<td>Be proportionate, efficient, and coordinated</td>
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<tr>
<td>4</td>
<td>Build and maintain confidence in the conduct and relevance of health research through transparency, clarity, accountability, and contestability</td>
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In the United Kingdom, however, none of these principles is fully (and in many instances even partially) met. Even Principle 1—safeguarding the well-being of research participants—is undermined by the mindless controls that are too often imposed and that lead to a false sense of security. Principles 2, 3, and 4 are observed in the breach. Yet we know that the public, in the United Kingdom, has an appetite for research. Most patients, given the opportunity, want to take part in clinical trials. Half a million members of the general public have contributed their personal details (in anonymised form), as well as blood, urine, and saliva, to UK Biobank. In order to meet the aspirations of patients, the public, and the health research community (including both the life sciences industries and academic investigators), the following measures are being taken:

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1 Participant in the activities of the IOM Forum on Drug Discovery, Development, and Translation. This discussion paper is based on a submission to the Forum’s November 2011 workshop, Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing Copyright 2012 by the National Academy of Sciences. All rights reserved. in international case studies in the area of clinical research transformation.
1. In response to the advice of the Academy of Medical Sciences’ report, the government has created (as of December 1, 2011) a Health Research Agency (HRA). In line with the academy’s proposals, it is intended that this new body fulfill two functions. First, it will bring together the current disparate arrangements for providing ethics approvals for health research. The National Research Ethics Service has already moved into the HRA and other bodies will do so shortly. Some of the arrangements for ethics review are enshrined in primary legislation and will take a little time to unravel, but there is a real determination, on the part of the government, to ensure that rapid progress is made. Second, the Academy of Medical Sciences expects the HRA to coordinate the research governance arrangements in individual NHS hospitals. For multicentre studies a “lead” institution could take responsibility for the global checks, leaving individual hospitals to confirm the availability of patients and staff time. Consortia of individual NHS hospitals have already started to do this. Alternatively or additionally, the HRA could itself undertake the global checks. Whatever arrangements that emerge, individual hospitals—as independent legal entities—will need to agree, formally, to take part in particular studies. It will therefore be incumbent on the new agency to earn and retain the confidence of the NHS hospitals themselves as well as the wider research community and the public.

2. In its report on the current climate for health research, the academy was highly critical of both the principles and the operational details of the EU’s Clinical Trials Directive. This directive is over-burdensome (including so-called “non-investigational” studies that have no place in the context of drug regulation), disproportionate, and applied inconsistently across the European Union. As a member state of the European Union, the United Kingdom has no alternative but to subscribe to the provisions of the EU Clinical Trials Directive. Nevertheless, the UK government is committed to re-negotiating the provisions of the directive to ensure that, in revised form, it is less burdensome, appropriately proportionate, and applied evenly across the European Union. At the same time, it will seek to ensure that patients’ interests are safeguarded.

3. The National Institute for Health Research (NIHR) is developing metrics that will allow it to monitor the time taken for regulatory and governance approvals. The research charity, Cancer Research UK, estimates that in 2009 the time between its award of a grant to conduct a trial and the entry of the first patient averaged 631 days. The NIHR seeks for this to come down to 70 days. NHS hospitals failing to meet this requirement will face financial penalties.

Britain has a long and proud history of health research. The regulatory and governance arrangements instituted over the past 30 years have seriously eroded its historical position. The measures recently enacted, as well as those planned for the near future, should allow the United Kingdom to regain its rightful place in this endeavour (Rawlins, 2011).

REFERENCES
