Minutes*

Senate Research Committee
Monday, April 29, 2013
2:00 - 4:00
238A Morrill Hall

Present: Linda Bearinger (chair), Arlene Carney, Jerry Cohen, Susan Everson-Rose, Maria Gini, Goran Hellekant, Brian Herman, Brian Johnston, Seung-Ho Joo, Frances Lawrenz, Hinh Ly, Suzanne Paulson, Federico Ponce de Leon, LaDora Thompson, Kathleen Thomas, Thomas Vaughan, Karen Williams, Lynn Zentner

Absent: Benjamin Fuller, Greg Haugstad, Tucker LeBien, Richard Leppert, Kyla Wahlstrom

Guests: Professor Michael Kyba (incoming committee member); Professor Michael Oakes (Institutional Review Board), Debra Dykhuis, Patrice Webster (Human Subjects Protection Program)

Other: Emily Lawrence (Office of the President)

[In these minutes: (1) community-engaged research; (2) changes in federal research guidance; (3) federal faculty workload survey]

1. Community-Engaged Research

Professor Bearinger welcomed Professor Oakes and Msses. Dykhuis and Webster to the meeting to discuss, first, IRB review of community-engaged research.

Professor Oakes noted that he is vice chair of the Institutional Review Board (IRB) and chair of the social sciences IRB. He reported that Associate Vice President Furco (Public Engagement) has been working with the IRB for a long time to help clarify issues and concerns surrounding IRB requirements for the conduct of community-engaged research. The core idea of community-engaged research is that a researcher is working closely with members of the community and collaborates fully with them; it is important to understand that the community members are not only the subjects of research, they are also researchers themselves, helping to guide the research. Community-engaged research has run into barriers and the line between researcher and subject is blurred. Who is the researcher and who is the PI? How is it possible to get IRB approval when the research proposal has not been fully developed?

Professor Oakes met with Vice Provost Furco a few months ago to discuss how the IRB could help the University's community-engaged researchers. No policy changes resulted. Instead, Professor Oakes tried to dispel myths and clarify the IRB position about how community-engaged scholars can do their work with IRB support. The result was an FAQ that reflects what has been done at the University for at least the last ten years. [The FAQ is appended to these minutes.]

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate, the Administration, or the Board of Regents.

Professor Bearinger noted that Associate Vice President Furco had a list of issues related to public engagement and some of them related to research. What are the challenges? Professor Oakes said that he believes Dr. Furco and the community-engaged researchers are on board with the IRB and each other. There may be some lingering myths about community-engaged research (such as that one must have research fully planned before one can talk to citizens in the community). Other institutions' IRBs have blocked community-engaged work—but doing so it way out of bounds for an IRB and that has not happened at the University. He concluded that things are fine and that there simply is need to get the word out to dispel myths.

Ms. Dykhuis reported that her office is in the process of redefining IRB applications and there are places to indicate community-engaged/participatory research so that they can be sure it receives the right kind of review. Professor Oakes said that they look at community-engaged research differently and reiterated the point that they take a different view of who the research subjects are and how projects roll out (rather than requiring a fully-written protocol, as is required, for example, for drug trials). The IRB is happy to help with community-engaged research; a researcher can obtain provisional approval, begin the work, and then obtain approval later as the research moves along. These approvals can be obtained electronically.

Professor Bearinger recommended that there be links from the IRB, Office of the Vice President for Research, and the Public Engagement websites to the FAQs so that they are readily accessible.

Professor Oakes turned to the second issue at hand, a scientific review process for research studies that have not gone through NIH or a similar agency for scientific peer review. The IRB has been working to develop a protocol for review of such studies. The IRB wants a separate scientific review of medical studies that pose greater than minimal risks to subjects that have not otherwise been peer-reviewed--because it is difficult for the IRB to both spend time and bring to a review the expertise needed to determine if a proposed study has scientific validity AND evaluate the protection of human subjects.

The related issue is non-medical (i.e., social and behavioral science) studies that have not gone through peer review, Professor Oakes said. Most of the non-medical studies do not have more-than-minimal risk to human subjects, although a few may. He said he wished to be clear and on the record that the IRB has no desire for a separate peer-review process for non-medical research; the IRB is capable of dealing with those proposals and has been doing so for many years.

