

Minutes\*

**Senate Research Committee  
Monday, September 30, 2002  
1:15 - 3:00  
238A Morrill Hall**

- Present: Gary Balas (chair), Melissa Anderson, Gerry Baldrige, Victor Bloomfield, Kathleen Conklin, Sharon Danes, Robin Dittman, Sabine Fritz, David Hamilton, Paul Johnson, Katherine Klink, Phillip Larsen, James Luby, Scott McConnell, Sharon Neet, James Orf, Mark Paller, Virginia Seybold, Thomas Schumacher, Barbara VanDrasek
- Absent: James Cotter, Kris Davidson, Lawrence Jacobs, Wendy Pradt Lougee
- Guests: Assistant Vice President and Associate Dean Esam El-Fakahany (Office of the Vice President for Research); Senior Vice President Frank Cerra; Edward Wink, Sheryl Goldberg (Sponsored Projects Administration), Winnifred Schumi (Oversight Analysis and Reporting)
- Other: none

[In these minutes: (1) post doc office (support for, and support for post docs that it would provide); (2) research secrecy (structure for handling requests for exceptions to the Regents' policy); (3) bioterrorism, University research, facility security, foreign nationals, regulations, and related issues]

Professor Balas convened the meeting at 1:15 and noted there were three items on the agenda: a new post-doc office, revisiting the research secrecy proposal, and discussion of bioterrorism research. He turned first to Interim Dean Bloomfield.

**1. Post-Doc Office**

Dean Bloomfield said there is a national movement, strongly supported by the Graduate School, to take greater cognizance of the fact the University has a lot of post docs (nearly 900), to recognize that they perform important functions in research and mentoring graduate students, and that they often fall between the cracks when it comes to where they exist in the institution. They are not students anymore and they are not regular employees in the sense of civil service or P&A (although those employed as research associates on individual faculty grants are employees). People who come with their own fellowships are not employees and have only a very tenuous connection to the University, although the Graduate School has tried to remedy that situation by getting them access to the graduate student health plan. It seems that there are a number of concerns that post docs have or might have, being so dependent on the good will of their research mentor, and needing the kind of services that the University provides graduate students or new faculty.

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As a result of the foregoing concerns, the Graduate School proposed to start a postdoctoral office. They want to do as well by these valuable people as they can. At the same time, they recognize that graduate students are not getting some of the services as completely as they would like; for example, college career service offices often concentrate more on undergraduate placement and advising, although they are not closed to graduate students. Another part of the initiative, thus, is working with college offices to see if those services can be extended to graduate students and post docs.

Dean Bloomfield said that Associate Dean El-Fakahany has been in charge of the enterprise, trying to get it started and organized, and turned to him for additional explanation. Dr. El-Fakahany said their purpose in presenting the idea to the Committee today is to provide it with some idea of what they have in mind; they are discussing it with various groups around the University to get reactions.

Why post docs and graduate students, who are already taught by their mentors and in the classroom? Dr. El-Fakahany said that in a day of a very competitive job market, the University is not providing its graduate students, and particularly its post docs, with the tools to be competitive and to be able to apply at top-five institutions. The University is not preparing them for alternate careers after they finish their training. In the case of graduate students, many programs are providing such supports, but in the case of post docs the relationship is primarily with the mentor and whether more than research experience is provided varies with the mentor. Post docs are a very valuable population for the University; whenever a new one comes to his lab, he or she comes with new ideas and technology. They mentor graduate students in part by serving as good examples. The better the University prepares its post docs to get a job in the future, the better post docs the University will be able to recruit.

The main function of the office will be to help the post docs while they are here, ensure that they are being employed under fair conditions, being served well, and to help prepare them for the next step, providing them the tools for applying for a job and being competitive. Since these tools are commonly needed by both post docs and graduate students, he and Dean Bloomfield decided to develop both types of programs in parallel in order to avoid duplication.

Mr. Baldrige said that in Genomics and Cell Biology they have had discussions about the post docs and the University distinction between post docs and research associates and whether they can write grants. That seems to be a very confusing point in various departments; will these issues be addressed? Dr. El-Fakahany said they will be and agreed that there is confusion about the title and what a person is qualified to do. The goal includes clarifying titles, he said.

To a certain extent that clarification occurred with Human Resources last year, Dean Bloomfield said, although the results were not well-disseminated. They wanted to disentangle the post doctoral associate--the appointment on a faculty member's grant--from post doctoral fellow--the appointment if one of a faculty member's students gets a scholarship. Those are distinct job classifications. But if one stays more than three years, one should move on to a more regular position; that more regular position is Research Associate, a P&A class employee with access to the retirement plan and all the benefits that post docs now do not receive. In the College of Biological Sciences, research associates can apply for grants; post docs cannot, except for post-doctoral fellowships. That is not true in the Medical School.

