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A Message from the Director

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Below you will find an outstanding article focusing on "Ethics and Conflict of Interest" written by Dr. Michael McDonald whom is the Director of the Centre for Applied Ethics at the University of British Columbia, Vancouver, B.C. The mission of the Centre is to **bring moral philosophy into the public domain** by advancing research in applied ethics, supporting courses with a significant ethical component and acting as a community resource.

I trust that you will read and benefit from this article.

Ethics and Conflict of Interest

You've seen the headlines, "Politician caught in conflict of interest" or "professional denies conflict of interest allegations." You probably were thankful that you were not the subject of the newspaper story. But you also may have wondered what exactly is a conflict of interest, why such conflicts are ethically significant, and what you can do to avoid being in one.

Definition

I define a conflict of interest as "a situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties." There are three key elements in this definition. First, there is a private or personal interest. Often this is a financial interest, but it could also be another sort of interest, say, to provide a special advantage to a spouse or child. Taken by themselves, there is nothing wrong with pursuing private or personal interests, for instance, changing jobs for more pay or helping your daughter improve her golf stroke.

The problem comes when this private interest comes into conflict with the second feature of the definition, an "official duty" – quite literally the duty you have because you have an office or act in an official capacity. As a professional you take on certain official responsibilities, by which you acquire obligations to clients, employers, or others. These obligations are supposed to trump private or personal interests.

Third, conflicts of interest interfere with professional responsibilities in a specific way, namely, by

interfering with objective professional judgment. A major reason clients and employers value professionals is that they expect professionals to be objective and independent. Factors, like private and personal interests, that either interfere or appear likely to interfere with objectivity are then a matter of legitimate concern to those who rely on professionals – be they clients, employers, professional colleagues, or the general public. So it is also important to avoid apparent and potential as well as actual conflicts of interests. An apparent conflict of interest is one that a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest.

Leading Examples

With this in mind, consider the following types of typical conflicts of interest listed by Canadian political scientists Ken Kernaghan and John Langford in their book, *The Responsible Public Servant*. They list seven categories:

[1] Self-dealing. For example, you work for government and use your official position to secure a contract for a private consulting company you own. Another instance is using your government position to get a summer job for your daughter.

[2] Accepting benefits. Bribery is one example; substantial [non token] gifts are another. For example, you are the purchasing agent for your department and you accept a case of liquor from a major supplier.

[3] Influence peddling. Here, the professional solicits benefits in exchange for using her influence to unfairly advance the interests of a particular party.

[4] Using your employer's property for private advantage. This could be as blatant as stealing office supplies for home use. Or it might be a bit more subtle, say, using software which is licensed to your employer for private consulting work of your own. In the first case, the employer's permission eliminates the conflict; while in the second, it doesn't.

[5] Using confidential information. While working for a private client, you learn that the client is planning to buy land in your region. You quickly rush out and buy the land in your wife's name.

[6] Outside employment or moonlighting. An example would be setting up a business on the side that is in direct competition with your employer. Another case would be taking on so many outside

clients that you don't have the time and energy to devote to your regular employer. In combination with [3] influence peddling, it might be that a professional employed in the public service sells private consulting services to an individual with the assurance that they will secure benefits from government: "If you use my company, I am sure that you will pass the environmental review."

[7] Post-employment. Here a dicey situation can be one in which a person who resigns from public or private employment and goes into business in the same area. For example, a former public servant sets up a practice lobbying the former department in which she was employed.

Some tests

How do you determine if you are in a conflict of interest, whether actual, apparent, or potential? The key is to determine whether the situation you are in is likely to interfere or appear to interfere with the independent judgment you are supposed to show as a professional in performing your official duties. A good test is the 'trust test': would relevant others [my employer, my clients, professional colleagues, or the general public] trust my judgment if they knew I was in this situation. Trust, in my opinion, is at the ethical heart or core of this issue. Conflicts of interest involve the abuse, actual or potential, of the trust people have in professionals. This is why conflicts of interest not only injure particular clients and employers, but they also damage the whole profession by reducing the trust people generally have in professionals.

In fact, the 'trust test' suggests one very good way of dealing with a conflict of interest: reveal your private interest in the matter to relevant parties. Often if we let others know what might be influencing our judgment, they can be on their guard and not caught unaware.