With respect to medical studies, Professor Oakes stressed that the proposed scientific review would not amount to scientific censuring or infringement on academic freedom; while that is an interesting question, what the review will address is whether the questions posed are scientifically reasonable and whether the associated methods are capable of answering such questions. It is more important that there be peer review when proposed research will exceed minimal risks to human subjects and lives are at stake, which is why the IRB wants extra peer review in those cases.

Professor Oakes stressed that the IRB does not believe they need external scientific review on the non-medical side, although if non-medical research involves more than minimal risk to human subjects, the IRB will occasionally seek out internal or external consultants to help to weigh the risks and benefits, as usual.

Professor Bearinger commented that there will be three "cut points" or variables to consider, social versus medical sciences, whether there has been peer review (such as through NIH), and the level of risk. When all three converge in one study (medical, no peer review, and more-than-minimal risk), the IRB will develop a plan on how to review the proposal. Professor Oakes agreed and said the IRB would involve the Office of the Vice President for Research, the Vice President for the Health Sciences, and the leadership in regulatory affairs in developing a plan for review of these proposals.

Professor Bearinger recalled that at the end of last year, a subgroup of this Committee was going to draft a plan for review of research proposals that had not had peer review; the Committee was later told that it did not need to do so because the IRB and others were developing a plan. So nothing happened following the draft of a proposed plan developed by a subcommittee of this Committee. Professor Oakes said that the IRB is close to having an operational plan; with the leadership changes, they are just making sure that everyone is on the same page. They have a standard operating procedure; there are funding issues, but once everything is resolved, the plan can be brought to this Committee for review and can then be implemented. In the meantime, the IRB continues to review and approve medical studies with more-than-minimal risk, but it is not an efficient process and they want to improve it. Nothing will change for social sciences review.

Ms. Dykhuis said that her office has required assessment of medical studies with more-than-minimal risk since 2007, and the reviews have taken place inside the Academic Health Center (in the Clinical and Translational Science Institute, or CTSI). Professor Oakes' effort, she said, is to provide review outside of CTSI, which does not want to provide that service function any longer. Her office is providing the replacement function and they have a draft plan. There will be a peer-review system for medical studies with more than minimal risk to human subjects before a proposal reaches the IRB. She confirmed, in response to a question from Professor Vaughan, that proposals that have gone through NIH or similar review will not be subject to the internal review process before they go to the IRB. Professor Oakes agreed; there will be brief "outsourcing" of review for non-peer-reviewed proposals before they reach the IRB in order that the process does not get bogged down. Federal law requires review; they are simply trying to make the process more efficient.

Professor Cohen said that when the subgroup of this Committee was discussing a proposal to deal with research that hadn't gone through peer review, one idea they dealt with was dealing with the public perception of propriety. When the department reviewing proposed research is the department that is proposing the research, there is only local review. He said he was also bothered by the distinction between medical and non-medical research; there is much biological research conducted outside the Academic Health Center. The goal is a "clean" review for academic excellence, a review separated from the researcher who will do the work. He said he did not believe the proposal being made would achieve that goal.

Professor Oakes said that this is their informal goal with internal peer review so that the science can be seen as credible. He agreed that there is a fine line between reasonable science and not permitting research to be conducted that involves academic freedom and censorship. The idea they have proposed is that people on campus can conduct a review quickly and efficiently without censoring proposals.

Professor Bearinger said, apropos of Professor Cohen's point, that there could be a conflict of interest in the internal review if it is conducted in the same unit. Professor Oakes said that current practice is that the review is done within the same unit, which is why they are changing it.

Professor Thomas said that under the current practice, there are multiple ways to get a review, through CTSI as well as through other avenues. She agreed with the problem of public perception and conflict of interest questions if a department reviews its own research proposal. Will there be a new committee that everyone uses so that there will no longer be multiple options?

The new committee they are proposing would the committee of last resort for someone who has no other committee to use (such as NIH, NSF, or internal), Professor Oakes said. A departmental committee would have to have scholars from outside the department or the review would not be accepted. Anyone proposing research could set up a committee, but that would be a lot less efficient, so the idea is to have a new committee composed of a group of scholars who could do the work well and who are not conflicted.