There is a non-P&A research associate class, Mr. Baldrige said, so it gets very messy with all of those distinctions. In addition, a lot of post docs stay longer than three years because finding a job is difficult so it is necessary to take into account those individuals as well.

One important distinction between the two is that post doc implies a training period whereas research associate does not; the latter is an employee, Dr. VanDrasek said. The University will want to retain that distinction, she said. If the philosophy really is that a post doc is a transitional training program, if one is on a research grant as a post doc, one should do that for no more than three years (and that is what the rules provide), Dean Bloomfield said; after that one should move on to a more permanent job. At that point the faculty mentor must decide if the person is worth paying a somewhat higher salary and giving full benefits--and at that point the person is 35 years old and ought to be getting them.

Mr. Baldrige said that he is a research associate who has been at the University since 1989. There are a large number of people who have been here a long time; he urged that the new office also offer help to such individuals. There is a lot of confusion among department administrators about what the rules are for research associates, such as whether they are eligible to initiate grant applications on their own. It would help to have a central office to which people could go for a clear interpretation of the rules. The rules seem to vary by college, Dean Bloomfield said. There is a Regents' policy on PI eligibility; it allows for local control (it allows departmental faculty to vote to allow research associates to be PIs, or not; some have chosen to do so and some have not). From that point of view, it means negotiation within the unit. That is also to be one of the functions of the office, to provide career counseling to both graduate students and post docs, Dr. El-Fakahany added, and to search job opportunities for both groups.

Professor Balas referred to the handout that Drs. Bloomfield and El-Fakahany provided about the proposed office. The level of support is to be a quarter-time associate dean, a half-time office coordinator, and a quarter-time undergraduate assistant. It seems, however, that the expectations of what the office will provide go beyond what the proposed staff could provide. An office coordinator could not provide career counseling, for example. How would all these tasks be performed with such limited personnel? And where would the funds come from? The idea is to leverage on activities already occurring in the colleges, Dr. El-Fakahany said. They have great programs in career development; there are also central administrative counseling services available. But these services are usually advertised mainly to undergraduates and professional students; post docs and graduate students are not aware of their existence. They plan to get together with these offices to determine how feasible it would be for them to expand their services to graduate students and post docs. The personnel being proposed would coordinate these efforts and serve as a central point for information to come together so there would be a sort of one-stop. Dean Bloomfield agreed, saying that the office needed to take advantage of what is already going on. In addition, one would hope that with small additional expenditures activities already open to graduate students (e.g., Preparing Future Faculty) could be opened to post docs.

Do they plan to address the salary issues, Professor Balas asked? With graduate students there is a range; is that something that will be taken up by the post doc office as well? Will there be rules such as setting a minimum and maximum salary for a post doc? One of the functions of the office will be to ensure that there are fair employment conditions, Dr. El-Fakahany said, as hiring accord to the NIH scale. On the web there is a salary policy that sets a certain minimum for post docs. Dean Bloomfield said that one awkward point is that the NIH scale is going up fairly dramatically while other parts of the University that may have post docs whose support is not from NIH cannot meet the higher NIH minimum with existing resources. They have had a discussion about HR setting a minimum salary at the NIH minimum and decided not to because there are too many departments that cannot afford it. But they do want to be advocates for post doc welfare and be sure they receive a living wage, he said. More important, Dr. El-Fakahany said, is the nature of the contract between the mentor and the post doc; usually it is very vague.

It does not say if it is renewable, the terms for renewal, how the post doc will be evaluated, what the expectations will be, and so. They want to be sure that these kinds of things become clearer.

Professor McConnell asked if they had given any thought to having an advisory panel of post docs who might advise the associate dean directing the post doc office. Dean Bloomfield said they would certainly want to do something like that. It seems that there is no central office now that has responsibility for post docs, Professor McConnell then said, except for this one; is there a concern that the office might have no teeth? If it decided to set minimum salary standards, how might that be realized? They could not do that without Human Resources involvement, Dean Bloomfield said, and the intention is that the office would partner with HR. Part of the office charge entails addressing working conditions and salaries, which is the responsibility of HR. The career development and mentoring activities are things the Graduate School has done for graduate students.

