Minutes*

Senate Research Committee
Monday, February 10, 2003
1:15 - 3:00
238A Morrill Hall

Present: Gary Balas (chair), Melissa Anderson, Gerry Baldridge, Kathleen Conklin, Robin Dittman, Sabine Fritz, Steve Gantt, David Hamilton, Sharon Neet, James Orf, Mark Paller, Charles Spetland, Barbara VanDrasek

Absent: Victor Bloomfield, James Cotter, Sharon Danes, Yev Garif, Lawrence Jacobs, Paul Johnson, Katherine Klink, Phillip Larsen, James Luby, Scott McConnell, Ted Powell, Virginia Seybold, Thomas Schumacher, Mehul Vora

Guests: Barbara Shiels (Office of the General Counsel); Richard Sommerstad (Patents and Technology Marketing); Edward Wink (Sponsored Projects Administration), Winnifred Schumi (Oversight Analysis and Reporting)

Other: none

[In these minutes: (1) announcements; (2) composition of the committee; (3) HIPAA policies; (4) research-to-products event]

1. Announcements

Professor Balas convened the meeting at 1:30 and turned to Dr. Hamilton for announcements.

Dr. Hamilton noted that the draft survey concerning the IRB had been distributed to Committee members; he asked that they comment quickly so that his office and the Faculty Consultative Committee can send out the survey.

Dr. Hamilton also said the Committee would be interested to know that the federal budget is "all fouled up" and that there may be a continuing resolution from Congress that would fund the '03 budget at the same level as in '02. More will be known at the end of the month. This is not good news; for one thing, the proposed doubling of the NIH budget may not be accomplished.

2. Committee Composition

Professor Balas next noted that the Student Senate Consultative Committee has proposed adding two students to the Committee, in light of the addition of several faculty and two P&A positions last year. Would adding two students make the Committee too large, he asked?

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Committee members deliberated briefly about the proposal and concluded it had no objection to the proposal. Dr. Hamilton noted that only two of the three student seats on the Committee are now filled--and those two students come from the same department. Since the goal of representation is breadth of disciplines, having two students from the same department is not a good idea.

3. HIPAA Policies

At Professor Balas's request, Dr. Hamilton now turned the attention of Committee members to the Health Insurance Portability and Accountability Act (HIPAA) policy and procedures for research. He recalled that he brought the Regents' policy to the Committee for consultation; that policy needs administrative policies and procedures to implement it. He said he would like to have the Committee's views on the policy and procedures--but he cautioned that these have been prepared in response to legal requirements and the University must adopt them so it has a regulated way to deal with health information issues.

Ms. Shiels, from the General Counsel's office, explained that the policy provides that the University will comply with HIPAA and state law. Whenever someone at the University uses Protected Health Information (PHI) for research, they will do one of five things (the language is directly from the policy):

> Health information will be used or disclosed for research purposes only if one of the following conditions is met: (1) the individuals who are the subject of the protected health information provide appropriate Authorization for the use or disclosure; (2) the Institutional Review Board ("IRB") has approved a waiver of the need to obtain Authorization from the individual(s); (3) the IRB has approved an alteration of the individual Authorization requirement and the use or disclosure is in accordance with the approved alteration (4) the information is part of a limited data set and the researcher has signed a data use agreement; (5) the information is de-identified data. Uses and disclosures for research must be in accordance with any waiver, alteration, data use agreement or authorization applicable to the research.

Is this very different from what is done now, Professor Conklin asked? It is not, Ms. Shiels said, but there are more layers and more technical regulations. Anyone using human subjects must protect their confidentiality, something that is already embedded in IRB reviews.

The IRB is the primary body that reviews proposals, Professor Balas noted; it is already busy. Will this lead to a lot more business for the IRB? It will, Ms. Shiels said, and it has received additional funds and has hired an individual to work on HIPAA issues. The IRB forms will be amended to add a question about access to PHI (either obtaining or looking at health records); if so, the researcher will have to fill out an appendix on how he or she will deal with HIPAA regulations and policy.

Ms. Shiels explained how the IRB process would work and said they are trying to make it as efficient as possible for researchers. Will there be a need to expand the IRB panels, Professor Balas asked? Ms. Shiels said she hoped not; Dr. Hamilton, however, said the IRB does need more people to serve on panels. How does one get the word out that the IRB work is important and valuable, Professor Balas asked? That is a big problem, Dr. Hamilton replied, and not just at Minnesota. Getting people to serve on the IRB is not easy because there are no incentives, a problem his office is trying to address.

There will be a coordinated review of proposals rather than two separate reviews by the IRB, Ms. Shiels said. As the IRB looks at informed consent, risks, etc., it will also review any waiver or alteration requested under HIPAA. Will there be a separate document, Professor Orf asked? That is the direction they are going, Ms. Shiels said; there is no way to get the HIPAA authorization to fewer than two pages and they worried it would get lost if simply incorporated in the informed consent forms--or that informed consent and concern about risks could get lost in the HIPAA requirements. Ms. Shiels also explained that for any proposal with more than minimum risk to subjects, there would have to be full committee review.

How frequently is this expected to occur, Professor Orf asked? Minnesota has its own law on health records, Ms. Shiels said, and it is very restrictive. Without the Minnesota law, the waiver option under HIPAA would probably be exercised quite a bit, but the Minnesota law will restrict the use of the waiver. This is not insignificant, she said; anyone who reviews large numbers of records would normally seek a waiver. There is a coalition of health care providers seeking to have the Minnesota law amended; if it is not, some researchers at Minnesota will be at a disadvantage with respect to colleagues elsewhere in the country.

