

REPORT OF THE IRB WORKING GROUP
FOR RESEARCH IN THE SOCIAL AND BEHAVIORAL
SCIENCES
June, 2007

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OVERVIEW STATEMENT:

In responding to the charge to this committee, the IRB Working Group for Behavioral and Social Sciences Research has identified issues and made recommendations for communication to the Faculty Senate, the Institutional Official, and the IRB Policy Committee. We viewed our task as finding ways to facilitate the work of investigators who do research in areas that come under the purview of the Behavioral and Social Sciences IRB, while simultaneously ensuring the safety and welfare of the individuals who so generously participate in the research. In the course of our work, we have learned that many of the difficulties encountered by OSU investigators are not unique. Indeed, many of these faculty concerns are representative of those being discussed at the national level by professional societies and organizations, by federal panels, and at many other universities.

The Working Group has identified three main issues. First, it is clear that the most effective way to accomplish this dual task is to create appropriate policies and procedures for IRB oversight of research. Guidance statements have been produced, which are meant for consideration by the IRB Policy Committee as its members craft and implement new policies for the IRBs at the Ohio State University.

Second, the Working Group has made some recommendations for assessing the staffing levels of the University's Office of Responsible Research Practices (ORRP), and has suggested one model that might be successful in providing the kind of staff assistance that is most needed by our investigators.

Finally, the Working Group recommends continuing educational outreach to faculty and students across the university. Many of the difficulties that have arisen for researchers in the past several years have been attributable to both changing human subjects protection procedures at Ohio State and a lack of knowledge on the part of investigators about those changes. It is imperative that there be effective channels for communication and education in both directions: both to investigators from the ORRP and back to the ORRP from investigators.

IMPORTANT NOTE: The committee members who prepared this report have attempted to identify issues and areas of concern that affect research that falls under the purview of the Behavioral and Social Sciences IRB. The faculty members of this committee are not experts in the interpretation of the federal regulations governing such research. Thus, we are aware that some of the recommendations in this report may not be implementable as expressed. Nonetheless, we have included these recommendations for consideration by the IRB Policy Committee, in the hope that they can create policies and procedures that address these issues in the context of compliance.

General Principles Underlying the Working Group Recommendations

The IRB Working Group for Behavioral and Social Sciences Research believes that a one-size-fits-all, institution-wide approach to developing policies and procedures governing the protection of human subjects in research conducted at OSU can sometimes place an unnecessary

burden on behavioral and social science, humanistic, educational, and community-based research. Such policies are typically predicated on a biomedical research model that does not take into account the very different methodologies and research techniques employed in many behavioral and social science studies. Accordingly, the Working Group has prepared a series of guidance statements for the IRB Policy Committee, to aid them in formulating policies and interpretations that accommodate these methodologies. Three general principles underlie all of the recommendations of the Working Group:

- 1.) The vast majority of behavioral and social science research involves minimal risk to the participants. Therefore, OSU policies and procedures for behavioral and social science research that involves minimal risk should be developed in the least restrictive way possible, while still complying with federal regulations regarding the protection of human subjects. This concept should apply to all sorts of minimal risk research, including some research that is more biomedical in nature.
- 2.) As responsibilities for compliance are transitioned to the new Office of Research Compliance, the culture of the Office of Responsible Research Practices (ORRP) should continue to evolve into one in which staff work with investigators to facilitate research within the framework of federal regulations. This evolution may require a different allocation of personnel and resources than is currently in place. One goal that should be vigorously pursued is the further simplification of the paperwork requirements for protocol submission and review, including the current effort to secure software for web-based procedures.
- 3.) The Working Group recognizes from many anecdotally-collected reports that many difficulties encountered by principal investigators result from a lack of knowledge about existing federal requirements and Ohio State University IRB policies and procedures. In some cases, it has been difficult to learn about changes in OSU's interpretation of federal requirements. A strong educational effort is clearly needed. This effort will require the cooperative actions of the IRBs, the ORRP, the IRB Policy Committee, College Research Officers and Deans, and faculty and students engaged in research. It is beyond the scope of this Working Group to develop a detailed plan for this educational effort over the long run, but we do provide some preliminary recommendations.

It is important to note in our policy guidance statements that some recommendations listed under a particular topic are applicable to several of the other topics (see, for example, recommendations about open-ended interviewing, included under Educational Research, but also applicable to International Research and Ethnographic Research).