One of the challenges is giving the topic enough weight within the institution that it will make a difference, Professor McConnell said. Articulating in this plan what the communication responsibilities are, having the board of advisors, knowing the relationship between the associate dean and the Dean of the Graduate School, whether there are faculty governance committees the office will connect to, will help to ensure the office does not get lost in the shuffle.

Dr. Hamilton agreed that post docs have fallen through the cracks and he applauded the work on a new office. He said he had a sense that the next group falling through the cracks could be the research associates; would they be welcomed in this office? Dean Bloomfield said they are much more regular employees who work through Human Resources but there is no reason they should not have access to career development activities (e.g., responsible conduct of research training) as much as graduate students or post docs. Cost or capacity might be an issue but they would need to be worked out. His personal bias, Dr. Bloomfield said, is the University ought to be the best employer it can be for all classes of employees because it then attracts the best employees who work best for the University.

Dr. VanDrasek said she understood that the effort was just getting started and needed to develop over time, but hoped that in the longer term there could be some culture change with PIs and some outreach so that post docs are not seen as cheap labor. Career services will also need some help understanding what it means to assist people who are not undergraduates; they all have undergraduates as their focus right now. One of the important issues for the college-based career services offices, Dean Bloomfield said, is that in many cases the same kind of job might go to the Academic Health Center, to COAFES, to Biological Sciences, to IT; jobs that would employ biological scientists or mathematicians or psychologists in biology-related jobs, for example, are all over the place. One thing they would like to do is have a sharing of job postings and the kinds of companies in the Twin Cities and the region. A dean trying for a spousal hire, for instance, might need to know what kinds of jobs there are in the community, but often that kind of information is not known. Sharing it would a good side benefit of this office, if the college offices can be persuaded to share it.

Does he see contact with post docs more through a web site or personal interactions, Professor Balas asked? It is both, Dr. El-Fakahany said. The web site will be very comprehensive in terms of identifying University programs and who to contact about questions. When it comes to career development, however, there would be a lot of interaction between the post doc and the faculty of the advisory panel that Professor McConnell mentioned.

Research associates enjoy faculty benefits, Mr. Baldrige said; the weakest part of a post doc appointment is poor health coverage and no retirement benefits. The discussion of salary is too narrow. Even faculty do not receive retirement benefits for the first two years they are here, Dean Bloomfield pointed out. What they are saying is that if the University honors its existing employment policy, people should not be in a post doc appointment for more than three years. Where did that policy come from, one Committee member asked? There were major discussions last year; it went through faculty governance and is now embedded in Human Resources job descriptions of those classes, Dean Bloomfield replied. There was discussion of employment conditions for research associates.

Post docs seem to vary significantly across the University, Professor Balas said. In his college they do not stay beyond three years, but in some they may. There will be a large number of issues to deal with, some of which may be college-specific; it is not clear how such a small staff will be able to handle them. They will have to set priorities, Dr. El-Fakahany said, and start with what is applicable to the general population. For instance, any post doc in any college would want to learn how to write good proposals or how to interview well for a position. For college-specific items, they will let the college offer the services to their post docs. The effort can be improved down the road; money is the issue, Dr. El-Fakahany said, for any faculty development effort. They are going to start cheap and show success; it is to be hoped the success will pay off.

The difficult part in this is that this is an educational process, Professor Seybold said. There was a major effort in the last year to make benefits more consistent for post doctoral fellows and associates but that information has not gotten to the colleges or the staff in departmental offices that make appointments. She still struggles getting trainees appointed appropriately because the appointment goes through whatever department the person is in--and they sometimes appoint them in the wrong place so they don't receive health benefits. To the extent there will be a post doc office that creates a focus on information and dissemination of the information will be helpful, she said.

Dean Bloomfield said he appreciated the suggestions from the Committee but took away the sense that people believed establishing the office would be a positive step and that they should go forward with it. Professor Balas agreed and expressed thanks that the proposal was brought to the Committee.

## **2. Research Secrecy**

Professor Balas reported that the Faculty Consultative Committee endorsed the proposed course of action for dealing with research secrecy and requests for exceptions from the Regents' policy that this Committee had recommended at its last meeting. The major part of the proposal called for creating a standing subcommittee to review requests for exceptions and to develop criteria by which to judge such requests. The only issue to be brought back is how the subcommittee should be appointed.

The Faculty Consultative Committee recommended that the standing subcommittee be appointed in the normal way that all subcommittees are appointed, which is by the Committee on Committees. Professor Balas said he did not know that was the process and wanted to bring the option back to the Committee for its approval. The Senate Research Committee can nominate individuals--such nominations would probably be encouraged--and the goal would be to have people serve on the subcommittee for longer than they may serve on the Research Committee.

