# IRB Taskforce
# REPORT
### January 5, 2011

## Summary

The IRB Taskforce was appointed by Faculty Council in April 2009; the formation of the taskforce was announced at the General Faculty meeting on April 30, 2009. Meetings commenced in May 2009. The final meeting of the Taskforce was held on January 22, 2010. During its discussions and deliberation, the taskforce considered numerous issues of IRB operation which were reported to be a concern to faculty members. Data were collected and many discussions with IRB staff were conducted. The taskforce feels that many issues of concern to faculty have been addressed as numerous changes have been implemented or are in process or in the planning stage. Given the high level of cooperation emanating from the IRB staff and the significant changes which have occurred or are in process, the Taskforce considers its goals to have been achieved. It recommends that if future issues arise, that those issues be passed directly to the IRB staff or be indirectly communicated to them via other means to allow progress toward additional improvements. The Taskforce also recommends that the Faculty Council reevaluate the progress after 3 years have passed. If faculty report unresolved or new issues at that time, the formation of another taskforce should be considered.

## Taskforce Membership

Members of Taskforce were Jay Dow, Clyde Bentley, David Brunsma, Jean Ispa, Michael Kramer, Jeffrey Milyo, Lilliard Richardson, Nils Beck and Jamie Arndt. Lori Franz chaired the Taskforce and Kate Markie and Michele Reznicek were ex-officio to the committee. Michele Reznicek was replaced by Michelle Kennett for the final meeting.

## Goal of Taskforce

At the first meeting of the Taskforce, these over arching goals were defined:

- Protect Human Subjects
- Protect MU from Harm to Research Activities
- Facilitate Research and Research Productivity

To facilitate research and research productivity, the Taskforce focused on two major actions items:

1. Evaluate the appropriateness of accreditation for the Campus IRB.
2. Identify and facilitate resolution of IRB issues facing social and behavioral science researchers.

The remainder of this report discusses the results of the Taskforce's action.

## Action Item 1: Evaluate the Status of Accreditation at MU

The Taskforce's evaluation of AAHRPP accreditation at MU addressed two major questions:

A. What are the faculty concerns about IRB accreditation?
B. Should the Campus IRB (CIRB) choose to forego accreditation?

The Taskforce identified a number of faculty concerns about accreditation and acknowledges that accreditation remains an issue to many faculty . Specifically these observations summarize some of the issues that make accreditation a target for faculty criticism:

- AAHRPP standards go beyond the federal guidelines, holding faculty to standards that are more stringent than federal code. To many social and behavioral researchers, this is seen to lead to an unnecessary burden.
- Accreditation leads to an increased cost of compliance. It can be observed that IRB costs have doubled. The use of a fee structure by the accrediting agency based on the number of applications processed is objectionable as some feel accreditation is designed to increase the number of applications.
- Faculty felt, perhaps wrongly, that the IRB administrators did not represent the faculty sufficiently in negotiations with AAHRPP.
- The knowledge of other research institutions who do not have accredited IRBs and which have fewer issues with their IRBs causes faculty to question the value of accreditation.
- Based on other experiences with agencies which accredit other organizational units on campus, faculty are skeptical of the value added vs the administrative work generated.

According to Rob Hall, MU began the process of seeking accreditation when the Central VA in Washington DC determined that VA hospitals would only affiliate with research entities with accreditation. For MU, there were only two possible accreditation entities: PHRP and AAHRPP. Shortly after the perceived need for accreditation, PHRP ceased to exist. The VA shifted all accreditation efforts toward AHARP. According to Hall, three different times MU officials approached AAHRPP to determine if there was any way to accredit only the Health Sciences

IRB. Under AAHRPP's processes, the Health Sciences can only be accredited separately, if MU can demonstrate that the Health Sciences is a "separate campus." Cooperation with the VA is essential to the health sciences' research productivity so accreditation is seen as mission critical for the Health Sciences.

Thus, only if MU were to establish that the Health Sciences is a "legally separate" entity, would it be possible to discuss disassociation of the main campus from the Health Sciences, leaving only the Health Sciences accredited. To create a separate campus, there would have to be different reporting relationships and totally separate budgets. The separate campus would not report through Chancellor Deaton. There would be increased costs to maintain a new separate organization which would dwarf any saving from the IRB. The cooperative and interdisciplinary relationships which exist might be diminished by budget battles and other unintended consequences could occur. Finally, such a major restructuring would be very disruptive and divisive.