I. GUIDANCE STATEMENTS FOR THE IRB POLICY COMMITTEE

A. “Unchecking the box”

All human subjects research receiving funding from federal government sources is required to conform to a set of federal regulations governing the protection of human subjects known as the “Common Rule” 45 CFR 46. Research that is not federally funded, however, is not automatically required to conform to these regulations, which were created largely with a biomedical research model in mind. As a result some of the Common Rule requirements are problematic for research in the behavioral and social sciences, humanities, and education. Institutions can specify whether non-federally-funded research will be subject to Common Rule requirements.

The IRB Working Group discussed issues related to the University’s longstanding decision to apply the Common Rule regulations to sponsored research as well as non-sponsored research at Ohio State. This issue is referred to as “unchecking the box,” where “the box” is item 4(b) of the U.S. Federal-Wide Assurance (FWA), the assurance of compliance that the University must annually submit to the federal Office for Human Research Protections (OHRP). Institutions that check Box 4(b) agree to evaluate all research that their affiliated investigators conduct, regardless of funding status, according to the Common Rule regulations. Because much research in the behavioral and social sciences is not federally sponsored, this issue has relevance for our Working Group.

At present, it appears that at least 174 other educational institutions, including many of our peers and aspirational peers, have decided to uncheck the box. Presumably, this has been done primarily to remove direct federal oversight of non-federally funded research. Most notably, unchecking the box removes the requirement to report serious noncompliance and unanticipated problems in non-federally funded research to OHRP. However, unchecking the box does not eliminate the ethical requirement for IRB review of human subjects research.

The IRB Working Group recommends that Ohio State also uncheck the box, thus relieving some of the regulatory burden for protocols for non-federally-funded research. This action should provide additional flexibility in developing policies and procedures that are more sensitive to the concerns of researchers in the behavioral and social sciences, humanities, and education.

B. Definition of “change” in an IRB protocol

Federal guidelines for the protection of human subjects in research state that “changes in a research activity” must be approved by an Institutional Review Board before being implemented in a research protocol. However, nowhere in these federal guidelines, nor in other guidance used to interpret these guidelines, is there a definition of what constitutes a “change in research activity.” Many IRBs at institutions around the country have strictly interpreted this

regulation, stating that ANY change, even the correction of typographical errors on questionnaires, must be submitted as an amendment to the IRB.

A number of members of the IRB Working Group feel that this cannot be the intent of the federal regulations when applied to minimal-risk educational, behavioral, and social sciences research. The strict interpretation of this rule causes considerable unnecessary paperwork and further slows the bureaucratic response time of IRBs and staff. Most importantly, many of the changes that would fall into the strict interpretation have absolutely no material impact on a human subject's participation in a study. For example, although adding questions to a questionnaire might very well change the nature of a subject's participation, deleting questions most likely would not. Certainly, considerably more flexibility is possible in open-ended interview protocols, and it is difficult to argue that deleting a question from a formal questionnaire poses a greater risk to the participant.

It is obvious that no document could be created that could cover all of the possible changes that might be made to a research protocol, with an associated judgment of "must submit an amendment" or "need not submit an amendment." Many investigators learn to write IRB protocols in a way that allows for some variation of stimuli, responses, questions, etc. and could use their own judgment in determining whether a change requires submission of an amendment to the protocol. However, there is some concern in leaving all such determinations up to investigators in the absence of any guidance. ***A list should be created containing examples of items that could be updated at the end of a protocol year rather than requiring submission of an immediate amendment. The IRB Working Group urges ORRP and the IRB Policy Committee to equate changes to a research protocol that require prior approval with changes in research activity that affect the subjects' participation in the research.***

Potential examples of changes that do not alter the nature of a subject's participation and thus would not require an immediate amendment:

1. Correction of grammatical, spelling, or typing errors in recruitment documents, consent forms, or questionnaire documents, where the correction does not alter the meaning of the text.
2. Changes in documents that do not materially affect participation of the subject in the study (e.g., phone numbers, room numbers, etc.).
3. Deletion of questions from a survey when such deletion does not change the nature of the survey or the nature of the subject's participation in the study.
4. Changes in wording of a question on a survey or in the material properties of a stimulus where the change neither alters the fundamental meaning of the item for the research project nor changes the nature of the subject's participation in the study.
5. Changes in data handling, storage or protection that increase the level of protection of subject confidentiality, de-identification, or security of the data from a project.