Dr. Hamilton suggested that this Committee define clearly the qualifications for serving on the subcommittee. The Committee on Committees has not always been able to find the right people for the right groups; it would not be helpful if the subcommittee were to be populated by people who should not be on it. Is there a rule that says the Committee on Committees has to make the appointments, Dr. VanDrasek asked? There is not, Professor Balas said; that is why he brought the issue back, because he was not comfortable with that as the selection method. It has just been the practice in the past.

There were two adjectives: one is "standing" and one is "sub," Professor McConnell said. He agreed that having people who do this for a period is important, as is selecting individuals who have some background. But to the extent that the group is not representative of nor part of this group is to ask for trouble; it adds another layer of review and evaluation, a different set of judges, and potentially a different set of criteria by which to judge requests. If it is a standing subcommittee with different people on it, it would be very important there be some ongoing agreement between this Committee and the subcommittee about the standards it will use. Otherwise the subcommittee will slow the process down.

Professor Balas said his fear was that this simply would be adding one more layer. It would make a decision, then this Committee would discuss why it made that decision--and possibly overrule what it decided. And whatever this Committee recommends could be ignored anyway, Dr. Paller said, because the recommendation must still go to the Senate. And then there would be three voices from the governance system going to the President, Professor Balas said. That is why he did not want to go forward without feedback from this Committee.

Professor Orf said he agreed with the reservation; the "subcommittee" implies that the members are members of this Committee. He said he would see nothing wrong with people going off this Committee but remaining on the subcommittee; one of the qualifications for the subcommittee should be that one is or has been a member of this Committee.

Professor Balas recalled that that the FCC had pointed out that members of other subcommittees (e.g., Retirement, Tenure) do not have to be members of the parent Faculty Affairs Committee but the chair of the subcommittee has to be a member. Those are different from what they are discussing here, Professor Orf said, in terms of the kind of expertise that is needed for the very reason there will be a subcommittee. Professor Balas said he agreed. The general policy discussions will take place in this group, Dr. VanDrasek pointed out, so subcommittee members need to be a part of this Committee.

Would people like him or Mr. Bohnhorst be able to serve on the subcommittee, Mr. Wink asked? Dr. Hamilton said the subcommittee would clearly need someone from the General Counsel's office as advisor, if nothing else. Professor McConnell said he would encourage such membership to be advisory or ex officio; when this Committee receives the issues, those people must provide the information. To include them in the voting and recommendations would cloud the process. Dr. Hamilton agreed.

Mr. Baldrige said he served on the Committee on Committees last year and said it struggled to find people willing to serve. There were a limited number of people on the committee, which restricted the range of contacts with people who might be willing to serve and who would be competent to serve. That is something to think about in terms of having the Committee on Committees perform this function.

Professor Balas said he would bring the matter back to the Faculty Consultative Committee and indicate that this Committee endorsed the initial report on the assumption that the subcommittee would be

made up of all or a majority of members from this Committee. And that this Committee would be involved in developing guidelines.

### **3. Bioterrorism Research**

Professor Balas now welcomed Senior Vice President Cerra to the meeting to talk about bioterrorism research. Dr. Cerra said he would begin with some comments and then take questions from Committee members.

First, what is the University doing to get itself prepared? This is a good time to bring up the issue because the task force on University safety and security appointed by former President Yudof had its first meeting yesterday under the new Vice President for University Services, Kathleen O'Brien (with the transition, its work was delayed, but it is now meeting). What will come from the task force into the consultative process is a procedural document on how the University responds to safety and security issues.

The document defines four levels of threats. Level 1 is the routine daily stuff, handled by usual University services. Level 2 is exemplified by the mishap in Chemical Engineering, where it is localized and contained response. The fourth level is a full-blown disaster, whatever it might be. The policy defines an "officer of the day" because one thing missing in current University policy was identification of a senior University official who has the power of the President to make things happen during times of need. The person will have a beeper 24 hours per day, 7 days per week, 365 days per year; the person will be the Vice President for University Services. Dr. Cerra will be the back-up; beyond that are the other vice presidents. The primary mode of communication will be through the 911 telephone system: if something happens, one dials 911; the police have a response system so that if the event rises above level 1, the "officer of the day" gets into the picture. The appropriate University people are then contacted and meet to follow established protocols.