Professor Bearinger asked Professor Oakes if he had any idea of the number of requests that would come to the new committee. Professor Oakes thought it would not be large because most studies are funded and speculated that it might average about two proposals per month.

Professor Bearinger thanked Professor Oakes and Msses. Dykhuis and Webster for their report.

2. Changes in Federal Research Guidance

Professor Bearinger now asked Associate Vice President Webb to review for the Committee proposed changes in federal research guidance (A-81).

Ms. Webb distributed copies of a set of slides and reported that the federal government has proposed a major change in the regulations that govern research grants, contracts, and cooperative agreements. The proposal is to eliminate the 8 different sets of regulations and replace them with a consolidated single set that would apply to federal and state governments, local government, tribes, hospitals, etc. The proposed consolidated regulations as they stand are 241 pages long; she said she would review a few of the changes and pointed out that individuals or the Committee can comment on the proposal at regulations.gov under Docket Number OMB-2013-0001by June 2, 3013. She is assembling the University's comments, and she noted that the University is part of the Council on Government Relations, composed of 180 institutions; the COGR response is 82 pages of comments. This is an intense process, she told the Committee.

The goals of the changes are to respond to comments received last year about regulatory improvements, to improve efficiency and transparency, to reduce waste, fraud, and abuse, and to achieve the best program outcomes while ensuring financial integrity, Ms. Webb said. The focus is on high-risk areas, analogous to risk tolerance analysis, and there is less focus on doing the accounting exactly right.

Ms. Webb highlighted items of interest to PIs at the University. She said there are a number of positive elements to the proposed changes but there are also items that are causing worry. She is part of a group of 6 university research officers who have been invited to meet with the deputy director of OMB to talk about the areas of concern and they hope to get some traction on the issues.

-- Funding opportunity announcements must be open for at least 30 days and follow a standard format. The University wants 90 days in order to get the information needed. Professor Bearinger said that 30

days was far too little time, particularly when more than one institution is involved in the research or it is community-partner research. It may be that there will be a compromise, Ms. Webb said. If the agency head determines that the research must be done quickly, then the open period could be 30 days; otherwise it would be longer. Professor Cohen said that there is no logical reason that scientists would want only 30 days; Professor Bearinger commented that she sometimes has the feeling that the people who write these regulations have no idea how unfeasible they are for PIs. That is the role that comments play, Ms. Webb said, so that they can understand the impact.

-- There are to be unique, government-wide numbers for each award, which would be an improvement for back-office operations.

-- Voluntary Committed Cost Sharing is not expected and is not to be used as a factor in the review of applications. This is a very positive change, Ms. Webb said, so when institutions choose to include cost-sharing, it will not make proposals more competitive.

-- Deviations from federally-negotiated F&A rates will only be allowed when variations are provided for in statute or regulation and when the agency head has approved a deviation; OMG must be notified of deviations. The rule today is that the government must use the negotiated F&A rate but the agencies don't follow the rule, Ms. Webb said, and universities have nowhere to go. The federal government should have an Ombuds process for times when agencies do not follow the rules. These new rules appear to be more refined. Ms. Webb said the impact of the proposed change is uncertain.

-- A new requirement to relate financial data to performance accomplishments whenever practicable (including unit cost data); agencies are to provide clear performance goals, indicators, and milestones expected. This may lead to new reporting burdens and financial accountability measures, Ms. Webb said, and is not a positive development. How much does it cost to train a graduate student? Or to produce a report? This applies a widget-manufacturing mentality to research.

-- Salaries of administrative and clerical staff would be allowable as a direct charge when individuals involved can be specifically identified with a project, are integral to the project, when such costs are not explicitly included in the budget (so must be forecast, and would mean rebudgeting), and the costs are not also covered in indirect costs (that is, already in the indirect cost pool). Professor Gini inquired how one would know if a cost were in the cost pool? Ms. Webb said that if a PI charges something as a direct cost, Sponsored Projects Administration will make sure it is not an indirect cost; the accounting system takes care of that. She also pointed out that this change could bring indirect administrative costs closer to the 26% cap, but the University is so far away from reaching it that it is not a worry.