**Since no evidence was brought forward that other institutions have avoided accreditation when their "legally connected" health sciences campuses have successfully attained accreditation from AAHARP, the issue of separate accreditation was put to rest by the Taskforce. The IRB Taskforce does not recommend that CIRB forgo accreditation (unless AAHRPP were to be convinced to accredit the Health Sciences separately from the campus).**

## Action Item 2: Identify and facilitate resolution of IRB issues facing social and behavioral science researchers.

The second action item for the taskforce was to facilitate, to the extent possible, the resolution of problems which exist for faculty with the MU CIRB. It was noted that faculty in the social and behavioral sciences were among those with the highest level of concerns. The Taskforce sought to identify potential changes to IRB procedures which could be improved in a manner consistent with accreditation requirements. To do this, two questions were posed to the taskforce.

- What are issues in MU's IRB operations that can be addressed?
- What are potential mechanisms to improve faculty/IRB Board interactions?

## Concerns

The following IRB Issues of concern were identified by Taskforce members:

1. Repetitious application processes for projects that are virtually identical in all aspects. Many researchers perform very similar experiments or data collection protocols which may only vary slightly, (i.e. A change in the questionnaire or in a task assigned to experimental groups). These

variations may not be material to the IRB issues (particularly on exempt projects). Regardless, a new application and full review is triggered when the issues associated with the protocol may have already been addressed. Even marginal changes in the protocol require a new review. Could there be an "exception form" where only the changes from a previous study are needed?

2. Applied researchers have difficulty timing the IRB application with accounting and contract requirements of their projects. IRB approval may be needed to gain certain accounting codes and contract approvals, but IRB requires information which is not available yet. State and other contracts may be seen as too difficult to pursue or impossible because of the belief that the researcher cannot be responsive to the client within the client's time frame.
3. Because organizational research requires that individuals fill out surveys about their organization, those individuals are treated like human subjects when they are not. This forces contracting of organizational studies into IRB review processes creating barriers for contracts.
4. Researchers file IRB applications to analyze secondary data where the respondents are already anonymous, wasting IRB and researcher time.
5. Co-researchers may be inappropriately left off projects because of the IRB constraints.
6. There is no recognition of other IRBs so duplicate approvals must be sought for all projects with other institutions. For instance, if you have a co-author at the University of Michigan, where research is being conducted. You still need MU IRB approval. Even projects with other UM schools , conducted at those institutions must have MU IRB approval if an MU researcher is involved. Some MU researchers do not want to work with coauthors at other campuses because of the increased effort and delay associated with the IRB. It has taken almost two months to get an exempt study approved between two UM campuses.
7. It is very difficult to work across UM campuses or on projects with other institutions because of the redundant, sometimes conflicting requirements of different IRBs . Duplicate approvals more than double the time and effort required. If Board A approves, then the MU IRB requests changes, then the changes have to go back to A's IRB. If they change or do not agree, then it goes back to the MU IRB.
8. Documentation for incentives can be excessive. Even small changes (giving away an iTouch instead of an iPod) require new documentation. Such things as letters from suppliers do not make sense to the researcher.
9. Researchers find it time consuming to gain approval to collect survey data from students, even when the data involves evaluation of projects or other course consistent work. Doctoral students in Education who are school administrators have trouble with research projects in their own schools when they want to sample teacher or students or collect data on effectiveness of certain processes.
10. IRB procedures restrain 1st Amendment rights afforded in Journalism. Different protocols are needed for interview research.
11. Surveying public officials is difficult as there may be other issues to consider. Interviewing public officials is specifically removed from HS protections by federal code, and is a first amendment issue that no political or social scientist will give up. We will interview public officials – especially elected officials -- regardless of HS protections because the right to do so is engrained in the Constitution, and we don't give up these rights to do research.