Eventually the document will come to the Committee. It does not disrupt anything currently in place; there is a research response team that would stay in place. The document defines the process of communication and decision-making and makes available an individual who can muster University resources with the authority of the President and get the appropriate response from the various emergency response communities. Some elements of the report need to be worked out, such as responsibilities, evacuation of buildings, and so on.

This Committee has been involved in the "select substance" review. The process in place to review all research labs on all campuses for "select substances" started with definitions (which get larger, not smaller, as the federal government decides what should be on the list). Most of the items on the list are chemical and biological agents that are felt to have potential for use as weapons of mass destruction. The government defines various levels of chemical and biological agents, with increasing destructive potential. The range is from the most benign to the highest-potential agents, such as anthrax, ebola, and smallpox. Each level of agent requires a corresponding facility that is designed to permit the safe handling of the agent by a knowledgeable user, with a Level 4 facility required for the most noxious agents. The University has three Level 3 facilities for dealing with those substances; there is no Level 4 facility in the state. The inventory is moving along; there is a policy being developed on how "select substances" will be managed. Eventually the Committee will need to consult on that as well. The model

is fairly-well described by the USA PATRIOT Act and is analogous to the management of narcotic substances.

There is a third policy about inter-institutional transfer of "select agents"; those protocols are being worked out. The list of "select agents" and where they are is considered privileged and exists only on a small number of computers not on the University's backbone. The inventory is done through one department at the University; federal law requires there be an individual designated at the institution to be charge of this. The President has designated the Director of Environmental Health and Safety; he is responsible for maintaining the file and for the reports that are to be submitted. The University has met the first deadline. There is not uniformity of opinion in Washington about who has jurisdiction over what, so responsibility appears to be divided between Agriculture, Health and Human Services, and others. The University is in compliance and its policies are being prepared. Further down the road, these efforts have to be put in the office of the University Compliance Officer, Thomas Schumacher.

The third item he wished to report on, Dr. Cerra said, is what the University is doing in research in bioterrorism. Does the University have faculty doing research on "select substances"? Yes. Is it substantive? Depends on your definition of substantive; there are several individuals in laboratories using agents on the "select substance" list. Some are bacterial toxins, some are chemical. From the inventory the University has done, Dr. Cerra said he is comfortable with where they are and who has them and that people are trained as they need to be. Right now the security is reasonable, although it may warrant closer examination in a couple of areas. At present, however, there appear not to be any problems.

Do the faculty plan to do more research in this area? Dr. Cerra said he did not know, but generally if the NIH puts a lot of money into an area, it is likely University faculty will compete for it. That is probably good and the faculty should probably be encouraged. This is public domain research, not defense contracts or such. Are there areas where the University currently has strength? Yes, zoonotic diseases (diseases that pass from animals to humans) and food safety (which crosses a number of colleges). Most faculty are not going after "select agent" research at this time; a major area of funding in the future will apparently be food safety and animal-borne diseases, two of the University's strengths.

It is in these two areas that there is the greatest "potential for weapons of mass destruction," in the phrase of the Department of Defense. Biological agents are emphasized rather than chemical agents because the former are easier to work with and have much greater lethality: a small drop of smallpox can infect a lot of people. In aerosol form, the impact is even worse. That is why the government is emphasizing biological agents.

There are other provisions of the PATRIOT Act that have do with foreign nationals and reporting requirements and institutional reporting requirements; the University is not fully able to respond to these requirements yet. A federal assurance is already required concerning individuals in labs (that they are not from certain countries, and so on). As the University did the "select substance" inventories it also did the other forms; generally the process has gone well.

So anyone operating a Level 3 facility must certify something about foreign national graduate students, Professor Balas asked? Anyone in any facility, Dr. Cerra said. Even with Class 1 substances there are reporting requirements and assurances.



Dean Bloomfield asked whether, if there are more faculty seeking more money to work in these areas, the University will need more P3 biologic containment facilities to handle the substances? So there will be a real institutional investment required? There will be, Dr. Cerra said, and that is what the survey being developed is designed to do--to assess their interest level in the second round of grants that will be coming. Part of what can be requested is a facility; one question is whether this is the time for the University to seek the resources to build a good P3 facility; the ones it has now are old, although they function and pass codes and are not ideal. They also do not have the capacity to do the kind of thing the faculty might want to do if they really get into these areas of research.

Dean Bloomfield also asked about restrictions on foreign nationals. In IT there is some familiarity with restrictions on research from the Department of Defense. The NIH culture is very open; there are a lot of biological scientists at the University whose minds will have to change if the research heads down that road. It is not a matter of "if," Dr. Hamilton said. They have tried to say this in meetings throughout the spring, including with this Committee. The restrictions are coming and must be dealt with. But there is an educational component, Dr. Cerra said; the education and training piece is being development and must be part and parcel of the effort. Everyone's preference is that it be part of the regular education and training for research, but at this point no one even understands all the regulations yet.