-- Charges to federal awards may include developing and maintaining protocols (human, animal), managing substances/chemicals, managing and securing project-specific data, and so on. This is positive and makes things clear, Ms. Webb said.

-- In effort reporting, elimination of examples of acceptable systems allows room for other models, as does the possibility that reports can be integrated with a payroll system, and a "responsible person" may certify. These changes are not as good as they had hoped for, Ms. Webb said, but they may allow department administrators to certify. Professor Thomas commented that this would not change much; the hard part of the process is figuring out if effort has been allocated CORRECTLY.

-- Salary/effort reporting requires a consistent definition of a full-time workload in order to qualify for extra-service pay. It must apply to all employees in a given class (not just federally-funded employees) and the supplementation amount is commensurate with the base pay rate and amount of additional work performed. There is also a new obligation to review the budget quarterly. This is new and undesirable and will mean more work, Ms. Webb said.

-- Dependent care costs during travel that are the direct result of the individual's travel requirement for the federal award and are only temporary during the travel period are allowable. This is new and desirable, Ms. Webb said, but the institution must do the same across the board for all funds.

-- Computing devices that cost less than $5,000 will be allowable as supplies cost for devices that are essential and allocable, but not solely dedicated to the performance of the federal award. The regulations finally get rid of the term "typewriter," Ms. Webb noted, and acknowledge the use of devices other than a desktop computer—so one can charge part of the cost of a cell phone or iPad, etc., but must show that they were allocated for use to the award. Professor Bearinger said this allowance could affect the administrative part of the F&A rate; Ms. Webb agreed but reiterated her point that it is highly unlikely the University would reach a level that would dip below the 26% cap. Professor Ly asked if the language includes both hardware and software; Ms. Webb said that while the overall change is welcome, there is new language that they do not like because it would mean keeping track of a lot more software than is required now. They are asking that the language be reconsidered. So this is a double-edged sword, Professor Ly concluded. Ms. Webb agreed. Professor Bearinger said that the change shifts the costs from a college to a grant, but if the costs are capped, then the PI and team have to budget for more expenses within a capped amount of funds, i.e., it shifts greater burden to the PI faculty.

-- There are a variety of new provisions regarding subrecipients, including the obligation to honor the subrecipient's federally-negotiated F&A rate; those without an F&A rate are entitled to a 10% rate; federal agencies can impose their own documentation requirements to verify how a grantee determined that a transaction is a subaward versus a vendor, the audit threshold is raised to $750K from $500K, there are more prescriptive requirements on subrecipient monitoring, and primary recipients may be able to use federal audit management decisions. These changes have mixed results, Ms. Webb said, some positive, some negative. This is a major problem are in the new regulations and it may get worse.

Ms. Webb reported that a draft of the University's comments will be available May 13 and will be circulated to the Committee. She concluded that some of the changes are favorable but that they are by far the biggest changes she's seen in the field in her 29 years in it.

Professor Bearinger thanked Associate Vice President Webb for the presentation, who then moved on to the next topic.

3. Faculty Workload Survey, Cont'd

Ms. Webb recalled that last September she had provided the Committee with early results of the Faculty Workload Survey conducted by the Federal Demonstration Partnership; in February she provided revised data but did not finish; today she will do so.

The differences in time away from actual research in federally-funded projects (to perform administrative tasks) varies by field; in the physical sciences and math it is about 35% of the time, in

clinical science and medicine it is about 43%, in engineering and computer science it is also about 43%, in agricultural sciences it is about 49%, and in education and the humanities it is about 54% and 55%, respectively. When these data were presented to the Federal Demonstration Partnership, those from NSF broke into applause but those from the Department of Education did not. No department had administrative demands that took less than 35% of a researcher's time; some reached 60%, Ms. Webb summarized. She asked if Committee members were surprised by the data.

Ms. Webb reviewed the differences in percent time away from research by funding agency; NSF was the lowest of those included (about 35%); the Department of Education was the highest about 60%); NIH was at 40% and DHHS (non-NIH) was at about 55%.