12. Slow IRB procedures are not consistent with the speed at which on-line and other new media publication of research can be reported. MU researcher s need to have the ability to be competitive with other researchers in their areas.
13. Consent letters are forced to be overly frightening and create a negative aura about the research.
14. When a research design needs to ask a specific question for a specific reason (consistency with comparable research for instance), the board may insist on a change. The IRB then interferes with the ability of the researcher to conduct his or her research and to publish that research.
15. The board is not consistent, so depending on board members, an application may get different responses. Some board members may be over zealous in their jobs, giving rise to questions about how board members are appointed and what instructions they are given. The selection of board member should be rethought to determine ways in which board members can advise on proposals in their area of expertise.
16. It would be helpful if there were some type of "exception" application. If there were a process that had been previously approved by the IRB or an established process by which students can be surveyed, it would be helpful to just provide information about how the proposed study differs from the preapproved process.
17. The process is overly complex. When MU is asked to survey student athletes, MU IRB approval must be obtained.. Because the NCAA wants to assure their data is collected, the NCAA research division (in 2007) offered to apply for IRB approval at institutions if the Faculty Athletics Representative at the institution made the request. Thus a PhD qualified, NCAA research staff member completed the MU application along with those at a large number of other institutions. MU's IRB process was reported by them to be the "most cumbersome, most detailed and most time consuming" of all the processes. Subsequently, they have refused to fill out any more applications, but they prepare responses to IRB questions for all institutions using the MU website so that all information is provided and can be cut and pasted. Even with that help, it takes 3+ hours to complete the application. Meanwhile, faculty reps at other peer institutions report that 1) their institutions accept the NCAA documentation or accept the NCAA information as the application, or 2) they are approved after a short discussion about the project (verbal only) or 3) their process is not hard to deal with.
18. The readability of the emails regarding the IRB, the IRB website, and the IRB forms are in the 20-30 range on the Flesh Readability Scale which goes from 0-100. A readability score between 60-70 is recommended for most documents. Grade reading level on the documents varies from 14.6 to 17.5 on the documents tested. A clearer writing style would improve the researcher's efficiency in dealing with forms and requests. (Readability can be found by copying the text into Word .)
19. There are examples of cases in which the board has appeared overzealous in its interpretation of the regulations. Inconsistencies occur when different judgments are made.
20. The current departmental audit is perceived very negatively. Why are students listed if faculty are cosigners? How much work is this generating on already overburdened chairs? The implication of this audit is that it is the department chair's responsibility to enforce the IRB rules. Are not the IRB and Office of Research were responsible for enforcing the rules? The chair

is responsible for make sure that all the researchers in the department give him a copy of the form saying that they are in compliance with the IRB and then he's supposed to fill in a form saying that he confirms that it's all true with no better basis for that statement other than what they could turn in directly to the IRB. Are there other ways to sample researchers?

21. The information provided to the researcher on the departmental audit is not complete enough to easily check things off. No dates are listed nor are other investigators on the projects. More information would make this much easier to do. This looks expedient for the IRB folks, but difficult to wade through from the chairs and researchers.

## Initial Suggestions from Taskforce

The following suggestions were among those brought forward for improvements for "exempt" research:

1. Create a small subgroup of the IRB that only deals with projects which are proposed as exempt. (Add 2-3 members to the board if needed to do this.) Those individuals would only look at exempt proposals. They would help develop short-cuts to help exempt researchers in the application process. (Maybe several subgroups who only consider projects in an expertise group)
2. Use the University of Chicago model to remove consideration of projects using secondary datasets from the IRB process (if they meet certain characteristics.) Provide blanket approval to research or researchers using archived, de-identified data sets not meeting the definition of human subject research.
3. Provide blanket approvals for research involving interviews with public officials that are specifically removed from human subject's protections by federal code.
4. Create templates for exempt protocols that will be approved: 1) using prizes and incentives, 2) students with extra credit, 3) faculty doing research with their own classes, 4) journalistic interviews, 5) contract situations, 6) etc. The application would require stating any exceptions to the accepted protocol.
5. Consider the appointment process to the IRB. Consider recommending a new process (perhaps to the FC as well since they do all other committee nominations) with the proviso that nominations that emerge from such a process are just that: nominations that are advisory to the VC for Research. He or she can accept or reject in accordance with his/her privileges under CRR. Given the importance of the IRB, consider codifying some rules for membership on the IRB and selection for various leadership positions on the board.

Other suggestions

1. Rewrite standard communications to researchers in a less bureaucratic, legalistic tone.
2. Determine if letters of consent can be written with a more positive tone.
3. Review website language to avoid legalese that is unnecessary.

4. Provide more menus or layers in the application process to help researchers find the appropriate forms easily.

## Planning for resolution of IRB issues identified by the taskforce.

At the 10/20/2009 meeting of the Taskforce, the decision was made to streamline the list of issues by grouping them into five categories. An "issue champion" was named for each category, with the request that the champion work with the IRB Compliance Officer to determine how the issue might be addressed. For issues which improvements are possible, the champion worked with the compliance officer and /or IRB staff to determine how and when the improvements could be made. It was noted that some resources may need to be made available to accomplish changes to the IRB website.