C. Refining the policy on “Exempt” research for behavioral and social sciences protocols

The Working Group strongly recommends a change in existing policy regarding research that can be classified as exempt from review. Last year OSU faculty and staff conducted over 750 human subject research projects that were determined to be exempt from IRB review. Because these projects were appropriately exempt, they were not subject to additional federal regulations that can sometimes constrain the participation of outside collaborators. To further maximize the flexibility afforded within the current federal regulations, the Working Group strongly recommends a change in existing OSU policy regarding research that can be classified as exempt from IRB review and still conform with all federal regulations. The following categories of research are currently listed as not eligible for exemption at the Ohio State University:

1. Research involving prisoners
2. Research involving children
3. Research subject to FDA regulation
4. Research involving coercion, undue influence, deception, risks of discomforts greater than those encountered in daily life, or any practice that does not meet the ethical principles of the Belmont Report
5. Research conducted outside the United States

The Working Group recommends that the last two categories be replaced with:

- 4. Research in which participation is nonvoluntary (i.e., involving coercion or undue influence), or any practice that does not meet the ethical principles of the Belmont Report*
- 5. Research involving deception*

D. Deception in behavioral and social sciences research

No change to current policies is recommended.

E. Issues regarding “engagement” in research

Department of Health and Human Services and Department of Education guidance statements, “Engagement of Institutions in Research,” provide definitions and examples to assist institutions in interpreting the federal regulations requiring IRB review and oversight of non-exempt human subjects research. These guidance statements, which are largely focused on biomedical research environments, do not aid researchers in the behavioral and social sciences in terms of defining what constitutes engagement. *The IRB Working Group recommends that the IRB Policy Committee consider novel processes for assuring human subjects protection in social and behavioral studies conducted at non-OSU sites and/or involving non-OSU personnel. The conditions under which IRB Authorization Agreements and Individual Investigator Agreements can be used to define responsibilities of organizations and individuals involved in research for which the OSU IRB agrees to serve as the IRB of record should be*

expanded and clarified. In addition, the IRB Policy Committee should look at ways to use the OHRP's description of "routine" job activities to cover some activities in behavioral and social sciences research, especially for non-federally-funded studies. Finally, investigators should be provided additional assistance in navigating the federal guidance regarding engagement at early stages of research project development to avoid unnecessary administrative delays in study implementation.

F. International research in the behavioral and social sciences

The Working Group recommends that the IRB Policy Committee modify the OSU policy stating that no international research can be categorized as exempt. Specific issues are addressed below.

- 1) **Exempt status.** *The IRB Working Group strongly supports the recommendation to change the policy on Exempt research to allow international research that represents no more than minimal risk to subjects to qualify for exempt status, provided the research meets the other requirements for exempt status.*
- 2) **Review by IRBs in other countries.** *If a local IRB exists and is appropriately constituted to review a protocol for a research collaborator working in another country, the local IRB should provide review for the collaborator's activities. However, in many countries such IRBs either do not exist or are special-purpose in nature and not appropriate to review particular research protocols. In addition, much international research in the behavioral and social sciences takes place in rural areas not affiliated with universities or other research institutions. ***In these cases, the IRB Working Group recommends that OSU's IRB serve as the IRB of record for the foreign site with approval of the investigator's department and college if the research poses minimal risk to the participants.****
- 3) **Use of survey firms or data collection organizations in other countries.** *In cases where an Ohio State investigator plans to use a survey firm or data collection organization in another country to gather data for a non-federally sponsored project, the IRB Working Group recommends that the survey firm should not be required to have a U.S. Federal-Wide-Assurance (FWA). ***The Working Group recommends that the IRB accept a statement from the survey organization regarding how employees engaged in interviewing or surveying human subjects are trained and the ethical principles to which the organization subscribes. The Working Group also suggests that the IRB Policy Committee and ORRP staff create a short form that can be completed by the organization for providing such information. In addition, the OSU IRB could serve as the IRB of record for the foreign survey firm if necessary, under the guidelines noted above.****
- 4) **Training for international collaborators.** *For some international collaborators, lack of English proficiency may make completion of CITI training or other similar programs impossible. ***For these cases, the PI of the research protocol should be****

permitted to suggest the nature of alternate training provided to international collaborators engaged in the project as part of the IRB application and approval process. The policy should specify the components of adequate training.