Professor Bearinger said she brought the data to her colleagues, who rely primarily on NIH and the DHHS (non-NIH) for funding; they burst into tears and were not at all surprised. Professor Cohen said that NSF should be ashamed of itself at 35%. The Department of Energy is awful and should be nowhere near that level. Professor Vaughan asked if percent time equaled percent of the funding; Ms. Webb suggested that the two should be correlated.

Professor Bearinger said that she would like to convene PIs and bring them to Washington to help them understand the administrative burden that’s been added, particularly due to increased reporting requirements. Department of Education and Health Resources and Services Administration requirements are far more demanding than NIH, particularly in terms of expectations for progress reports and reporting on performance measures and. Professor Cohen said that some granting agencies can't tell if they are granting agencies or professional societies because they always want meetings. Professor Bearinger said they may want to showcase their research. Ms. Webb said that the public may not understand what they are getting from research funding, so they are trying to market what they are getting.

Ms. Webb turned to the factors that are associated with higher or lower levels of administrative responsibilities on grants. They include academic rank (non-faculty have greater), administrative role (deans and chancellors have the most administrative burden), type of project (there is a sharp jump in administrative time required for training or curricular development), amount of funding (more than $3 million in awards requires significantly more administrative work), principal field of research, funding agency (smaller ones require more administrative work), type of institution (smaller, non-doctoral institutions require more administrative work), and demographics (women, Hispanics, and African-Americans have higher administrative burdens). Professor Thomas asked, apropos of the last item, if that could be because they are in non-profit positions. Professor Bearinger thought that might be possible.

Ms. Webb provided some sample research workload opinion items (percentages are those who agreed, 2012):

Administrative workload associated with federally-funded research grants has increased in the last 5 or 6 years.
68%

The federally-mandated requirements for research accomplish their intended goals.
26%

The time spent meeting federal requirements for research provides benefit worth the cost.

21%

Because of research administrative workload, I am generally less willing to submit federal grant proposals than in the past.
26%

When I have questions about federal regulations related to research, obtaining answers is straightforward.
21%

Ms. Webb said she found it troubling that about PIs can't get answers to their questions about 20% of the time either locally or from the agencies. But all of the numbers are disturbing. Professor Thomas commented that it is not surprising that only 26% of the respondents said they were less willing to submit federal grant proposals—because without the grants, many would not have a job.

More complete results of the survey are available at http://sites.nationalacademies.org/PGA/fdp/PGA_081164

Professor Bearinger asked about data at the institutional level; her understanding was that they would not be available. Ms. Webb said the school-level data may be available if more than 50 people from an institution responded. Would that replace a survey by the University, Professor Bearinger asked? Ms. Webb said she was not sure. She does not know how many University of Minnesota people responded to the survey, although it was sent to about 1200 people here.

Professor Hellekant said that if only the FDP numbers were used, they would not provide the information needed from PIs at the University. He noted another survey that had come from Research Animal Resources and said it did not address details and seemed primarily intended to protect the unit rather than provide information needed. The FDP data will not address questions of displeasure with local entities and a University survey could provide information about the IRB, IACUC, and so on, to find out how to make it easier to do research.

Associate Vice President Lawrenz reported that the survey from Research Animal Resources was not from the University, it was from an external consulting group doing a review of the RAR system. She agreed that some of the questions on the survey were not particularly good. Professor Hellekant said that they probably used standard questions, but to get useful information, people must be able to comment on things that affect their own research.

Professor Bearinger said that the Committee members and the Committee should have a role in asking questions on the survey that the Office of the Vice President for Research is preparing. It is not clear that an external organization could understand the questions. Professor Cohen said the FDP is intended to look at federal burdens while a campus survey asks what it is doing to overcome those burdens; it is difficult to separate what the University is doing that creates a burdensome IRB versus the fact that IRBs are just burdensome. Professor Bearinger said she hoped the Committee could receive an update on results for the University in the fall.

Professor Bearinger thanked Associate Vice President Webb for her reports and adjourned the meeting at 4:05.

