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Time to open up

If scientists want the public to continue to volunteer for research projects, they must learn to be a lot more forthcoming about the ways in which the information they garner will be used.

Few biomedical researchers who work with human volunteers are entirely happy with the rules that govern and preserve research ethics. Scientists working on an experiment or a clinical trial can find that the complex web of regulations that they must follow is a confusing burden. These rules, they feel, simply add time, cost and complication to their studies.

Institutions are wary of falling foul of regulations that even highly trained staff are hard-pressed to interpret. And research participants — the volunteers without whom research such as clinical trials would not be possible — often don't understand all the implications contained in the voluminous documents that they must sign before they take part in the research. Although these forms are ostensibly designed to protect participants, they are more often directed at protecting institutions from liability.

The notion of informed consent has become especially problematic in this modern age of 'big data'. The need to seek and obtain permission from volunteers can be traced back to research-ethics principles introduced in response to revelations about the way Nazi doctors tortured people during the Second World War. Decades ago, researchers could not glean much information from a piece of stored tissue. But now, it is no longer possible to explain to a research subject all the possible ways in which their offered data might be used in the future, and it is becoming less feasible to guarantee their privacy under (correct) rules that mandate the deposition of research data in public databanks. Some large data-collection projects have therefore adopted very broad informed-consent provisions, in which research participants simply agree that their data may be used for a wide and unspecified variety of purposes. But as potential volunteers become savvier to the value and vulnerability of their personal data, they may become less receptive to this approach. Indeed, as our feature on page 312 shows, this may already be happening.

Technology and some creative thinking should be able to provide a solution to this problem. In an era when people can control who sees what types of personal information on their Facebook page, programmers should be able to design similar tools to give research volunteers a degree of influence over who uses their data and for which types of research. Experiments along these lines are now being tried by the company Private Access, based in Irvine, California.

Scholars of ethics and law are also trying to think of new models for informed consent that could accommodate the needs of both researchers and research participants. For instance, a group based at Duke University in Durham, North Carolina, and the University of North Carolina at Chapel Hill has proposed remodelling consent provisions based on laws that protect trade secrets. In its favour, this model would provide the option of giving donors something in return for handing over their samples to a large data collection, such as a biobank. It would ask the donors what they want in return for the information embedded in the samples, such as financial compensation (which many already receive) or a say in the types of research their information is used for.

Other researchers have proposed reforms that head in the opposite direction — for instance, by relaxing the rules on consent for research involving 'de-identified' specimens, which are stripped of information that could link them back to their source.

This approach may seem attractive because it would seem to lessen cost and burden on the researchers, and could make the most of currently under-exploited medical records and data samples. Extreme caution is needed, however. It would take only one high-profile case of an unwanted data disclosure to undermine support for research — and not just for the field in question. Researchers need only look to the backlash against newborn screening in the United States and tissue research in the United Kingdom to realize how failing to obtain consent can set back their cause.

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As this journal has argued previously, a more appropriate solution to the conundrum of informed consent is to introduce greater openness to the process.

Scientists could agree to give results containing medically relevant findings back to participants in genetic studies, such as information about their health. Although some have argued that this approach, as well as patient-controlled approaches, will add time, cost and complication to studies, no one really knows if this is the case. Such concerns must not be allowed to derail the idea.

Most large studies are funded by taxpayers or patient-advocacy groups. Researchers are therefore obliged to listen when patients and members of the public argue that they want to have more information — not less — to ensure that they agree to offer their continued participation in research. It might not make everybody happy, but it should keep everybody involved. ■

Renewed vigour

Stem-cell researchers must engage with politicians to keep their work alive in Europe.

Research involving human embryonic stem (ES) cells is once more under scrutiny in Europe. In a situation that will stir memories of the acrimonious debates of 2006, legislators must again assess whether this kind of work should still be funded under the forthcoming €80-billion (US$100-billion) Horizon 2020 research programme.

Now, as then, opinion is split. Some countries and some members of