



Office of the Vice Chancellor for  
Research and Graduate Education

UNIVERSITY OF WISCONSIN-MADISON

**MEMO**

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FROM: IRB Working Group (David Beebe, Barbara Bowers, Mark Burkard, Eric Camburn, Betty  
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RE: Report from the Institutional Review Board (IRB) Working Group

Please see the report from the IRB Working Group below.

**Introduction:**

The Institutional Review Board (IRB) Working Group was asked to review the IRB Survey Report, benchmarking data gathered from peer institutions, and existing University of Wisconsin-Madison (UW-Madison) Human Research Protection Program (HRRP) policies in order to respond to the following questions:

1. What changes could be made to current IRB policies, processes, and procedures to address faculty concerns raised in the IRB Survey?
2. Are the IRB offices sufficiently staffed and resourced?
3. Currently, there are three IRBs: two minimal risk IRBs (Educational and Social Behavioral Sciences, Health and Health Sciences Minimal Risk) and the Health Sciences IRB. Is the current administrative and funding model for the IRBs optimal? Given the volume of protocols at UW-Madison, what is the optimal number of IRBs to serve the research enterprise?
4. Are there sufficient opportunities for input from faculty and staff PIs? If greater input is warranted, how might this be achieved?
5. How are IRB policies reviewed at UW-Madison and potentially changed? What is the present committee structure in place for this process and should it be modified?
6. The survey results indicated that a substantial number of faculty perceived IRB oversight as overly conservative by imposing a set of regulations on investigators that unnecessarily exceed the federal standards. The Office of the Vice Chancellor for Research and Graduate Education (OVCRGE) seeks the committee's advice about whether there are any current practices and university-wide policies that could be modified to reduce the regulatory burden, without in any way violating federal policy or jeopardizing UW-Madison's accreditation status, which the campus is committed to maintaining.
7. Based on the available benchmarking data compiled by the OVCRGE, what initiatives at peer institutions might UW-Madison adopt?
8. Are the IRB and HRPP websites well organized to allow study teams easy access to information needed for protocol development and submission? How can this be improved? How can

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communication, in general, and consistency of communication between the PIs and IRB staff be improved?

9. Are there ways to shorten the time to review protocols?

The IRB Working Group met several times to review the background materials and discuss the issues outlined in the eight questions presented in the charge from the OVCRGE. The group also met with Casey Nagy, Consultant to University Administration, and members of the IRB staff. Given the broad scope of the charge, the importance of the issues that were raised in the IRB Survey to the UW-Madison research enterprise, the extensive research materials provided to the IRB Working Group by Nagy and OVCRGE staff, the IRB Working Group has taken considerable time to carefully formulate recommendations and to prepare the following report. The IRB Working Group focused primarily on addressing issues of current IRB policies and procedures and ways to minimize the burden on investigators while preserving the protection of research participants (Questions 1, 4, 5 and 6). The group offers specific recommendations regarding staffing, communication, the review process, and the IRB/HRPP websites (Questions 2, 7, 8, 9).

### **Working Group Summary and Conclusions:**

The IRB Working Group strongly argues that at the heart of any model of IRB operations must be a set of core principles that guide decision making with regards to governance, policy, and process. The first, and foremost principle, must be the protection of human subjects. A key element of this principle is ensuring that risk levels are appropriately evaluated and that decisions are made on a rational basis that balances real and potential risks and benefits.

The IRB Working Group identified the following core principles and used them to guide its review of materials and recommendations development. These core principles are:

1. Protection of human subjects with depth of review that is commensurate with the level of risk posed by the research
2. Promotion of research
3. Respect for investigators and IRB staff

The working group has extensively discussed governance, policy, and process related to the UW-Madison IRB. It is clear from campus surveys and discussions that UW-Madison researchers have a variety of concerns about the three core principles. At the same time, the working group agrees that the campus is strongly committed to the role of faculty in shared governance, and the campus is uniquely situated to rethink its operations in a manner that would enable the UW-Madison campus to create a prototype of research oversight that could provide an aspirational model for other universities to follow.

