Working with international donors: Possibilities and pitfalls

When it comes to seeking funding from international donors, complications can arise in the area of compliance. **John Westensee** provides insight into the implementation and monitoring of policies, procedures and controls .

On 17 November 2005, the front page article in *Research Europe* was headlined "Speaking American". It is an all too familiar story about an institution that just carries on doing business as usual without checking the specific rules for a project funded by an international donor. It is also a story about how one small detail in this process can escalate into a big problem.

Gothenburg University in Sweden receives funding for ten projects worth EUR3 million from the National Institutes of Health (NIH) in the US. In order to receive NIH grants, the institution needs to have a Federalwide Assurance (FWA), which basically states which recognised Institutional Review Board (IRB) examines the ethics of research proposals and which rules and regulations are to be followed. On the surface, the form is very easy to fill in and acceptance is easy to obtain. The tricky part is that by filling in the form, you certify that you are in compliance with many different rules and regulations. When submitting proposals, you may be caught up in the practical details, and it is not uncommon to simply fill in such a form with the intention to have a look at the details when there is more time. Somehow, however, you never seem to get the time to do it.

In this case, closer scrutiny of the details would have shown that the role of the IRB differs between the US and Sweden. In Sweden, the IRB approves a project at the application stage and it does not perform regular oversight during the project period, if the project runs according to plan. This is done according to national law. In the US however, the IRB has to review the research at least once a year. This creates a kind of 'catch 22' situation: the Swedish university has to comply with national law, and according to national law the IRB only performs its review once. The IRB is not obliged to comply with US rules. The US funder on the other hand states that their rules apply for US money and they do not accept national laws in other countries that are not as stringent as in the US. So who is right? For sure, the university is caught in the middle when its ten grants have been suspended until the issue with the FWA has been resolved.

It would be quite easy to draw up a list of similar cases, especially in relation to US federal and EU Commission funding. These funders are mentioned as they are large scale funders and therefore can offer a picture of where we are headed when dealing with external grants in the future.

In terms of the area of external funding for research projects, conditions have changed dramatically over the last 20-30 years. Just the last ten years have seen big changes. The level of detail and control has increased dramatically. It has now become more and more difficult for an individual researcher just to write a simple five-page project description and get any significant funding that way. Similarly, it is almost impossible for a single researcher to manage a project since you now need extensive administrative expertise when dealing with the rules and regulations in big projects. This is the reason why problems started in Gothenburg University; the researchers tried to resolve the issues themselves instead of using the proper administrative expertise.

The level of detail and control has increased dramatically. It has now become more and more difficult for an individual researcher just to write a simple five-page project description and get any significant funding that way.

The biggest problem is that many institutions in reality do not have the necessary administrative expertise at hand to deal with many of these complex issues. In the US and the UK, however, many universities have set up research support offices (or sponsored programmes offices) to deal with these issues. In many other countries, universities are now realising that they need to upgrade the administrative side as in the US and UK and are now setting up offices with the specific task of supporting the research area in all phases (proposals, administration, dissemination and exploitation). A research intensive university needs offices like the above to deal with these issues professionally, and there is a huge need for information sharing, best practice, further and continuing education. The idea is to recognise research administration as a profession; these offices now need a whole arsenal of expertise and knowledge. To help achieve this, the Society of Research Administrators International (SRA International) has ventured to define a 'body of knowledge' on their homepage at www.srainternational.org. It is very much focused on American issues but is an excellent starting point for discussions between the research administration societies on how to define a global body of knowledge.

Going back to the problem at Gothenburg University, the lesson to be learned must be that you approach a new funder

like the NIH professionally and with your eyes open. It is not enough to assume that it is just 'business as usual'. In this case, it would be helpful to have a look at the relevant section of the abovementioned body of knowledge to give you an idea of what to prepare for. Examples of issues to deal with could be:

A Compliance & Assurances

1. Overview of Federal Regulatory Compliance
2. Establishment and Management of Compliance Programs

B Project Integrity

1. Promotion of Responsible Conduct in Research
2. Conflict of Interest
3. Research Misconduct
4. Protection of Human Subjects
5. Humane Care and Use of Animals
6. Biohazards and Radiation Safety
7. Representations and Certifications

These are just examples of which policies, procedures and controls the university should introduce, and the research support office is an essential unit in this respect. It is not enough to simply write down a policy. It must also be implemented and updated, and implementation should be monitored in order to make sure that the right people are trained and the proper procedures are used. Most institutions have policies addressing these issues, but I think in many cases there is no active follow-up or monitoring being performed by the institution, and instead researchers are relied upon to 'do the right thing'. This approach is not enough; you can easily imagine the reaction if somebody from management or administration were to bother the researcher with an educational programme and control mechanisms in these areas.

Yet, in my mind there is no way of avoiding this situation, and I do not think we should try to avoid it. It is a healthy sign that you address these issues in a professional and structured way, and a sign of responsibility that helps you keep the public trust in your institution. In order to achieve this, you need to invest a tremendous amount of time integrating these practices into everyday business at all levels – it is not just the responsibility of a certain office. It has to be supported from the top-level management down to others in the organisation.

Finally, when actually dealing with the NIH, you should access their homepage at www.nih.gov to get all relevant information. Information on protection of human subjects can be found at www.hhs.gov/ohrp and www.nihtraining.com/ohsrsite. RG

John Westensee is Head of Research Support at Aarhus University Hospital in Aarhus, Denmark. Email: jwest@as.aaa.dk.
Watch for his upcoming book directed toward new researchers with practical advice on how to carry out research projects and the search for external funding, due out in December 2006.