But sometimes it isn't enough to know that there is a particular private interest influencing a professional's judgment; the client, employer, etc. expects that the professional will stay out of such situations. So the second way to avoid conflicts of interests is to absent yourself from decision making or advice giving if you have a private interest. So in the case of potential self-dealing, the conscientious professional will say that she can't be involved in a situation where she is both bidding on a government contract and deciding as a public servant who is awarded the contract. She will either step aside and completely [and, I mean, completely] absent herself from determining who gets the contract or refrain from bidding on such contracts in the first place – which is probably the wisest course of action.

A final word

It may take some skill and good judgment to recognize that you are in a conflict of interest situation. This is because private and personal

interests can cloud a person's objectivity. So it may be a lot easier to recognize when others are in a conflict, than when you are. This suggests that it may be useful to talk to a trusted colleague or friend when you are in doubt.

But once you recognize that you are in or are headed into a conflict of interest situation, the ethical responses are straightforward: get out of the situation, or, if you can't, make known to all affected parties your private interest. These responses will preserve the trust essential to professional objectivity.

It is important to realize that avoiding conflicts of interest is only one part of being a conscientious professional. Another part is the difficult task of making choices when the ethics of the situation aren't clear or when there are good moral reasons for acting in diametrically opposing ways. This is typical in the case of whistle blowing, in which a duty of loyalty to a client or employer counsels confidentiality but this conflicts with a duty to warn the public of a serious harm or danger.

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**UNIVERSITY OF ARIZONA
RESEARCH AND SERVICE GROUP (RSSG)**

**HUMAN SUBJECT
PROTECTION PROGRAM**

≡Highlights≡

Research With Children

Careful attention must be paid to research that includes children as participants. The Belmont Report includes special provisions regarding **respect for persons** and providing the opportunity for children to choose to the extent that they are able to participate or not in research. This provision known as assent is an affirmative agreement of the child to participate and follows permission from the parent or legal guardian.

The Belmont Report also describes the issue related to **justice** and the use of children as research participants. According to the principal of justice, an order of preference in the selection of classes of subjects is advocated in that children should not bear the burdens of research unless absolutely necessary. In essence, the inclusion of children in research should be one where their participation is necessary to answer the scientific question being investigated. Additionally, justice addresses how participants are selected and that selection avoid the

injustice that arises from exclusion based on social, racial, sexual, and cultural biases.

In research with children, the Belmont Report addresses the risks associated with participation. The risks must be reasonable in relation to anticipated benefits, if any to participants as well as the importance of the knowledge that may reasonably be expected to result. The explanation given in the FDA E11 guidance document states that research with children should consider the age and development of the participants and the possibility of risk to physical and cognitive growth and development along with possible effects on skeletal, behavioral, cognitive, sexual, and immune maturation and development.

Additional safeguards are required to protect the rights and welfare of children involved in research. These special protections can be found in Subpart D of 45 CFR 46 and 21 CFR 50 and apply to all participants who have not attained the legal age under the applicable law of the jurisdiction in which the research will be conducted. For example, the regulations encourage the protection of children by allowing the conduct of research only if it falls into one of the following three conditions:

- Research presenting “no greater than minimal risk to children”.
- Research involving an intervention or procedure presenting more than minimal risk to children that offers the “prospect of direct benefit” or may “contribute to the...well-being” of the child.
- Research involving an intervention or procedure that presents only a “minor increase over minimal risk,” yet does not offer any “prospect of direct benefit” or “contributes to the well-being” of the child.

If the Institutional Review Board (IRB) cannot approve the research using one or more of these three categories, it must either not approve the research or refer it to the Secretary of the DHHS and /or the FDA Commissioner.

Although research that includes children as participants requires extra care and precautions, when done correctly it can provide important information to further the understanding, prevention, or alleviation of conditions affecting the health and welfare of children.

*Nelson, R. M.. (2005). Research Involving Children. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 366-372). Sudbury, MA: Jones and Bartlett.

University of Arizona – Animal Care Quality Care for Research Animals



eSirius is Coming!