Dr. Bloomfield noted that the Graduate School every year puts on an all-University forum on some research issue. He said they thought about focusing on research secrecy next year, but the forum could be framed in a way to address some of the questions being raised at this meeting. Dr. Cerra thought that would be a good idea and said he would include the HIPPA (Health Information Privacy and Portability Act--see below) regulations, with which the University must also be involved.

To what extent is dosing or amount of "select substance" considered in the taxonomy, Professor Seybold asked? Does there need to be a discussion about minimum thresholds? The bottle of arsenic on the laboratory shelf could do more damage than the micrograms of counter-toxin that must be kept under lock and key. Dr. Cerra said that Dr. Hamilton had raised this question at a meeting earlier in the day, about a substance that is a "select substance" but is used commonly for column extractions in the laboratory. Right now there are no thresholds in the federal law, he said; if one has the smallest quantity that can be measured, it has to be reported. He said he wished it were not that way but that is the law. They were talking about this at an earlier meeting; many people who have these have very small quantities that have limited use. How is the University going to respond and interpret the regulations? He said he did not know the answer but said there are constraints on federal reporting requirements that the University must comply with. The political process would have to be used to get modification of the regulations.

Given what they tried to do, they did a decent job, Dr. Cerra said of the federal regulations. But they have quirks, such that even if one has a tiny pinch of a substance, it must still be reported.

Dr. Larsen said that on the St. Paul campus they have been "hardening" their facilities in the sense of providing opportunities for training in order to create cultural changes. There is also technology that can be introduced, such as motion detectors and the like. Is there any thought about including these latter expenses in a capital request to the legislature in order to obtain help with the costs? Yes, no, and maybe, Dr. Cerra responded. The University did have a request in to the last session for security equipment, alarm equipment, and so on; none of it was funded. In the budgeting process, the University

put about \$2.2 million (\$1.6 million recurring) into the Chief of Police (now chief security officer) budget. They developed a risk-based priority system for funding so certain facilities received high priority in funding for security; most of them have been completed. This year, as the budget process unfolds, the needs must get into that process so the needs are at least known. In the same way, there are personnel and database needs related to education and training efforts. Then the University needs to make fundamental decisions about how to fund them and then identify what can be recouped through indirect costs, what are capital expenses, what might the state fund, and so on. This will all happen within the next five or six months. In his view, there will be capital expenses that will come under HEAPR funding.

On the research side, the USDA has also identified bio-security as a priority, Dr. Larsen recalled. USDA is responsible for a certain list of agents, Dr. Cerra said, and most of them have been covered.

How expensive is a Level 3 facility, if the University decided it needed one, Professor Balas inquired? It seems not to have a very focused view on how to fund research and large capital expenses. If the University has to allocate money to construct something like this, would it take away funds from other activities? Is this a direction the University wants to go, with restrictions on foreign nationals and restricted access to these facilities? Dr. Cerra pointed out that the University does not exert authority over the direction the faculty want to pursue in research; it tries to support as best it can what they want to do. His guess, he said, is that faculty across the campus--agriculture, biological sciences, and so on--will want to move in this direction. If viewed that way, and one thinks of it as an investment, and looks at the funding sources for capital expenses being made available through federal government programs, it is not as bad as it seems in the sense of taking resources from one place and putting them somewhere else. That is all in process; the law is not "cold" on these points. The regulatory/procedural pieces that derive from the law are only now being written (how the RFPs will work, what the funding for capital expenses will be, how much one can get, etc.)

In terms of cost, it is premature to think about, Dr. Cerra said. Level 3 facilities are not too bad but it depends on how much space one wants to make available. Would there be one facility in St. Paul and one in Minneapolis? Or one for everybody? Will there be a partnership with the State of Minnesota? These questions have not been answered. The conversation about a P4 facility is entirely different. Such a facility would raise University policy issues that would have to be discussed. But he has not heard anyone saying the University should be doing P4 research. The nearest such facility to the University is in Winnipeg. The cost comes in air handling, access restrictions, disposables, and so on. And a P4 facility must be a separate building with a self-contained ventilation and disposal system, Dr. Paller pointed out. It should also be a building that cannot be blown up, Dr. Cerra added. Preliminary estimates for a P3 facility for plants involved tens of millions of dollars, not a few million, Dr. Larsen said. That is right, Dr. Cerra said.