One of the procedures that comes with the policy is "Creating and Disclosing a Limited Data Set," which describes how a researcher can use individual health records if personal information is removed before the agency that holds the data releases it to the researcher. The holder of the data is responsible for removing the data but the researcher must still be careful because it could be possible to link records to individuals. The hospital or clinic is to remove the data and have a signed agreement with the researcher accepting the restrictions and barring attempts to identify individuals. The researcher must give criteria to the holder of the data so they know what records to provide, Professor Orf asked? That is correct, Ms. Shiels said. She said they did not expect the limited data set option to be used very often because it is difficult to tell how cooperative organizations that hold the data will be--or how useful the data would be. This provision is a compromise with the federal government.

Another procedure, "De-identification of data," will probably produce data that are rarely useful to a researcher. She also affirmed that the University provides data sets to researchers and is required to remove identification from the records. Ms. Shiels, responding to a question about who at the University would be responsible for removing identifying information, said she did not believe there could be one central office; whichever department or unit holds the data would be responsible for removing identifiers before releasing them. That does not provide a lot of oversight to the process, Dr. Hamilton observed; Ms. Shiels said that down the road the University will have to review how it is doing. The law does not speak to reviewing performance; at this point the University is focusing on trying to get the necessary mechanisms in place to comply with the law.

What if a researcher needs the identifier information, Professor Balas asked? The researcher may either obtain individual authorization from the research subjects for use of the data or may petition the IRB for a waiver. The researcher must also report when the data are disclosed for other research purposes:

"Researchers . . . must account for disclosures made for purposes other than the original research purpose for which they obtained the PHI. Accountings are required for:

1. PHI disclosed to another researcher who has obtained a IRB waiver or alteration of the individual authorization requirements;
2. PHI disclosed to another researcher for an activity preparatory to research;
3. PHI disclosed to another researcher as allowed for research using individual health information of decedents; and
4. Disclosures made as required by law."

In terms of required agreements for release of data, (1) there will be a model agreement for the University when it provides a limited data set to researchers, (2) when the University researcher is receiving data, who signs may depend on the agency releasing the data; some may accept the signature of the researcher while others, worried about HIPAA violations, may want a University signature as well. They have not determined yet who would sign for the University, Ms. Shiels said.

Ms. Shiels noted that research using health records of deceased individuals requires a "mini-level review" because such data are not protected and can be used without IRB approval.

The ramifications of this policy and procedures, and the consequences of error, may lead to a lot of lawyers being involved, Professor Orf commented. Ms. Shiels said that everyone with access to PHI will be required to go through training. The IRB will have mechanisms in place to evaluate requests for data. But it is true, she agreed, that the stakes are higher under HIPAA because it establishes both criminal and civil penalties for violations. The University is taking HIPAA very seriously and is making an extensive effort to comply, but obviously compliance will not be perfect. The federal government has indicated that initially it will focus on egregious abusers (e.g., those who sell PHI) and will take into account good-faith efforts by institutions.

What about students who do survey research, Professor Anderson asked? That would depend on what information they are collecting, Ms. Shiels said, but she surmised that in most cases they will not be obtaining PHI. If an individual doing survey research has access to PHI, however, the research would be covered by HIPAA. Health information in other places (e.g., student records, employment records used only for employment purposes) is not covered by HIPAA but it would fall under the usual IRB procedures.

Committee members made several suggestions about how to improve the documents, including more hypertext links, explaining acronyms sooner, and creating a glossary of terms. Professor Balas observed that if people's eyes glaze over reading this material it will not serve its intended purpose. Ms. Shiels also reported that the IRB is preparing a more user-friendly set of HIPAA materials. And understanding of the policy and procedures cannot separated from the training, Dr. Hamilton pointed out; all of the elements of compliance will be discussed in training.

Professor Orf asked about obtaining individual authorization: Is the researcher responsible for knowing that the person who signs the authorization can do so? How will that be implemented? Can a designated helper obtain the signatures or must the researcher do it? Who is responsible for obtaining informed consent under HIPAA, Ms. Shiels responded? The law does not say; practically speaking, presumably a researcher would obtain the needed HIPAA waiver and informed consent at the same time so that subjects would not be approached twice about use of data. Typically, she said, it would probably be the researcher who obtains the consent. That is not required by the law but is likely the most practical way to proceed.

It was agreed that Committee members would send to Ms. Shiels (shiel001@umn.edu), no later than February 17, any comments they may have on the documents. Professor Balas thanked Mr. Janssen and Ms. Shiels for joining the meeting.

4. Research to Product Event

Professor Balas next welcomed Richard Sommerstad from Patents and Technology Marketing to describe a "Research to Products" event that will be held during Founders' Week, on February 27th. The event was planned because of a wide variation in the audiences interested in University research. Those invited include public officials (a number of legislators will be attending), faculty, collaborators with the University (e.g., foundations, councils), business leaders, and venture capitalists. Many are unaware of the University's contributions so it seems wise to have a recurring session that connects the various communities with what the University is doing in terms of research that leads to products. For example, few realize the Honeycrisp apple came from the University, that it has developed two varieties of grape for wine-making, or that much tofu is made from soybeans developed at the University.

There will be about 120 faculty, 19 legislators, the mayors of both Minneapolis and St. Paul as well as mayors from around the state, 113 business leaders, and about 150 investors who have indicated they plan to attend at least one of the events scheduled for the day. Future events will likely be held at a different time of the year so that the University's plants can be included.

Mr. Sommerstad reported that the media have been invited; one television station intends to do some short spots about start-up companies from the University in conjunction with the event.

Professor Balas thanked Mr. Sommerstad and adjourned the meeting at 3:00.

-- Gary Engstrand