In their efforts, working group members felt the need to underscore the structural reasons that have led IRBs around the country to create ever more rigorous rules that gradually and slowly increase investigator burden without materially improving the protection of research participants. These roles pose significant consequences for resource allocation and discovery of new knowledge. The IRB must first, and foremost, protect the safety and well-being of human subjects who take part in research conducted by UW-Madison researchers. While the working group fully recognizes and supports the essential role of the IRB in ensuring the protection of research participants, the group came to the conclusion that the current structure of the IRB system has failed to strike the appropriate balance between protection of human subjects and advancing the cause of high-quality research that itself contributes to the welfare of research participants. The group believes this failure is due to an over-emphasis regulatory risk mitigation, rather than a focus on the protection of human subjects and the need to support research as a fundamental good.

In April 2017, Chancellor Blank testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs on federal regulations on research. She began:

My message today is very clear: We have spent many years adding layer upon layer of federal regulations, and we're at a point where this is seriously impeding the productivity of our scientists.

While Chancellor Blank was describing the burdens imposed by federal regulations across a wide range of policies, the problems she identified are magnified by the expansive interpretation of those rules by UW-Madison leadership. She concluded with the following observation and recommendation:

We must operate from a shared set of ethical principles that guide scientific research. But the way in which these principles are translated into regulations by various federal agencies has created a system of unnecessary delays and expenses.

The IRB Working Group believes that this criticism also applies to the way current UW-Madison IRBs implement those rules, through internal decisions that create unnecessary delays and expense. While the group recognizes that the IRB is guided by laws, rules, regulations, and policies handed down by multiple federal agencies, it also recognizes that the increased burden on investigators comes at a time where there is less -- not more -- administrative support for individual researchers. This means that faculty and staff spend more time managing regulatory matters than is necessary to achieve appropriate human subject protections. The IRB Working Group stresses that this increased time investment is not the fault of any individual or set of individuals. The IRB Working Group regards the flaws as constituting an institutional failure in which the incentives (or administrative structure) that shape IRB policy are misaligned with the UW-Madison's research mission. This misalignment means that faculty and staff spend more time managing regulatory matters, leaving less time for research activities (e.g. designing new research projects, obtaining grants). Furthermore, these regulatory hurdles and delays expend valuable resources that are diverted directly from scientific productivity. The IRB Working Group concludes that the criticism of federal regulations also applies to the way that UW-Madison implements those rules, through internal decisions that create unnecessary delays and expenses.

These unnecessary delays and expenses have arisen, in part, due to the history of delegating the daily administrative oversight of the Health Sciences and ED/SBS IRBs to the Deputy Institutional Officers (IOs), insufficient faculty participation in reviewing and approving IRB policies, failure to consider opportunity costs, and delegation of decisions about interpretation and determination of research risks to staff who often lack the necessary research training and experience.

The IRB Working Group recognizes that IRB staff members face a number of additional pressures that go beyond the core principle of protecting human subjects. These pressures include: protecting the university from risks of all kinds (legal, financial, and public relations, among others); pressure from the Association for the Accreditation of Human Research Protection Program, Inc. (AAHRPP) and its preferences for, and interpretation of, policies; and UW-Madison administrative desire/need to maintain AAHRPP accreditation.

It is the working group's suggestion that there needs to be an appropriate relationship among the following factors: a) The very real pressures placed on UW-Madison's IRB's; b) The effort to reduce regulatory burden on researchers; and c) The way UW-Madison manages its IRB and its relationship to managing and evaluating risk.

The IRB Working Group's goal is not to undermine protections for human subjects, but to develop efficient means to appropriately balance the real risks and real benefits in order to promote the conduct of

world-class research *while* protecting human subjects. With this in mind the working group views the promotion of high-quality, ethically-sound research as the second core principle that should guide IRB decision making.

