Office of Regulatory Compliance and Safety
Review Committee

Recommendations submitted to

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Office of the President

by

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Office of Regulatory Compliance and Safety Review Committee

The Office of Regulatory Compliance and Safety (ORCS) Review Committee was convened by Dr. David Shaw, Vice President for Research, on August 23, 2010. The membership of the committee included:

- Kari Babski-Reeves, Industrial and Systems Engineering, Chair
- Roger Baker, Facilities Management Administration
- Anna Chromiak, Biochemistry and Molecular Biology
- Janet Donaldson, Biological Sciences
- Brendon Hale, Kinesiology
- Mark Lawrence, College of Veterinary Medicine Basic Sciences Department
- Joe Massey, Plant and Soil Sciences
- Donna Rogers, Institute for Clean Energy Technology
- Peter Ryan, Associate Provost for Academic Affairs

The dual charge of the committee was to:

1. Review policies from ORCS, specifically focusing on how ORCS can meet compliance regulations and at the same time improve the support to research programs at MSU; and
2. Review the current structure of ORCS, specifically focusing on whether having the compliance area and the safety/environmental area combined is the optimal structure.

The committee was also asked to benchmark ORCS against peer institutions and provide an evaluation of these findings in relation to MSU.

Benchmarking University Selection

The committee met to identify universities for benchmarking. A review of current peer land grant universities was reviewed (Appendix A) and the following universities were selected for benchmarking:

- Auburn University
- Colorado State University
- Pennsylvania State University
- University of Arkansas
- University of Mississippi Medical Center
- University of Tennessee—Knoxville
- University of Wisconsin—Madison

The following report is presented as two distinct sections. Section 1 details the review of ORCS Policy and Procedures. Section 2 details the review of the ORCS organizational structure.
Section 1: Review of ORCS Policy and Procedures

The ORCS consists of general safety for the MSU campus as well as regulatory committees that oversee research conducted on campus. Because a review of all policies and procedures from both a safety and research compliance perspective could not be conducted in a timely fashion, the committee elected to focus only on research compliance in the review process. This by no means is meant to convey the impression that safety is not, or should not, be a priority or be systematically reviewed. This decision was to focus the committee’s efforts such that recommendations could be provided in a timely fashion.

Data Collection Methods
The ORCS review committee took several steps to arrive at recommendations to improve the role of ORCS in the support of institutional research, regardless of funding source. First, the ORCS review committee reviewed the policies and procedures of three compliance committees on campus: Institutional Review Board for Research Involving Human Subjects (IRB), Institutional Biosafety Committee (IBC), and Institutional Animal Care and Usage Committee (IACUC). The Radiation, Chemical and Laboratory Safety Committee (RCLS) was not reviewed as current policies are driven solely by federal and state mandates. The policies and procedures were benchmarked against peer and peer plus universities. Second, the ORCS review committee reviewed the results of the survey distributed by ORCS summer/fall of 2010. Third, a series of interviews with ORCS staff, compliance committee leaders, and compliance committee members were conducted. Data from these methods were used to develop the list of recommendations provided below. Additional information on the data collection methods is briefly provided below.

Compliance Committee Policy and Procedures Review
The policy subcommittee initially downloaded all MSU committee policies and procedures (PPs), as posted on ORCS.msstate.edu. These PPs were benchmarked against the peer and peer-plus universities identified above. The subcommittee met to discuss each of the policies. During this discussion a number of policies and procedures were identified for non-review for the following reasons:
1. The PP was not viewed as problematic (per our efforts or other sources of data).
2. The PP was driven by a federal regulation.

The specific policies and procedures not reviewed for each compliance committee are listed below:

IRB
• Conflict of Interest for IRB Members or Consultants
• Consent, Parental Permission, and Child Assent
• Consultants to the IRB
• Convened IRB Review of Research
• Convened IRB Review of Research
• Emergency Use of a Test Article on Human Subjects
• Humanitarian use of a Device on Human Subjects
• Records of the IRB
• Significant Risk and Non-significant Risk for a Medical Device Study
• Unanticipated Problems Involving Risks to Participants or Others
• Use and Ownership of Existing Human Subjects Data Sets
• Vulnerable Participants - Children
The ORCS survey results were provided to this committee. As ORCS had provided a listing of actions taken to address the deficiencies identified through this survey to Dr. Shaw directly, no further review of these results will be presented in this document.

