FDP Research Compliance Committee

Monday, January 12, 2009

1:00 p.m. – 2:15 p.m.

For its second meeting, the Research Compliance Committee (RCC) had a guest speaker, Ivor Pritchard from the Office of Human Research Projections. Currently the Senior Advisor to the Director in the Office for Human Subjects Protections (OHRP), he recently left the position of Acting Director of OHRP. Earlier this day Dr. Pritchard delivered the Keynote Address entitled "Against Meetings: Education, Exemptions, and External IRBs," where he discussed possible demonstrations that FDP could pursue.

Possible Demonstration Number 1 - Using the Standards-Based Reform Model to Reduce the Number of Re-Tests/Review Meetings

Possible Demonstration Number 2 - Reducing IRB Member/Meeting Time Dedicated to Exemption Decisions

Possible Demonstration Number 3 - Reducing Duplication of Meeting Review Efforts

Seeking to address the faculty burden of compliance, the RCC used this opportunity to discuss with Dr. Pritchard in more detail possible initiatives to reduce the administrative burden related to obtaining Institutional Review Board (IRB) approvals and exemptions. The compliance issues discussed in the RCC meeting included:

Possible Demonstration Number 1 – Institutions broached the topic that perhaps existing training programs are too comprehensive, rather than being parsed out by offering a suite resources pertaining to particular IRB compliance issues. Dr. Pritchard indicated that OHRP does not have the resources to develop such a specialized training program and suggested that we enlist our schools of education. They know what standards-based education is and could help develop such a program.

Training Opportunities for Streamlining Reviews - Training should be provided to those who are preparing an application for an IRB review. Institutions would reap benefits of being more knowledgeable on the criteria for IRB approval so it gets approved more quickly and would reduce the redundancies typical of duplication of effort. An institutional representative asked whether OHRP could create an online tutorial to help prepare faculty in developing an application. Dr. Pritchard responded that they have something already operating with respect to IRB administrators, which is in addition to their general education events that are topically related. They devote most of their money to regional meetings where they identify all institutions that have an FWA and invite them for a 2-day meeting where participants are led them through the nuts and bolts of IRB administration. He suggests we think about developing a mechanistic training program for our investigators. The challenge will be to get the investigators' attention. Dr. Pritchard indicated that OHRP is working on developing on-line capability for training relevant to the regulatory requirements in various areas, but they have not done this specific one.

It was requested that perhaps OHRP could conduct special training for expedited/exemption reviews. Dr. Pritchard answered that this training is a regular part of their normal training.

Possible Demonstration Number 2 - IRB members generally are asked to do expedited review. He proposes that institutions consider hiring a full time person to do all expedited reviews. That individual could be made a member of the IRB so that s/he can do the expedited review also, and may attend the convened meetings. The idea is that this one person who focuses entirely on the expedited rules will possess the expertise to be most efficient in processing these reviews to identify minimal risk. Also, this gives the IRB office a consistent standard for defining and identifying minimal risk since it would be the same person making that determination each time.

FDP could test this and determine if it results in a faster review, fewer requests for changes and fewer complaints about inconsistent decisions.

A question was posed to determine whether the IRB Chair must sign the approval letter. Dr. Pritchard answered that if someone else does the review and makes the exemption decision, it makes sense to delegate that task. In expedited review, that person must be a member of the IRB to sign the approval letter, but this is not required for exemption decisions.

Matching Risk with Punishment - A representative indicated that universities seem to spend an enormous amount of time trying to decide what the decision should be and worry about the possible consequences, should the decision be wrong. It was suggested that OHRP consider separating out punishment by the level of risk involved, so that a university can measure the risk and implement that decision. Dr. Pritchard answered by stating that the OHRP approach to corrective action is to try to fix the problem, whatever it is, based on the nature of problem. Some problems are relatively simple but involve big risk, so the solution could be simple, whereas other problems with smaller risk may still involve more elaborate kind of fixing. They are interested in getting the regulatory requirements met. Further, they put determination letters up on the web for transparency because they want people to learn what OHRP does in response to discovery of regulatory noncompliance. If it is a little problem they ask for a little solution, if it is a big problem they are looking for a big solution.

Guidance Requested on Best Practices - Dr. Pritchard was asked if OHRP might be willing to put together a committee on best practices that would provide guidance that is articulated and documented by determination letters in areas such as exemptions and expedited reviews. Dr. Pritchard pointed out the downsides of OHRP doing this. First, they do not necessarily have the every day administrative experience regarding the cost of implementing alternative procedures, some which may be more complex to implement than others. OHRP has preferred to issue guidance and allow the universities to determine the best practice. Second, a guidance document along those lines might be interpreted as expressing requirements, and therefore we risk having more requirements imposed by our risk adverse attorneys. The better strategy seems to be for FDP to conceive of the ideas and send OHRP a letter to inform them of our plan. They will respond if it falls within OHRP's jurisdiction, suggest that we collect data on the perceived efficiencies realized, and suggest that we look at indicators about human subjects protections that would be relevant to the project. Then we would have a letter that says it's legally okay to do the proposed demonstration.

Possible Demonstration Sponsored by OHRP – A university representative asked whether OHRP would be willing to sponsor or be an FDP partner on a demonstration. Dr. Pritchard indicated that OHRP is willing to consider a letter of inquiry asking whether a proposed demonstration would be a regulatory problem. It would become more difficult where it was presumed that OHRP was endorsing a particular

demonstration. OHRP can not be in the position of supporting a research activity while also being responsible for oversight of the same research. Dr Pritchard suggested that RCC design a proposed demonstration, write to OHRP to determine whether there are any regulatory problems or objections to doing what we propose and then that, in effect, would give us clearance to proceed.

Advice on How to Accomplish Change Within Institutions – Dr. Pritchard acknowledged that it is complicated to effectuate change because it really depends on how each institution is set up and whether there is an incentive to make change on the part of the person in the position of power to make the change. Questions to consider include:

- Will the university get in trouble with the law/regulators;
- What will be the measureable outcomes, particularly with the faculty;
- How will FDP obtain good data on the impact of change.

Information will be needed on what the old versus new practices accomplishes. The new practices must be justified in terms of time, effort and cost, all of which must be significantly better, not just as good as old system if we seek broad participation.

Dr. Pritchard suggests RCC approach this by making the argument in the abstract and then identify 10 institutions willing to participate and 10 willing to stay in current mechanisms/strategies, and compare the data.

Other Ethical Considerations - For streamlining, there was a suggestion that OHRP change regulations to allow universities to avoid reviewing when it does not protect human subjects - regulations without benefits are unnecessary burdens. Dr. Pritchard suggests that we submit a request for guidance – how to interpret minimal risk. He pointed out that the NAS review document looks at considerations for minimal risk. The key will be to push the interpreters of minimal risk toward consensus. Also, remember that whether something is minimal risk is not the only ethical concern.

Additional Discussion Points – Dr. Pritchard stated that OHRP is always interested in receiving feedback on the guidance documents issued. It would be very helpful to send them messages when we find that guidance helped us solve a problem. Normally they only receive the negative feedback, which helps them understand where they have created a problem, but would also like to know what is helpful in fixing the problems.

The audience acknowledged that Dr. Pritchard has been very helpful and wondered whether a change in leadership will affect a change in enforcing guidance. Dr. Pritchard stated that they have historically avoided changing their minds after giving clear guidance on a topic.

The new Director has been in the office for just a short period of time, but Dr. Pritchard assured us that the Director is seriously interested in avoiding burdens on administration that do not provide human subjects protections. He wants to make OHRP as user friendly as possible.

Submitted 2-13-09

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