-- Gary Engstrand

University of Minnesota

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Human Subjects Protection and Community-Engaged Research
FAQs created from Public Engagement Council meeting with Michael Oakes on November 29, 2011

Federal regulations require that the subjects of research carried out by the university be informed of any risk associated with their participation in the research and that those risks be minimized to the greatest extent possible for the type of research being conducted. This is referred to as "human subjects protection." At universities, Institutional Review Boards (IRBs) are constituted to evaluate research proposals, work with researchers, and issue decisions to protect the subjects of research. At the University of Minnesota, the IRB, working collaboratively with the Human Research Protection Program in the Office of the Vice President for Research, provides oversight and ensures compliance with human subjects protection.

Community-engaged research can present challenges to researchers and those involved in human subjects protection. These challenges are threefold. First, by design, the involvement of community members occurs during the development the research questions through development of the study design throughout the research process. Therefore, it can be challenging to determine when IRB approval should be sought and when changes in protocols must be reported and approved. Second, community members are often involved in both the role of research collaborator and research subject, making it difficult to know when to ensure consent to participate in the research. And, third, for some research projects, it may become necessary to have community members (who are research subjects) identify other potential research participants. This “snowball sampling” approach can be problematic for ensuring that participants do not feel coerced into participating in the study.

The Public Engagement Council invited Professor Michael Oakes, co-chair of the Faculty/Staff Social 3 Committee of the IRB at the U to a meeting to discuss these challenges. The following are a set of frequently asked questions and answers resulting from that conversation. Additional information is available at the Human Research Protection Program website (http://www.research.umn.edu/subjects/) and by contacting its staff at 612-626-5654.

Question: Do projects that involve the community in either classroom- or research-based activities where information is collected from the public require human subjects review?

Yes, all projects in which human subjects are used as a source of information require a “human subjects review.” In many cases, the review will result in either an “exemption” from a full review or an “expedited” review. This occurs when the risks to the human subjects is extremely small. The purpose of the review then is to ensure that the proper steps are taken to inform the subjects of the nature of the research or class project, to ensure that they are aware of any risks, and to provide contact information to the subjects for any additional questions they might have.

Question: Is there need for a new set of guidelines for the IRB, given the nature of community engaged participatory research?

No. Since, the goal of human subjects protection is to be respectful of research subjects and to ensure that they are not harmed or coerced, community-based projects should use the same procedures and processes as all other research or classroom-based projects involving human subjects. At the University of Minnesota, the Human Subjects Protection Program would like to begin working with the instructor or researcher early on in the study development. This early involvement in study design and protocol development will help ensure that the process and approvals occur quicker and without surprises that could delay the project.

Question: Who is the subject in community-engaged research?

In this type of research, members of the community can be both researchers and subjects. They provide information about the content of the research question, but they may be also involved in framing the research question and identifying subjects and protocols for the research. This means that the line between subject and researcher becomes blurred. Therefore, it is important to ensure that community member participation in the research is entirely voluntary and that community partners do not feel coerced. There are many ways to mitigate any potential coercion (i.e., the participant is empowered and has the option of saying no at any point). As part of the IRB review process, University researchers will be required to demonstrate how potential subjects can "opt out" of participating. In general, the best way to develop these processes is in collaboration with the IRB office.

Question: Can researchers approach the community directly prior to human subjects review and approval?

Yes. In fact, initial conversations with community members are necessary to begin to shape the direction and/or scope of the research. These conversations would be considered as part of the early stages of preparing for the research. It is also during this early phase of the research that researchers should start having discussions with the IRB office about the project to ensure a smooth and successful IRB review process.

Question: What about instances where the research is not perfectly laid out from the beginning, but will be discovered and changed along the way?

The IRB process is designed so that changes can occur in the research protocols or processes. For example, a project could receive "provisional approval," for the research as it is laid out at the beginning. If parts of the project change or evolve over time, the researcher can then submit an application for change of protocol. Again, the best way of ensuring a smooth and successful IRB review process is to be in touch with the IRB office throughout the project – from the initial community conversations through changes in research questions, participant groups, or protocols.

Question: How do you demonstrate consent in an IRB application for engaged research?