- 5) **Translation of materials.** *When translation of materials into a particular local dialect of a foreign language is required, the PI should be permitted to address any concerns raised by the evaluation of the translation by the outside translator.* In addition, it would be very beneficial to PIs if there were a list of individuals who were willing to provide translation services available on the ORRP website.

G. Special concerns in ethnographic and humanistic research

Many research activities engaged in by scholars do not fit the standard scientific research paradigm. Particular examples of this include ethnography, ethnomusicology, oral history, and open-ended interviewing. There are important differences in the goals of this research, as compared to standard scientific paradigms; for example, where the usual goal of testing an individual in a scientific study is to gain knowledge that can be generalized to a population, typically in humanistic work the goal is to interview an individual because of his/her specific achievements and knowledge, as with a famous artist or activist. This is true not only of research on public figures, but also of much humanistic research with ordinary people and small communities. Much humanistic research is framed not as experiment but as documentation, interpretation, or conversation.

Although much of this research falls into the “exempt” category of human subjects review, some of these activities require IRB oversight. Thus, it is important for both policymakers and humanistic researchers to understand the issues that affect the interests of the individuals who participate. Below are listed some of the ways in which this type of research differs fundamentally from standard scientific paradigms, with the resulting difficulties for the researcher in meeting some of the non-negotiable requirements of IRBs.

- 1) **Subject anonymity/confidentiality:** Often oral historians, biographers and other researchers in this tradition will choose a participant for specific reasons rather than representativeness of a population. In these cases it is impossible and undesirable to maintain subject confidentiality. *The appropriateness of providing credit versus confidentiality should be determined by the IRB by a case-by-case basis.*
- 2) **Open-ended interviewing:** Research on culturally-sensitive interviewing methods has established that it is less intrusive and more productive to follow the ordinary norms of conversation in the community where the interview takes place. In open-ended interviewing, not only is it possible that the researcher will probe with additional questions on a topic that might not be specified in advance, but it is also possible that the direction of the conversation will include changes in topic not foreseen by the interviewer in advance. Methodological concerns dictate that the researcher will typically probe with additional questions on a topic that might not be

specified in advance. *This necessary flexibility should be allowed for in submitted protocols.*

- 3) **Participant observation:** In participant observation, the researcher may become part of a community for a lengthy period of time, with involvement in many aspects of the subjects' lives that go beyond the specific research project in some respects. This type of study can be very difficult to fit into the standard IRB protocol questions. *IRB Forms should be revised to more easily accommodate descriptions of this type of research.*
- 4) **Issues of informed consent:** In many venues, obtaining a written documentation of consent will compromise the project and deter participation by subjects, as in ethnographic research in politically sensitive locations. Even some oral consent scripts can pose problems because of interpretation of wording. *Investigators from humanistic research perspectives should be made aware of the option of waiving informed consent or waiving documentation of informed consent. This information should be more easily found on the ORRP web site.*
- 5) **Destruction of data:** In many cases the original data (audiotapes, videotapes, for example) constitute an archive of cultural or historical importance that should not be destroyed. *Investigators should be able to specify situations in which data destruction is undesirable.*
- 6) **Translation requirements:** Some research participants speak a language that does not have a written form or is not the language of literacy. Requiring literal translations of all documents and questions by an outside person can pose difficulties for the researcher. In these situations, the researcher is likely to be fluent in the local dialect or language, and a paid translator might not be. Indeed, much humanistic work presupposes a fluent researcher conducting the project in the local language rather than translating from English. *Educational efforts should be increased to inform investigators of alternative options to paid, outside translations.*
- 7) **Approved OSU research sites:** Much humanistic research does not occur on university property or at sites subject to review by other institutional review boards. Instead, this research takes place in homes, public places, and community settings—sites controlled by the participants rather than the researcher. *In sites solely controlled by the participants, arrangements should be made to permit this research to take place without additional oversight.*

H. Research in educational settings

Educational research often involves collaborative research with teachers on curricular and pedagogical issues or collection of data from students, parents, and teachers, sometimes in dozens or even hundreds of schools at once. Appropriate policies and procedures need to be

developed to address the unique aspects of this work. Some recommendations are included below:

- 1) **Participation of school districts:** *For research taking place in school districts that do not have a federal-wide assurance or a local IRB, a letter from a school principal, school district official, or Board of Education agreeing to participate in the research project should serve as documentation of an initial agreement to participate in the research project. To facilitate this research, consideration should be given to extension of OSU's FWA for federally funded research or development of standard agreements for non-federally funded research as described in Section E "Issues regarding 'engagement' in research." A template form could be made available for use in such situations. IRB Authorization Agreements should be used to define responsibilities of the schools involved in research for which the OSU IRB agrees to serve as the IRB of record.*

- 2) **On-site research collaborators:** *In addition to the requirements described above for school districts, teachers and school employees engaged in research must have received adequate training in human subjects protection to collaborate in OSU studies. The IRB Working Group recommends that the online CITI programs in human research protection be used, unless circumstances of the research make this impractical (e.g., international locations for which the appropriate language and/or technology is not available). Alternate training mechanisms must then be considered. As described in Section E, investigators conducting research in educational settings should be provided additional assistance in interpreting the federal guidance regarding engagement, including activities in which teachers or school employees are "not engaged," for example, when sending home permission forms for parents or distributing questionnaires to already-consented participants for return to an OSU investigator.*

- 3) **Consent forms:** *The IRB Working Group believes that the presently required OSU consent form template is written at a level too high for lower-literacy participants or parents of participants. For research in settings that might require consent from lower-literacy individuals, the PI should be permitted to submit a non-template consent form geared to the appropriate reading level of the participants. Alternatively, a lower-literacy form of the present consent template at a reading level no greater than 5.0 could be developed. If this approach is chosen, the form should be modular, with elements that can be deleted if not relevant to the particular project, to minimize the length of the form.*

I. Community-based research

Community-based research presents a special set of challenges for IRB review. Some of the issues that arise are similar to those encountered in educational research and humanistic research, as described above. There are also considerations that parallel those in international research. In particular, issues involving engagement of community collaborators, waivers of informed consent, open-ended interviewing, translation of materials, training of collaborators,

and extending the approval of the OSU IRB to cover the community performance site and collaborators may be encountered. Investigators should be made aware of options to execute Individual Investigator Agreements, to provide alternative human subjects training in situations where the CITI course is not an option, and to specify how the involvement of individuals in the community is or is not part of their daily job responsibilities. Given the increasing emphasis on outreach scholarship at OSU, it is important to find ways to facilitate community-based research projects. It is also important for investigators to understand the available options in putting together a protocol for community-based research.

J. Appeal mechanisms

If an investigator disagrees with an IRB determination, requested modification, or a study-specific finding, the investigator can appeal the decision. Investigators already have the ability to attend meetings of the IRB at which their protocols are discussed and/or to request a meeting with the IRB chair, the full Board, or a member of the ORRP staff to address issues raised in an IRB review. Researchers also have the right to appeal to the Institutional Official if they believe that the IRB did not follow policy or that the investigator did not receive adequate due process from the IRB. However, many investigators are not aware that these options exist, and no formal appeal process is specified on the ORRP website. It is important for investigators to know what their options are when they question a set of recommendations from the IRB or from ORRP staff. *The Working Group urges ORRP and the IRB Policy Committee to find ways to inform investigators about these options.*

K. Role of the IRB in evaluating the quality of science in proposals

Federal regulations require IRBs to evaluate research protocols and ensure that the design of the study is consistent with sound scientific principles, ethical norms, and regulatory requirements. Some individuals have argued that scientific flaws in a protocol, whether major or minor, constitute harm to the subjects who participate in that study. However, there are two problems with such an interpretation.

First, non-experts in a particular research field may not be well informed about scientific conventions for that field, and might judge a protocol to be scientifically “flawed” when it is not. This is a particular concern for research in the areas served by the Behavioral and Social Sciences IRB, where the research topics often address significant individual and social problems on which many individual IRB members have opinions. When the research has received federal funding, it is clear that a community of scholarly peers has deemed the research to have scientific merit. Even when not externally funded, research proposed by highly trained individuals in a field (i.e., faculty members) should be assumed to be methodologically sound.

Second, even protocols with small scientific flaws can still provide valuable scientific data. The members of the IRB should be concerned primarily with protecting the safety and welfare of the human participants, and should evaluate the scientific content of protocols in the context of the risk/benefit ratio of the research. For example, even studies that promise a relatively small benefit can create a favorable risk/benefit ratio when the accompanying risk is minimal.