This principle would be used to improve decision making so that:

- Risks and benefits of research needs are evaluated sensibly, with decisions tied more closely to the Common Rule and the core principles guiding decision making.
- The need for protocols to be reviewed with speed and efficiency is underscored.
- The process for approving minimal risk research is streamlined to reduce the amount of time and effort required by PI's and their staff to get approval.
- The IRB serves as a leader minimizing investigator (and participant) burden.

Another key principle identified by the working group is the promotion of a climate of mutual respect for investigators and IRB staff. All too often in recent years, the relationship between investigators and IRB staff has been adversarial, **specifically, these two sides do not seem to share the same goal: to ensure the ethical conduct of research.** This type of relationship potentially undermines both of the first two core principles and leads IRB staff to feel they are constantly under attack and underappreciated. At the same time, investigators feel that IRB staff exhibit a mistrust of researchers, especially during the pre-review process. The working group feels that there needs to be a cultural shift on campus that brings the OVCRGE, IRB staff, and investigators into a more collaborative and constructive environment.

The working group feels that one way to potentially build a more collaborative relationship between investigators and the IRB, is to increase the role of faculty in the overall governance of the research protection process on campus. Specifically, the working group suggests that UW-Madison establish a high-level committee that would serve to evaluate the governance, policy, and processes involved in the oversight of human subject research. Perhaps these functions could be folded into the charge of the existing Cross-Campus Committee on Human Research Protection Advisory Committee (HHRP Committee). However, in the view of the working group, the scope of this committee and its governance would need to be modified in order to foster the cultural shift that the working group feels is necessary in order to create a model system of IRB governance.

The current Cross-Campus Committee charter (<https://research.wisc.edu/kb-article/?id=29791>) specifies that it has authority to review policies. However, it does not have the authority to *disapprove* policy changes (rather, it has the authority to “[Review] all current and proposed policies for the HRPP and advise the IO on those policies” [Committee charter 1 (c)]. The working group recommends that this authority be enhanced so that major changes in policy or rule interpretations, such as those affecting content of IRB applications, *must* be approved by the HRPP Committee before they can go into effect. As part of the process, proposed major changes also must be explicitly justified with regard to the need, the regulatory or legal basis, and how the change will enhance the protection of human subjects. Finally, the working group recommends that major policy changes be subjected to advance notice and public comment requirements, so that researchers are aware of proposed changes and have an opportunity to provide feedback to the HRPP Committee about the impact of the changes on their research activities or regulatory burden.

The working group acknowledges that this proposal would constitute a significant change in IRB policy and governance structures, and that many details remain to be worked out, notably, the definition of a “major change” as one that potentially adds to the regulatory burden on faculty and research staff, versus those that may reduce them, and how to structure the HRPP Committee so that it does not function as a roadblock to necessary policy change. The working group has confidence that UW-Madison researchers

operate in good faith and with sound ethical principles, and that their perspectives are often neglected in the creation and promulgation of IRB policies.

In the working group's view, the HRRP Committee should be driven by the core principles described herein, and should have the goal of being a model for other institutions. The working group suggests that the HRPP Committee be a conduit for ideas, complaints, and suggestions gathered from IRB staff, current IRB members, and from investigators more generally. The idea is that the committee should be open to ideas, concerns, and suggestions from all individuals involved in the research process. In order to ensure input from faculty researchers, and that their experience and knowledge are represented when policies, procedures, requirements, and rule interpretations are developed or changed, the working group strongly suggests that there should be more faculty representation on the HRPP Committee. The working group also recommends that HRPP Committee members should reflect the diversity of research methods and populations on campus.

Ideally, both internal IRB staff meetings and regular IRB full meetings would serve as places to identify issues and concerns along with the normal business of reviewing protocols. Working group members want the UW-Madison administration to empower IRB staff and IRB committee members to bring forth questions, ideas, and suggestions to improve policies, procedures, requirements, and rule interpretations the come up or are on the horizon.