Letters of intent are due in November, Professor Balas recalled Dr. Cerra saying earlier. That means that by the end of the year the University could be applying for money for a P3 facility if the faculty choose to go in that direction. It would be in the letter of intent if the funding agency likes the research scope the faculty have laid out; there would be planning grant money and then formal grant submission. They are looking at big grants, he added, not small one.

Professor McConnell commented on an element of University policy. It has restrictions on accepting grants and contracts that are secret but it does not have restrictions on accepting grants and

contracts that limit the participation of foreign nationals. It comes in under export control regulations, Mr. Wink said; if the information is export-controlled, then it cannot be divulged to foreign nationals, which is where the research secrecy policy comes into play. So then it may come to the education effort, Professor McConnell said: if faculty are considering doing research that has restrictions on the participation of graduate students, it is incumbent on somebody--who?--to let those faculty know that they may run into the research secrecy policy. This is relatively unpredictable; people may decide to invest a lot of time and effort into something the University will decide it cannot take.

There has already been work on one grant on bioterrorism, Mr. Wink reported, that his office thought it would not be possible for the University to accept. In the very early planning stages they talked to the attorney and got everything cleared up. Dr. Cerra said there are other implications as well. In general Professor McConnell's point is part of the education and training function; the University will have to be sure there are modules that deal with these issues and that people have access to the courses.

The University will have to do more than that, Dr. Hamilton opined. The Committee will be talking about the effect of the Responsible Conduct of Research training, but this is different in kind from compliance on financial issues. This is life or death if not done properly. It will have to be dealt with differently. It may also be an entirely different group of researchers, unlike those in engineering who have dealt with the Department of Defense, Professor Balas observed.

There are other pieces beyond education, Dr. Cerra said. Another Mr. Wink alluded to: as applications in these areas go forward, there will have to be questions about the University's capacity to deal with the substances and whether another level of training will be required for the people using them. The PATRIOT Act has not dealt with the latter; the University has not dealt with the former, but the routing form may have to be altered to address it. That is an educational issue as well, Dr. Hamilton said, and departments will have to look at it very carefully.

Professor McConnell wondered if there might be some appropriate anticipation that could be prompted from the administration--and the knowledgeable administrators are at this meeting. He suggested there is probably an identifiable group of faculty who would pursue these kinds of research opportunities. It also sounds like these new opportunities are "ripe with risk"--they will involve investigators who are more used to NIH standards and not used to the restrictions that have arisen in NSF and Department of Defense funding. The University in general knows where these faculty are; Dr. Cerra agreed. This might be a good time for the Graduate School, the Vice President for Research, and the Senior Vice President for the Health Sciences to let those faculty know that there are restrictions and to get them thinking before they get to the language-writing part of the process in Sponsored Projects Administration. Dr. Cerra said the point was a good one and the University should do it.

Dr. Bloomfield said there is a partial analogy with radioisotope training, which biologists know they have to do and--and they know the penalty is considerable if they do it wrong. What is not analogous is that training is fairly perfunctory; most of it is common sense, which it may not be with biological agents. In addition, however, there are the secrecy issues (export, foreign nationals, and so on): Biologists are familiar with some of them but not all.

If the University finds more and more applications and interest in the area, Dr. Cerra said, it may have to revisit the safety and emergency response systems. It may not be prepared to handle a mishap--

and a mishap will occur. That all gets back to whether the University has the appropriate planning in place.

Mr. Baldrige asked about the inventory process. Will the University rely on self-certified inventories of pathogens and compounds that fall under the purview of the law or will there be an independent regulatory inspection of laboratories that use them? The thinking now, likely to end up in the draft policy that will come to the Committee, was set with the base line of mandatory inspections. Every freezer and every cupboard has been gone through and a lot of stuff has been discarded. For anyone who wanted to keep something, the substance has been inventoried. In the Vice President for Research office, there is a yearly voluntary electronic disclosure that will somehow be linked to the database; that needs to be connected to what goes through Sponsored Projects Administration. The new restrictions on inter-university transferred must also all be logged and codified. One unanswered question: Will there be an inspections program on a sample basis (e.g., take 15% of the labs at random and inspect them)? They do this in the clinical research compliance arena and it works well; people have gotten used to it. Should something like that be done here as well? The inclination appears to be that the University should, but it will depend on having the right educational systems in place so people know what they are supposed to do.

The goal in all of this is to ensure the University complies while keeping the regulatory burden as low as possible, Dr. Cerra said. And not need 10 keys to get into one's lab, Professor Seybold added.