University of Arizona - Animal Care
Quality Care for Research Animals

University Animal Care (UAC) is in the beginning stages of implementing an online research information management software package called **eSirius** which encompasses the submission, review, and approval of protocol applications and amendments, animal requisitions, account management, invoicing, and census management in a secure environment. The current software (Sirius) used by University Animal Care is an older product and unfortunately is no longer supported by the software company (NTM). Even though the current software has worked well in the past, UAC Business Services is concerned about future issues occurring that could possibly jeopardize the business operations of Animal Care. A good comparison to make for this change in software programs is the move from DOS to Windows based applications pre-2K. Just as DOS was no longer supported, Sirius as the older desktop server based program is also being replaced by a much more powerful and useful package. Another reason **eSirius** is being implemented at this time is to proactively anticipate the rise in animal populations, protocols, compliance reporting, animal requisitions, breeding colony cage cards and invoices in the near future with the opening of the Bio-5 research facility.

eSirius will be used by Principal Investigators and their staff members to submit protocols and/or animal requisitions, or to access invoices and account management tools in eSirius via a password protected homepage reducing paper usage, processing time and increasing efficiency. **eSirius** will also be used by the IACUC office staff and IACUC members for protocol management, facility inspections and compliance; by the UAC Directors office for AAALAC, USDA and OLAW reporting and compliance; by UAC Husbandry Purchasing and Bar Code staff for animal ordering, breeding colony support and animal census; by UAC Business Support staff for invoicing and account management; and by UAC Management staff for facility management.

eSirius implementation is expected to take several months and will include process testing and training phases prior to going “live.” Updates will be provided to the research community as new phases in the implementation process are entered.

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News from HIPAA.....

Feds Explain Provider ID Plans

The Centers for Medicare and Medicaid Services (CMS) has published a six-page tutorial on the national provider identifier.

Covered entities under HIPAA must use only the national identifier in HIPAA standard transactions by May 23, 2007. Small health plans as defined in HIPAA have an additional year to comply. Providers can apply for their identifier at the following web site: <https://nppes.cms.hhs.gov>.

The tutorial includes a previously announced transition plan for migrating to the identifier. Beginning January 3, 2006, and for the next nine months, Medicare will accept claims with a national provider identifier, but a legacy Medicare identifier also must be on the claim.

Once assigned, a provider's national identifier will not change regardless of job or location changes. Other tips in the tutorial include:

- Know the schedule of software vendors and insurance companies to be ready to accept the national identifier. Providers should submit transactions with the national identifier only when an insurer has indicated it is ready.
- Providers must share their national identifier with any entity that needs it to identify the provider in a standard transaction.
- Review state laws to determine if there are conflicts or supplements to the national provider identifier. Some states may require the identifier to be used on paper claims.

The Centers for Medicare and Medicaid Services is developing a mechanism to permit the bulk processing of national provider applications. This will enable an organization – with provider approval – to send multiple applications within a single electronic file.

Further, the centers expects to publish a notice in the coming months to explain its policy for disseminating data from the National Plan and Provider Enumeration System, which will manage the assignment of national provider and health plan identifiers.

You may find the text of the tutorial at the following web address: cms.hhs.gov/medlearn.



Good Laboratory Practices (GLP)

The Society of Quality Assurance will hold its annual meeting in Phoenix, Arizona April 23-27 2006. This is a great opportunity for training by SQA professionals.

Sunday, 23 April 2006

- ❖ Basic Training: Good Laboratory Practices - full day
- ❖ Basic Good Clinical Practices - full day
- ❖ Introduction to the Principles of Computer Validation for QA Professionals - full day
- ❖ Biotechnology: Methodology and Auditing - full day

Monday, 24 April 2006

- ❖ Advanced Training: Good Laboratory Practices - full day
- ❖ Advanced Good Clinical Practices - full day
- ❖ Advanced Concepts in Computer Validation - full day
- ❖ GLP and GCP Comparison: Auditing Animal Health Studies - full day

For more information contact Marilyn Marshall at marshalm@u.arizona.edu or 621-1469 or online at... <http://www.sqa.org/am2006/forms/SQA.AM06.Promo.RegBroch.24jan06.pdf>

Marilyn Marshall is also available for training of lab personnel in "Good Laboratory Practices" GLP and data validation.

Upcoming Conferences/Workshops

Teaching Research Ethics – A Workshop at Indiana University

Thirteenth Annual Workshop, May 10-13, 2006

The thirteenth annual Teaching Research Ethics Workshop will be held at Indiana University from May 10-13, 2006. Session topics include an overview of ethical theory, trainee and authorship issues, conflicts of interest, using human subjects in clinical and non-clinical research, and responsible data management. Information and registration are available at: <http://poynter.indiana.edu/tre>.

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*The P.R.I.E. newsletter is researched
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Words of Wisdom:

*“Somewhere, something incredible is
waiting to be known.”*

~ Carl Sagan