Training of IRB members should emphasize the differences in research conventions across specialization areas, such that members are predisposed to respect the scientific knowledge of faculty investigators in specialties different from their own and not “second-guess” the science. In addition, training should instruct the IRB members to focus on the risk/benefit ratio of a particular protocol.

II. RECOMMENDATIONS FOR STAFFING

One major problem that has been identified in many of the recent difficulties encountered by faculty investigators in obtaining successful review of their protocols is inadequate communication between investigator and ORRP staff members in the protocol submission process. Some of these problems clearly arise from the huge workload borne by ORRP staff in shepherding the large number of IRB protocols that are active at any given time across the university through the system. A second problem relates to a lack of common knowledge in the interaction—the investigator is not fully informed about processes, procedures, forms and regulations governing human subject research at OSU, and the staff member is not well informed about research conventions in the behavioral and social sciences and humanities. What is needed is an interface between the investigator and the IRB that can facilitate research rather than impede it, while simultaneously ensuring that human subjects are protected and that the work goes forward in compliance with necessary federal regulations.

Specific recommendations from the IRB Working Group include:

- 1) ***Continued improvement in the written and oral communications of ORRP staff with individual investigators.*** We recognize that there has already been a marked change in this area, such that ORRP staff are oriented toward providing assistance that facilitates the investigator’s research. Of particular note are the main campus office hours now offered by ORRP staff for students working on protocols. We are pleased with the progress that has already occurred and look forward to continued efforts in this direction.
- 2) ***An assessment of resources in the ORRP office.*** The volume of protocols flowing into the ORRP office and on to the IRBs has increased substantially in recent years. University-wide, there are over 3500 currently active protocols; approximately 1000 of these are overseen by the Behavioral and Social Sciences IRB. A substantial percentage of these protocols come from the College of Social and Behavioral Sciences and from the College of Education and Human Ecology. Smaller percentages come from other colleges, including Arts, Humanities, Social Work, Nursing, Public Health, Optometry, Engineering, Math and Physical Sciences, Business, and Biological Sciences.
- 3) ***The Working Group recommends that consideration be given to the addition of individuals who work directly with investigators in these areas to assist them with the IRB process.*** Concerns have been raised that individuals who work only for the

ORRP will not have the background necessary to understand research methodologies in particular areas, but that individuals who work only in the colleges will not have the necessary connection to ORRP to ensure against problems with submitted protocols. Thus, a model that shares the funding of these individuals between colleges and the Office of Research might allow the selection of individuals who can address both of these concerns. Colleges should be encouraged to participate in such joint positions to the degree that their constituents (faculty and students) generate IRB activity and would benefit from such assistance.

- 4) ***The Working Group also recommends that ORRP and investigator-oriented individuals work together to develop a resource list of protocols of various types (e.g., community- and school-based, international, involving protected populations, waiver of documented consent) that have been approved.*** Currently, there is a tremendous amount of guesswork and “reinventing the wheel” on the part of investigators in submitting IRB protocols. Access to descriptions of approved procedures would facilitate proposal preparation and potentially increase the amount and quality of research produced at the University, and might provide a set of precedents that will facilitate and increase the consistency of review efforts by IRB members as well.

III. EDUCATIONAL OUTREACH RECOMMENDATIONS

In talking with faculty and students in our respective units, the Working Group learned that many faculty and students are not informed about forms, policies, and procedures that are required for IRB approval. Indeed, some faculty members are not aware that their research is subject to IRB review and approval under OSU interpretations of the federal regulations. This situation requires additional educational effort. ***First, the ORRP website needs improvement so that policies, procedures, and forms are easily accessible by users.*** The addition of new staff, as described above, who can serve as an interface between investigators and the IRB should also facilitate this. However, improving the web interface could also reduce the need for hands-on assistance from staff.

The IRB Working Group also strongly supports the implementation of an electronic process for protocol submissions. The move to an electronic submission process should prove extremely helpful, if links to forms and policies are made at appropriate points.

Second, it will be necessary to hold meetings with faculty in different colleges to provide information about the IRB approval process so that new information can be provided directly to researchers. These meetings should not be generic “training” sessions, but should include faculty from the Working Group, IRB members, IRB Policy Committee members, and ORRP staff. It is especially important that these meetings be adapted to the concerns of different kinds of researchers, notably those in Colleges such as Arts, Humanities, and Education and Human Ecology, where the IRB process might still be seen as new and unfamiliar. Further, sessions for students should be increased, with topics generated in consultation with faculty in the appropriate areas. In conjunction with this, some mechanism is needed to reach faculty who

cannot attend these meetings. In the long run, it is important to have a climate in which new faculty and students are “socialized” by their colleagues in how to navigate the IRB approval process at OSU.

