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5 Questions: Magnus on the role of research ethics consultations

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In the past decade, a growing number of academic medical centers have begun offering research ethics consultation services, in which bioethics experts help scientists address the ethical and societal implications of their laboratory and clinical experiments. For instance, an investigator may want advice on the social and cultural ramifications of conducting genetic research among an indigenous population. But the role of these consults isn't always well-understood. Many researchers believe that Institutional Review Boards, which must approve any research involving human subjects, will address these kinds of ethical questions. However, there are some areas of research — such as those involving animal subjects or broad social risk — that fall outside of the regulatory purview of IRBs. The consultation services can help fill this gap, in addition to giving scientists a sounding board for exploring ethical questions early in their research-design process.

David Magnus, PhD, director of the Stanford Center for Biomedical Ethicsand the Thomas A. Raffin Professor in Medicine and Biomedical Ethics, is the senior author of a commentary published in the Jan. 25 issue of *Science Translational Medicine* that describes how the research consults can serve as a complement to IRBs. He and his co-authors — associate center director Mildred Cho, PhD, and research assistant Molly Havard — outline 11 "triggers" for these types of consultations. Magnus spoke with Susan Ipaktchian, a writer in the medical school's communications office, about the growth of the consults at Stanford's bioethics center, which was among the first to begin offering them and has one of the most active services in the country.

Q: Investigators for clinical trials have multiple demands on their time, so why should they seek a research ethics consultation when they believe they'll face similar questions from the IRB?

Magnus: One of the biggest misconceptions we face is the belief that there is no difference between a research ethics consultation service and IRB oversight. The truth is that investigators face many challenging issues that are not typically addressed by IRBs. The IRB depends upon investigators to be part of the research protection system by engaging in best practices and generally being aware of ethical issues that are not addressed by the IRB. For example, the IRB may be neutral about an investigator's plans regarding how to return "incidental findings" in research, such as when a DNA sample from a person enrolled in a genetics study shows that the participant has a medical condition unrelated to the study. But some guidance about best practices has emerged, and the research consult service can make specific recommendations about what to consider putting in the consent forms and which results should be returned. These are the types of issues that a research ethics consultation can help address and manage. In addition, through early involvement in research, we can work collaboratively with investigators and biostatistics consultants on improving research design.

Q: What do you see as the three main benefits of a research ethics consultation?

Magnus: It can improve the research design process by helping investigators anticipate future pitfalls that may hinder their research. It can help foster collaborative relationships between investigators and consultants that can lead to novel research opportunities for both. It can provide a non-threatening and non-regulatory forum for a wider,

interdisciplinary perspective on investigators' research.

Q: What kind of growth have you seen in the number of ethics consultations at Stanford, and are investigators coming to you earlier in the research process?

Magnus: The numbers have been steadily rising as more investigators see that we are here to provide support — and that we can be helpful. When the consult service first launched we had very few consults, perhaps one every other month. Now we have around two per month, and we hope to be at one consult per week by the end of the year.

Q: What are some of the issues that should trigger an ethics consultation?

Magnus: We provide a list of 11 "triggers" where investigators should at least consider whether we might be helpful. They include clinical trials in controversial frontier areas (such as stem cell trials); early phase, first-in-human pediatric trials; and innovative treatment. Others include issues that arise in tissue and DNA banking (surveys indicate that a majority of those involved in research protection feel that special policies in this area are needed); interpreting minimal-risk standards in pediatric research; research on indigenous peoples and certain ethnic groups; assistance in understanding community engagement in research; research in less-developed countries; dual-use research (e.g., research that can have implications for bioterrorism); and research that raises concerns about broad social acceptability. Our early experience highlighted the importance of returning research results and incidental findings as a key concern.

Q: Your commentary notes that when Stanford first implemented the research ethics consultations, almost half involved the handling of incidental findings. Is this still the most common reason that researchers come to your team?

Magnus: It certainly remains an important issue and a component of many consults, but looking back at the data from the past year, the diversity of topics has broadened. We have seen a growth in consults as part of the Stanford medical center's new policy governing innovative treatment and a growing number of consults around stem cell trials. Talking to colleagues from other institutions also highlights that there is significant institutional variation. For instance, a consult service that began life in a school of public health tended to have a lot of consults regarding research in less-developed countries. As a community of bioethicists, we are working together to try to share best practices and information on our programs.

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