Interviews
To facilitate the interviews, a set of questions was developed by the ORCS review committee. These questions were targeted toward the issues raised by the committee, the ORCS Survey Results, and the
Research Infrastructure Committee report (see Section 2 below). Interviewees were provided with a copy of the questions prior to meeting with the committee. Written responses from each interviewee are provided (Appendix B). The following meetings were held with the following:

1. Interviews with Program Officer, Chair, or equivalent
   • Kacey Strickland (September 2010)
   • Terry Coggins (September 2010)
   • Alicia Musselwhite (January 2011)
   • Jonathan Miller and Dwight Hare, IRB (December 2010)
   • Patricia Cox, IBC (October 2010)
   • Trina Smith, IACUC (not held due to weather)
2. Interviews with Compliance Boards
   • IRB (February 2011)
   • IBC (February 2011)
   • IACUC (February 2011)

Recommendations:

General Recommendations

1. Development of an Advisory and Appeals Committee (AAC). The roles of the advisory and appeals committee should include, but potentially will not be limited, to the following:
   a. Review, disseminate, and communicate any compliance committee policy and/or form changes prior to implementation. This is to allow the larger university community to become fully aware of any policy and/or form changes that could impact current or pending research protocols.
   b. Review and rule on appeals for regulatory compliance rulings (including but not limited to protocol modification(s) required for approval and non-compliance recommendations and rulings. (NOTE: the AAC will have no authority over protocol approval or disapproval. Rather, they can rule that protocol modifications required prior to approval are to be enforced or not.)

An example policy related to the formation of an AAC from the University of Wisconsin-Madison is provided in Appendix C. Note that this policy is for UWMs IRB. The ORCS review committee is suggesting that this Advisory and Appeals Committee span all regulatory compliance committees. One rationale for the establishment of this committee stems from disruptions in current projects due to policy and/or form changes being retroactively enforced. The ORCS committee recognizes that there are instances where federal regulations mandate that changes be made. By disseminating these required changes through this committee and providing a date for implementation, researchers can more adequately plan to make any necessary changes. For policy/form changes that are not federally mandated, this provides the university community the opportunity to provide feedback to the regulatory compliance committee suggesting a recommendation. Additionally, it will allow the VP for Research to review potential impacts on the research mission of university for non-federally regulated changes.
A second rationale for role (b) is that an improved appeals process should be implemented. Currently appeals are reviewed by the committee making the decision that is being appealed. While it is recognized that protocols can only be approved by these committees, a mechanism should exist for appeals to be heard by a neutral party. This could include cases where the PI disagrees with protocol revisions or disapproval, or for larger issues such as non-compliance. The ORCS review committee recommends the development of an standing university committee to be led by the VP for Research and Development (non-voting member), with 12 members from the university community (3 per regulatory compliance committee—IRB, IBC, IACUC, RadSafety) not currently serving on a compliance committee but with sufficient expertise of knowledge of the committees responsibilities (e.g., former members). This committee would meet as needed (or monthly).

2. **Regulatory Compliance Officers (i.e. those that report to the ORCS director) Should Not Serve as Voting Members on the Compliance Boards.** Two compliance committees cited the primary reason for including compliance officers as voting members is to meet quorum. It is commendable that the committees consider meeting quorum important because this prevents delays in protocol approval. However, this committee feels it is a conflict of interest for the executive (enforcement) arm of ORCS to vote in policy-making and protocol review decisions. Another committee indicated that voting privileges were used to minimize the burden of reviews to the committee members. It is because of this that the review committee would like to suggest that this recommendation only relate to issues that require full board review (thus allowing officers to make initial assessments of risk and determine whether a protocol can be approved without the need of full board review).
   a. Currently, the Director of ORCS attends all committee meetings. This practice should continue in order to minimize lack of oversight and miscommunication between the four regulatory compliance committees. Additionally, this helps to ensure institutional memory across changing boards.

3. **Implement an Electronic Submission System for Applications.** For a number of years, the use of an electronic system for submission of protocols has been identified as a need. The regulatory compliance committees and ORCS have attempted to identify a viable solution for electronic submissions using commercial packages. ITS has indicated signature verification as the primary deterrent to the implementation of such a system. In discussion with peer universities, most, if not all, use an in-house developed electronic submission system. MSU resources should be devoted to the development of an electronic submission system. The purpose of the system is not only for submissions (which hopefully would reduce the burden on the researchers in the development of protocols and also ORCS personnel) but allow for tracking and notification of all protocols’ statuses related to a particular principle investigator.
   a. A part of the electronic system should be the development of a single application that would allow the researcher to select which committee(s) to submit the application. As a number of the items requested by the committees are similar (e.g., researchers,
training, sites of work, purpose, methods, etc.), this would help to reduce the burden on
the researcher and also to provide cohesiveness between protocols that cross two or
more committees for approval.

b. It is the committee’s recommendation that electronically submitted protocols be linked
to the existing database (or move this information to a new database) that contains
training information and is linked to personnel’s MSU Net ID and password.