There was discussion about the protocols and education and about forms to file indicating substances in one's lab. The database related to these substances will need to be extraordinarily secure; time to fill out the required annual forms will be quite limited and the information deposited in the database. There needs to be a web site that has information on it, Dr. Cerra said, so that faculty can learn, for example, if what they want to use is a "select substance."

Professor Balas asked about foreign nationals and required reporting: Is it only for Level 1 substances? Mr. Schumacher said the law is not finished; the INS was instructed to develop a system and it has not yet finished doing so. Dr. Hamilton said there is an interesting sidebar to this: INS has not finished, but there is also a deadline for reporting, and they intend to stick to the deadline whether or not the system for reporting is finished. There is a host of things that faculty will be asked to certify about their students (e.g., is honest, etc.); before the University goes in those research directions it needs to evaluate the implications of these requirements. Mr. Schumacher said the questions he has seen have been related to status: are they currently enrolled, are they still in the program, and so on. In areas of export control, Mr. Wink added, the University cannot exchange information with foreign nationals--and students would be the largest group in that category.

Would information about Level 3 agents be included, Professor Balas asked? They could be, Dr. Cerra. The ones on the current list are not because none are proprietary but who knows about the future, he said. He said he fully expects more substances to be added to the list. In terms of language in grants and contracts, Mr. Wink said, if there is an issue with export control, it is the responsibility of the granting agency to tell the University. If the University is dealing with a company on information that is export controlled, the company has the responsibility to tell the University. If the University gets into that arena, however, it will probably not be doing the research anyway, he said.

Dr. Cerra inquired if the Committee had wrestled with the HIPPA regulations regarding research. Professor Balas said it has not. He said he is leading the charge for the University, which will include a presentation to the Executive Committee in October and to the Board of Regents in November. Part of that deals specifically with the requirements as they apply to research; not all of these issues are crystal clear, either.

HIPPA stands for the Health Information, Portability, and Accountability Act, which does two things, Dr. Cerra explained. One, it makes it more efficient to transfer health information where it needs to be transferred. Two, it protects certain information for the consumer so the information cannot move without the consumer's permission. It is a complex set of circumstances. If one is dealing with Protected Health Information (PHI), there is a long series of regulations about who has access to the information, where it can be transferred to, and so on. For example, a physician in a clinic with access to patient information can use the information without patient consent for billing purposes or to communicate with another physician. To send it elsewhere or do anything else with it requires written and informed consent of the patient. It has substantial implications for electronic medical records and (as frequently occurs in the private sector) for use of information by the pharmaceutical industry for marketing endeavors. It affects groups one might not think about, such as student teachers and social workers, all of whom deal with names, social security numbers, medical and psychiatric diagnoses, all of which are protected.

What the University has been doing for six months, with a project director, is coordinating its efforts, Fairview's efforts, University of Minnesota Physicians' efforts, the practice plans, the health professional schools, and the Provost's office so that the non-AHC units that encounter these kinds of information. There are two task forces: one dealing with education--what is the content people need to know about, what education and training is needed, how can this be done on line, how are competencies for use of computer technology defined, and how does the University educate and train? All of the Academic Health Center's 350-400 affiliation agreements will eventually have a paragraph that says "our students are educated and trained in the risk of using electronic information, how basic electronic information system work, are guaranteed certain competencies, and they have received training in Protected Health Information."

There is another piece that tries to answer questions about what HIPPA means to the individual, in life, what they need to know about it, how one gets educated and trained. The goal is to get this all done electronically. They are now defining the model and workplan; implementation will begin this fall and will be University-wide. There is a separate module on research that is partly definitional (is student teaching research?) The other end of the spectrum is Public Health, which uses large volumes of claims data; how well is it sanitized? If it is under a research contract, does it need to be sanitized?

There is a lot to think about as the University builds a compliance system, Dr. Cerra said, with the policies and procedures, the education and training, and the oversight systems. Last year they did an estimate of what the University needed in order to implement the system; part of the controversy was whether it supports both a Macintosh and PC system. The University has a budget of \$600,000 for this year; University Physicians has spent \$2 million, Fairview has spent \$3 million. They estimate a total cost of about \$9 - 10 million that cannot be recouped anywhere--it is simply required by the HIPPA law. During the budget process the University will work out what it believes necessary to support these activities during 2003-04.

Professor Balas said this has significant implications for research and said the Committee would take it up. He thanked Dr. Cerra for coming and adjourned the meeting at 3:00.

-- Gary Engstrand

University of Minnesota