The working group recognizes the potential impact of the proposed changes in the Common Rule and that these changes will address some concerns associated with minimal risk studies raised in the faculty survey. However, additional changes are necessary to move UW-Madison into the vanguard in both protecting human subjects and enhancing the critically important research programs that improve human health. Of note, the IRB Working Group anticipates that these further recommendations will both streamline reviews and *decrease* the workload for IRB staff. As previously stated, the working group is calling for a cultural shift on campus that brings IRB staff and investigators into a more collaborative and constructive environment.

### **Specific Recommendations:**

1. Risks and benefits of research need to be evaluated more sensibly, with decisions tied more closely to the Common Rule and the core principles used by the IRB Working Group in the development of this report. Also, the difference between IRB policy and IRB guidelines need to be more clearly articulated and consistent across IRB committees. This consistency could be achieved, in part, by having all three of the IRB committees administratively located in the OVCRGE. This alignment would ensure consistent administrative oversight of each of the committees, and provide the IO with the necessary authority to implement changes and recommendations by the IRB Working Group
2. The IRB Working Group recommends that steps be taken to achieve greater speed and efficiency in the review of protocols. Toward this goal, the working group recommends that the following changes be made:
  - The working group recommends a single, comprehensive, "redlined" review with all salient issues presented at the same time. The goal should be to get protocols to committee review as quickly as possible. No new issues should be brought up subsequent to this redlined review prior to IRB committee review. All subsequent issues should come from the committee rather than IRB staff.
  - IRB staff be provided with sufficient training in research methods so as to more effectively provide efficient and effective and consistent pre-review. The IRB Working Group recognizes the commitment of IRB staff to the protection of human subjects and recommends that the university

invest in ongoing research training to better prepare current staff for the review process for a campus that conducts such a large and diverse range of research methods and investigation. New staff hires should have the research experience necessary to better support determination of research risk related to the methods proposed in protocols presented for review. The working group recognizes that providing staff with training will require a commitment by central administration to provide additional funding for IRB staff training.

- The process for approving minimal risk research be streamlined so as to reduce the amount of time and effort required by PI's and their staff to get approval.
  - IRB review and approvals should be separated from Research and Sponsored Program (RSP) documentation requirements and funding questions, so that IRB staff do not need to read grant proposals or compare them with IRB applications.
  - Exclude, as possible, all non-human subject review tasks from the purview of the IRB. This will streamline reviews and eliminate the current institutional requirement for IRB review of research on non-human subjects (e.g. research on decedents).
  - Eliminate duplicate ongoing IRB reviews, for projects delegated to other institutions or recognized central IRBs under UW-Madison approved reliance agreements.
3. The IRB Working Group recommends that faculty/investigators are more fully involved in review of proposed policy changes, to better inform policy decisions of the impact of the change on research programs prior to implementation.
  4. The IRB Working Group feels that there needs to be a cultural shift on campus that brings the OVCERGE, IRB staff, and investigators into a more collaborative and constructive environment. Processes should be put in place to facilitate direct communication between investigators and IRB staff. Ideally, this communication would involve planned meetings or telephone conversations, which would be most efficient for resolving issues and clarifying concerns.
  5. The IRB Working Group recommends that IRB committee members reflect the diversity of research methods and populations represented at UW-Madison. The working group recommends creation of subcommittees or additional committees with expertise in the review of different types of research. For example, concerns were raised about the quality of review of qualitative research.
  6. The IRB Working Group recommends elimination of IRB fees, except for industry sponsored research.
  7. Although the Application Review for Research Oversight at Wisconsin (ARROW) has been much improved over the past several months, the IRB Working Group recommends that the ARROW team continue to make additional changes to the ARROW system to simplify the process and improve the flow of the application. For example, the working group recommends replacing open questions with drop down menus with response options where specific regulatory language is required. Also, inclusion of a simple, written protocol with the ARROW application might eliminate duplicative questions.
  8. The IRB Working Group recommends providing access to non-English speaking populations in research, by providing facile and efficient methods such as foreign-language short forms and pre-approved translated Health Insurance Portability and Accountability Act (HIPAA) templates.

Please let us know if you have any questions. Thanks for the opportunity to work on this important campus issue.