The groups/categories, the issues in the group, and the champion are listed below:

| | | |
|---|---|---|
| • Application processes | 1, 5-9 12, 16, 17 | Clyde Bentley |
| • Non IRB research | 3, 4, 10, 11 | Jay Dow |
| • Office/Board/Members | 8, 13, 14, 15-19, 18 | Jamie Arndt |
| • IRB Office | 2 | Jeff Milo |
| • IRB Audit | 20, 21 | Michael Kramer |

# Issue Resolution

## Staff Changes and Reorganization

During the months of November and December, the MU IRB underwent a major restructuring. The Compliance Officer who headed up the CIRB left the university. Michelle Kennett, Senior Compliance Officer of the Health Sciences IRB became the Senior Compliance Officer in charge of both the CIRB and the HSIRB. In recognition of the different missions of the two IRBs, there is no plan to combine the offices. Rather, a compliance officer has been named for each unit, Janelle Greening (CIRB) and Betty Wilson (HSIRB). Each reports to Michelle Kennett. They are responsible for monitoring and education. There has been and will be no major change in staffing.

## Application Processes

Since the beginning of the restructuring (and before), the CIRB staff has been working through many of the process issues identified by the Taskforce. Many changes have been made, including

- A new and improved exempt research form
- Streamlining of web pages and forms
- Designing of new web improvements and information
- Creating less bureaucratic communications

- Empowering staff to facilitate intervention before going to board
- Elimination of some accounting requirements
- Allowing review before all contingencies are covered
- Resolving communication issues between Grants and Contracts and Accounting with respect to required IRB approvals

The staff is continuing to address issues and has requested that suggestions and/or issues be sent directly to them so that continuous improvements can be made.

## Non IRB Research

Agreement has been reached to implement website information to better communicate with faculty about whether CIRB approval is needed for research using the University of Chicago model. Users of secondary data and some pre-approved studies will be advised of whether their work is in the domain of the IRB. There is also agreement to continue to work on greater clarity with respect to interviews of political officials, resolving when IRB approvals are needed.

## IRB Office and Board Members

It is observed that the new structure is and process changes are working and have improved IRB process for the better. The following suggestions have been discussed with CIRB staff and are under consideration or in progress:

- Develop and make available online a series of board approved templates of IRB applications such as consent forms, documentations of incentives, etc. These could include templates for different types of research, and/or departments (e.g., research with schoolchildren, with students as part of coursework, involving alcohol or admitting to illegal behavior, with public databases, etc) The intent is that by giving investigators pre-approved language with which to work, they would then make the modifications necessary to suit their project and that many of the concerns that compliance officers and board members raise would have been already addressed.
- Address inconsistency in review across reviewers and having to address issues that are seen as outside the purview of the risk/benefit charge with which the IRB is faced by enhancing board member training,. This would entail developing a training protocol for board members and staff that includes:
    - Guidelines and examples of appropriate and inappropriate domains for reviewers to comment on.
    - An example training application that each new board member is asked to review. This file could contain “planted” information that reviewers should “catch” as problematic and needing revision as well as information that reviewers might be tempted to flag but is really outside the domain of ethical consideration. After each board member reviews this mock application, the application could be discussed at a board meeting.

    - Create other aides to get IRB reviewers closer to being on the same page and thus reducing inconsistency in reviews.
- The IRB staff, Board Chairperson and other board members should be empowered to respectfully point out when an issue is being raised that is perceived as going beyond the IRB ethical charge of protecting human subjects.
- Make the composition of the IRB proportional to those who use the IRB. This might entail:
    - Identifying what % of projects come from each department/college and making sure that % is represented in IRB membership. Deans and/or Department Chairs would then be charged with finding people to nominate to serve.
    - The intent here is to balance the expertise of the board with the files it considers and thus potentially improve the quality of IRB review
    - The final appointments would be made by the VP of Research.
- Recruiting and retaining quality members for the board by considering an incentive for serving on the IRB.
- Protection against the chair of the board appearing to be a "permanent appointment." The appointment is not for a particular time length. Discuss openly with relevant parties to explore the pros and cons of making the appointment for a particular time period and determine ways in which reappointment could involve some sort of review process to the staff and board to provide some feedback.

## IRB Audit

A process is already in place to change the IRB audit process for the next iteration. In the future a new approach will involve the Compliance Officer looking at selected individual project to assist with education and improvement. Workshops will be held to assist faculty by communicating needed information more effectively.

## Conclusion

The IRB Taskforce feels that the new IRB office structure and the IRB staff intentions to continue to address the issues in this report along with new issues which arise should be given time to work. The Taskforce members are very pleased to see the progress that has been made and that is planned. For that reason, the Taskforce feels it has concluded its work. The Taskforce recommends that Faculty Council reevaluate the actions of the CIRB after three years have passed to see if any further action is needed.