It is also vitally important that there be a means of communication back to the ORRP and IRB from concerned faculty and students. Although the IRB Working Group has addressed many issues raised by investigators, we clearly have not addressed all of them. Additional concerns are likely to arise at later times. ***Thus, a mechanism for feedback from investigators and for addressing concerns raised in this process must be established.***

IV. OVERSIGHT AND IMPLEMENTATION OF WORKING GROUP RECOMMENDATIONS

Three important issues must be considered in going forward. First, the recommendations of the IRB Working Group should be communicated to all faculty and students at OSU. Second, the policy guidance suggestions in this report should be reviewed and discussed by the IRB Policy Committee and, wherever possible, be incorporated into policies and procedures that can be adopted in human subjects review. Finally, a mechanism for providing increased transparency and communication between the IRB Policy Committee, ORRP, the Office of Research and the faculty should be developed to ensure that the process of addressing the Working Group’s issues and suggestions does not stall.

The IRB Working Group plans to make its recommendations available to all faculty and students at Ohio State. ***The report will be communicated via email with links to a website, and visits to meetings for faculty and students across different colleges by members of the Working Group will be set up for any college or department that wishes to have such a meeting.***

The task of creating and implementing IRB and institutional policies and procedures that address the Working Group’s suggestions is formidable. ***To make this task more feasible, the Working Group recommends that its chair engage the College Research Officers to identify faculty from the colleges who can provide special expertise to the IRB Policy Committee and ORRP staff, to assist in crafting policies and procedures that address the Working Group’s suggestions and recommendations.***

As noted above, it is also important that there be continuing transparency and communication of IRB policy and procedure development among the faculty, the Office of Research, the IRB Policy Committee, and ORRP. ***To ensure that such consideration and implementation occurs, we recommend that an ad-hoc subcommittee of the University Research Committee be appointed for this purpose. This subcommittee should receive regular reports from the IRB Policy Committee regarding the development of new policies related to the Working Group’s recommendations and suggestions, and from the ORRP staff regarding progress in staffing, website development, and electronic submission procedures.***

In the longer term, it is important for the University Research Committee to participate actively in the human subject protection program at Ohio State, and to assess and suggest

additional improvements to the operations of ORRP and the IRB. *We strongly encourage the University Research Committee to set up a means to do so.*

CONCLUSION

Substantial and significant concerns raised by faculty brought about the formation of the IRB Working Group for research in the Behavioral and Social Sciences. We have attempted to address many of these concerns in our work, by identifying issues for consideration and making policy suggestions to the IRB Policy Committee. These include specific recommendations for changes to OSU policies, staffing assessments, and educational outreach. Thus, we urge the individuals and groups involved in guaranteeing the safety of the human participants in our research continue to improve communications with each other, to ensure both the protection of human subjects and the facilitation of important research efforts.



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To: Members of the Ad Hoc Committee to Address Faculty Concerns Regarding the Social and Behavioral Sciences Institutional Review Board

From: Robert McGrath, Senior Vice President for Research Allan Silverman, Chair, Faculty Council

Subject: Charge to the Committee

Date: June 30, 2006

Background:

Recently, approximately 160 faculty members from the College of Social and Behavioral Sciences (SBS) signed a petition that was delivered to the Office of Research (OR) voicing serious concerns about current practices of the Social and Behavioral IRB at Ohio State. The petition outlined what some faculty members considered to be systemic problems with the IRB operation and decision-making processes for non-biomedical human subjects protocols. The concerns addressed in the petition were expressed primarily, but not exclusively, from the Colleges of Social and Behavioral Sciences and Education who conduct human subjects research involving minimal or no health-related risk to participants.