The IRB is looking for a "consent process" first and foremost. The IRB requires involved participants to receive an information sheet with the names of the researchers, an explanation of what the participants will be expected to do and any risks associated with their involvement, and contact information for the

IRB office and University of Minnesota in case of questions or concerns. This information sheet must be tailored to the "target" audience or engaged population. It should be clear and written in language that is understandable by potential participants and not intimating. An intimidating or difficult to understand consent form or information sheet is "unacceptable" under the IRB framework.

Engaged research doesn't require a written consent form from involved participants. (In many cases, it is best to not require signatures, so that the study participants remain anonymous.) The regulations require participants provide "informed consent." Involved participants can provide verbal consent or provide consent by continuing to participate in the research. A signed, written consent form is not necessary for most community-engaged projects. What matters for engagement related research is that the subject/participant understands what s/he is committing to do.

Question: What is the IRB's position on "snowball sampling"?

Snowball sampling is a process by which a current participant provides the names of potential new participants in the study and the researcher then contacts those potential participants directly. This method of contacting new study participants through their social network is often necessary in community-based projects. The IRB does not prohibit "snowball sampling;" however, the IRB does frown upon it because of the possibility of participants feeling coerced into participation. A more acceptable approach is for the current participant to give the researcher's information to others they may know. If those potential participants then want to become involved in the research, they can contact the researchers directly. Staff of the IRB can assist researchers in modifying snowball sampling techniques to ensure that coercion and potential risks are mitigated.

Question: What is the IRB's position on researchers providing incentives to participants?

All researchers want high response rates, and some researchers have used drawings or raffles as a way to encourage participation. The IRB does not like drawings or raffles (e.g., "be in our study and have a chance to win an iPod"), since all participants are supposed to receive the same compensation for taking part in the study (i.e., the winner of the drawing receives greater compensation that the others who do not win).

Researchers should work with the IRB if they are interested in providing incentives for participation in a study. Some approaches are more acceptable and appropriate than others and can provide researchers with additional information important to the study (e.g., data on non-respondents and selection bias).

Question: Is there IRB training for researchers?

Everyone who does IRB regulated research is required to do some form of IRB research training. CITI online training is one mechanism of doing this. Students and faculty advisors need to get this training if they are going to be involved in research. The community members who are going to act as researchers also need to have this training. This is a bit more difficult in terms of getting them access to the training (because CITI access requires an x500 number). The IRB office can help facilitate this. A temporary x500 number can also be issued.

In some instances, a member of the IRB office will visit an entire group and provide an hour-long training. Whether or not engaged community members are considered to be participants or researchers is

a decision of the principal investigators. If they are considered researchers, they need to receive the training.

Question: What is the IRB process when students are participating in community-based work as a part of a service-learning course?

The best path is for the instructor to have a "class protocol approval." In this process, the instructor informs the IRB office of the nature and scope of the class activities and the full class receives a waiver or IRB approval (depending on the situation). The instructor then ensures that the students have appropriate human subjects training (CITI certification, for example) and that the approved protocols are followed. If students want to be involved beyond the scope of what has been approved for the class, the professor would need to contact the IRB office, and modify the original application or apply for a separate approval.

Question: If research is not going to be published, does it need IRB approval?

Whether the research is going to be published or not is irrelevant to whether the project needs IRB review and approval. What matters is whether the research is intended to be generalizable. If a study is designed to draw conclusions beyond the participants directly involved, then it is "regulated" by the IRB process. These generalizable conclusions can either be published or not.

In addition, there is a misconception that if research *is* going to be published, then it must have IRB approval. This statement is also not true. Many case studies are published and are not generalizable. These need not be IRB reviewed, since this is not regulated research. However, if a number of case studies are be combined in an attempt to draw some sort of generalizability, then that study would require IRB approval. There is a provision for getting approval for studies using existing data.

Question: What is your advice to researchers leading community-engaged research projects?

It is extremely important to engage with the Human Research Protection Program office and the Institutional Review Board early on in the research process and throughout the research. Not only can the staff and members of the IRB provide useful guidance on changes to federal regulations, but they can work with investigators to ensure compliance with federal regulations. Like many federal regulations, the human subjects protection requirements are constantly evolving, so working with these professionals can help investigators stay abreast with new process and practices. Secondly, these professionals can also assist investigators in thinking through the research study to ensure that current regulations are met.