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VIEWPOINT

Legal pathways for cross-border research: building a legal platform for biomedical academia

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A proposal for the development of a dynamic, online, grass roots WIKI + legal platform for sharing, discussing, validating and issuing authoritative and reliable legal forms and standards to aid the (European) biomedical research community in navigating the legal pathways that govern cross-border, multi-jurisdictional (EU) research (legal platform)

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Problem: national laws hinder EU efforts to stimulate EU wide biomedical research

EU Biomedical research is increasingly interdisciplinary and cross-border (eg, biobanking). The associated scientific inquiries are met by an increasingly complex set of rules and regulations that try to govern the legal issues raised by these developments. The complexities of national (EU Member State) legislation are multiplied exponentially for each additional EU jurisdiction involved in a given research project. The resultant situation has led to a highly proliferated patchwork of rules and regulations. The uncertainties surrounding the legality of cross-border data and sample transfers are but one example. Academic researchers and their institutions have so far coped by working with certain legal forms and standards. However, these forms typically:

(a) only provide limited, temporary, 'home made' solutions;
(b) are applicable only at a fixed point in time;
(c) tend to be project specific and may not measure up to the ever increasing legal standards;
(d) may expose their users of these to civil, regulatory or even criminal proceedings.

Obviously, the uncertainties created by the current patchwork may delay or even stifle interdisciplinary and international collaborations. Unlike their counterparts in industry, academic researchers typically cannot afford to hire outside commercial expertise to handle those issues.

Possible solution: further EU harmonisation

One way to solve this problem would be for the EU legislator to harmonise the rules and regulations that form the current patchwork. Although some harmonisation has been achieved and further harmonisation should certainly be pursued, harmonisation at the EU level is a time-consuming affair and is unlikely to iron out all differences as Member States are inclined to hang on to their discretion in implementing harmonisation directives.

Alternative solution: a dynamic, online, grass roots WIKI + legal platform

An alternative way to solve this problem would be by offering a dynamic, online, 24/days–7days/week accessible, grass roots platform for developing authoritative, peer reviewed, high-quality legal forms and multi-jurisdictional legal advice. Examples include: informed consent forms,

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material transfer agreements, collaborative research agreements, privacy forms, disclaimers and copyright notices. The topics could be broken down for specific research categories (epidemiology, stem cell and biobanking), as each category will raise specific concerns. Building the legal platform would involve the following steps:

- the platform would provide the opportunity for researchers and lawyers to *upload* any 'tried and tested' forms and documents on a WIKI platform;
- these uploads could then be discussed and refined by the members of the biomedical research community and the public at large, using the WIKI method and technology;
- the resultant documents could then be validated by way of peer review, under the supervision of an editorial board;
- in addition, the editorial board could commission the drafting of certain standards, which could then be reviewed by national experts for compliance with domestic requirements.

Thus, an interactive, dynamic authoritative network of legal pathways could be built, guiding all stakeholders in the biomedical research community, 24/days–7days/week, through the host of rules and regulations governing today's biomedical research. If hosted by the EU, the platform would, as an additional benefit, clearly establish the EU as a body committed to embedding modern biomedical science in the boundaries set by law.

Audience

The platform would be aimed at a broad, interdisciplinary audience of academic and industry researchers actively involved in biomedical research, patient advocacy groups, regulators and national and international law and policy-makers. It would provide these groups with reliable and up to date forms and documents to ensure that their involvement in biomedical research is compliant in the various jurisdictions in which it is conducted. The exact format in which to present the platform and legal protocols is to be determined and will have to reflect the complexities of the issue at hand. To find forms and documents in a field of interest, users would be able to browse the platform by category.

Composition of the board

Obviously, the editorial board should comprise legal experts, complemented by representatives from the biomedical research community (scientists, research participants, patient advocacy groups, regulatory agencies and industry). I am prepared, subject to certain conditions, to act as founding editor in chief of the platform.

Network of national correspondents

Part of the problem is the fact that researchers have to be compliant in various different jurisdictions. As the laws are national, the board should try to build a network of correspondents in relevant jurisdictions. Eventually, the network could even be subdivided into a set of regional networks, covering not only the EU, but also the US, Canada, Asia and Africa.

Additional functionalities

In addition to the above, the platform could be expanded so as to include other functionalities, including:

- A virtual hub to online sources of international and national biomedical legislation, codes of conduct etc. For example, someone who wants to set up a cross-border stem cell research collaboration will have online access to the specific rules in each jurisdiction concerned.
- overviews of recent legal developments (eg, Bush veto on stem cell research), and detailed descriptions of important case law (eg, The Washington University *vs* Dr W Catalona *et al*.).

Business model

Access will, in principle, be free. Collaboration will be on a volunteer basis, although board members may perhaps apply for EU subsidies. Sponsored links may be considered (Google model). Contributors will, in principle, not be paid. Their contributions can be seen as part of academic service, just as reviewing papers, grant applications or serving as editors for a journal. What contributors could get in return for their contribution is the academic credit among peers; the WIKI model secures that everyone can see who made which contribution. Finally, the platform will doubtlessly serve as a source of inspiration for further research and a real life instrument to find out the actual issues faced by biomedical scientists.

Launch

To get the platform off the ground as soon as possible and to ensure continuous uploads and support, publicity must be sought through appropriate channels, for example, publication of this proposal in this journal and other media, a poster at appropriate conferences etc. In fact, to be

truly grass roots and to yield the best results, the WIKI model only works if there is a high level of participation.

WIKI+

As some topics may be controversial and I do intend to provide tangible solutions rather than merely raising issues, the WIKI format in its pure form may not suffice, as it may be liable to vandalism and lack of quality. Instead, a WIKI+ format could be used which will allow for authorisation by a designated editorial board.

Outcome

As with other WIKI projects, it is unclear what, if any, results this approach may yield. In any event, it is a low-budget project that could be very exciting and will at a minimum bring together the work already being done for various cross-border projects, such as the GenomEUtwin.

Language

English as working language to start with.

Disclaimer

Although best efforts will be employed to secure that any forms and documents are compliant in each jurisdiction concerned, it has to be made very clear that they cannot replace individual legal advice in a particular case. To that end the terms and conditions that govern the use of this service will have to contain an effective and enforceable disclaimer.

Conclusion

The uncertainties for cross border biomedical research created by the current patchwork of laws and regulations could be addressed by the development of an online legal platform.