In response to the petition, the Office of Research leadership responsible for administering compliance on human subjects research met with the SBS faculty to exchange information regarding current practices of the SBS IRB. In addition to myself, the OR leadership consisted of Dr. Doug Kniss, Senior Associate Vice President for Research, Dr. Todd Guttman, Associate Vice President for Regulatory Affairs, and Dr. Judy Neidig, Director, Office of Responsible Research Practices (ORRP). In addition, during the past month, the OR leadership also met on several occasions with faculty representatives from the Senate Steering Committee, the Faculty Council leadership, the University Research Committee and the President's and Provost's Advisory Committee, all of whom have expressed similar concerns. In May, Dr. Kniss and I met with the deans and associate deans for research from the colleges whose faculty utilize the SBS IRB (in particular, the College of Social and Behavioral Sciences, the College of Education, the College of Human Ecology, the Colleges of the Arts and Sciences, the College of Humanities, the College of Nursing, and the College of Food, Agriculture and Environmental Sciences).

Action Plan and Committee Membership:

In consultation with the aforementioned groups, the following action plan was formulated. To avoid unnecessary duplication of effort and to insure effective communication among all constituencies, a single, ad hoc committee jointly sponsored by the Faculty Council and the Office of Research is being established and charged as outlined below. Human subjects research topics that will be addressed by the committee include, but are not limited to, large survey research, ethnography, classroom and field educational research, research involving minors, and research conducted at non-university sites – both domestic and international.

Dr. Jan Weisenberger, Associate Dean for Research in the College of Social and Behavioral Sciences, has kindly agreed to chair the committee. The committee membership (listed below) will be comprised of faculty members who conduct research in various aspects of social and behavioral science involving human subjects. As you are aware, you have been nominated by your college to serve on this important committee and I want to thank you in advance for agreeing to do so.

The committee membership will also include ex officio members (the Senior Associate Vice President for Research, the Associate Vice President for Regulatory Affairs, the Director of the Office of Responsible Research Practices, and the chairs of the SBS and Biomedical IRBs) who collectively will provide essential information on regulatory guidelines governing all human subjects research and best practices for operational procedures within the other Ohio State IRBs from the which the SBS IRB may benefit.

The committee membership has been selected to encompass representation from each of the major research areas mentioned above, while maintaining the committee size at an operationally efficient level. However with so many faculty members wishing to voice their concerns, we ask the committee to consider organizing town hall meetings focused on particular themes, or to utilize other mechanisms which will promote input from all concerned faculty members and provide for open dialogue that addresses the specific concerns expressed by the university community.

Charge to the Committee:

The Faculty Council and the Office of Research request that you give careful consideration to the operational practices and decision-making procedures for the Social and Behavioral Sciences IRB and subsequently provide recommendations for improvement. In particular, we request that you:

1. Assess the current landscape for human subjects research that is reviewed by the SBS IRB;
2. Assess best practices among all IRBs at Ohio State;
3. Assess best practices for SBS IRBs at peer institutions;
4. Reach out to engage a large cross-section of faculty conducting human subjects research from many different constituencies;
5. Clearly define the specific concerns of faculty members engaged in human subjects research that is reviewed by the SBS IRB;
6. Evaluate the practices within ORRP that directly relate to the SBS IRB;
7. Facilitate communication between faculty, the compliance staff and the SBS IRB;
8. Assist the OR compliance staff with assessing the practical impact of specific regulatory interpretations on the conduct of human subjects research;
9. Ensure that the rights and health of all human subjects participating in research conducted at Ohio State are fully protected;
10. Make recommendations to the Senior Vice President for Research for improved IRB practices and policies that address the stated concerns of the faculty, while ensuring that the culture and practice of compliance for the conduct of human subjects research at Ohio State adheres to all applicable federal regulations and guidelines.

The recommendations of the ad hoc committee will be invaluable to improving the operation of the SBS IRB. However, it is important to note that federal guidelines clearly define the IRB as the definitive authoritative body on campus for review and approval of protocols for the conduct of human subjects research. Therefore, the recommendations provided by the ad hoc committee should not be perceived as binding upon the IRB or as providing oversight of the IRB's final decisions.

I request that the committee strive to conclude its deliberations by December 1, 2006. Implementation of recommendations provided by the ad hoc committee will occur in cooperation with the standing IRB Policy Committee, which provides advice for addressing faculty concerns and operational practices for all three of Ohio State's IRBs.

Thank you again for your willingness to serve on this important committee. I am confident that your careful consideration of the complex issues at hand and your subsequent recommendations will greatly aid in establishing a culture and a practice of compliance that is both efficient and supportive of all researchers utilizing the Social and Behavioral IRB.