4. **Improved Means for Meeting Quorum Should be Implemented.** Recommendations include:
   a. Implementing alternative committee members for the primary committee members
      (similar to how MSU IRB operates). If the primary member is unable to attend the
      meeting, the secondary member can attend and vote in his or her stead. As is true in
      the IRB, alternative members are voting members only for specific individuals, as
      membership is based on expertise.
   b. Allowing members to attend meetings from remote sites (off the main MSU campus) via
      teleconferencing or videoconferencing when possible. Again, the IRB has been
      proactive in establishing a teleconference line and uses this mechanism often.

5. **Term Limits Should be Placed and Enforced on Voting Members for All Regulatory Compliance
   Committees.** It is suggested that a limit of two consecutive terms (six years) be implemented.
   This is to reduce the loading on individuals electing to serve on the committees, and to increase
   university participation and knowledge of the roles and responsibilities of the compliance
   committees. Individual committee members can serve a third term only if serving as the acting
   committee chair/co-chair when their second term expires. This individual will need to be
   replaced immediately upon fulfillment of their responsibilities as committee chair. However,
   this could be subject to review by the AAC if the situation is deemed necessary.

6. **Recommendations for New or Replacement Compliance Committee Members Should be
   Made by Current Committee Members.** Burden for identification of new members should not
   fall solely on the compliance committee chair or regulatory compliance officers.

7. **Identification of Committee Chair Replacements Should be Identified at Least 1 year in
   Advance.** All committees should identify their Chair-elect a minimum of 1 year in advance of
   their term. This is to allow the individual time to prepare for serving in that capacity. The
   university should designate funds to allow this member, and others as funding is available, to
   attend relevant conferences for appropriate education and training experiences.

8. **Use of Federal Regulation Verbage (or copy of the federal regulation should be provided) for
   all Regulatory Compliance Policies and Procedures.** This is to reduce confusion and individual
   interpretation of federal guidelines in the performance of compliance committee duties.

9. **Creation of Process Flow Chart for Review Process Available Online for All Committees.** To
   educate and minimize confusion with the university community, the four regulatory compliance
offices should develop a detailed flow chart detailing the steps, alternative routes/review levels for a protocol.

Committee Specific Recommendations

IRB

1. **Implement Time Limits for the Review of Protocols Based on Level of Risk.** The time required to review protocols is still identified as the single largest issue associated with IRB protocol reviews. The IRB has instituted a DashBoard which allows researchers to track a protocol through the review process. At the time of this review, sufficient time had not passed to determine the amount of time protocols typically spends within the compliance office. Based on conversations with other universities and experiences at other universities, the committee recommends the following time limits be instituted for the review of protocols (except under times of extreme workload):
   - a. Administrative (Exempt) Review—10 working days
   - b. Expedited Review—15 working days
   - c. Full Review—20 working days (or 1 month)

   These time limits only apply to the initial response of review by the IRB to the researcher.

   It should be noted that the ORCS review committee found the IRB to be extremely concerned about this issue. When researchers indicate the need for a rapid response, the IRB staff are extremely accommodating. Therefore, it is not a finding of this committee that in general the IRB delays research unduly. However, because a number of researchers on campus are requesting immediate review of protocols, protocols without time constraints may be pushed lower on the scale. A review of the practice of the IRB to push protocols up in priority needs to be considered. Often there is sufficient time between notification of an award and receipt of funds for researchers to apply for and receive approval for funded research protocols.

2. **Elimination of Student Protocol Submissions.** There are two reasons for this recommendation. First, currently, the IRB serves an educational function in allowing students to submit research protocols. The ORCS review committee understands this mission and finds it commendable. However, protocol submissions should be the responsibility of the faculty and as such all protocols should be submitted by faculty. Second, findings of this committee indicate some faculty members are currently not fulfilling their supervisory role in the review of submitted applications by students. Therefore, editing and reviewing activities outside of determining risk and benefit (the role of the IRB) are being completed by the IRB staff. As the IRB has a number of responsibilities, it is not appropriate for IRB staff to be acting as a mentor to student researchers. Faculty should be held accountable for their students research.
1. **Efforts Should be Continued to Reanalyze the Risk Assessment of Microorganisms Currently used on Campus.** Historically, the IBC has treated certain BSL-1 organisms as BSL-2 due to agricultural risks. The committee would like to commend the IBC on realizing this is an issue and would like to encourage this same approach be extended to additional organisms. However, this may not be an appropriate practice for all protocols. The VP for Research should prescribe the stance of the university, to the extent possible, on this issue. Beyond that, the IBC will need to justify the increased precautions for a BSL-1 organism to BSL-2 status.

2. **Implementation of an Annual Meeting that is Open to all IBC PIs to Discuss Additions, Deletions, or Modifications to Standing Policies/Forms.** This recommendation may coordinate with the AAC described above. However, if the AAC is not formed, then this recommendation will need to be implemented independently. Currently, it is perceived that changes to policies/forms occur irregularly and sometimes without clear and/or adequate justification (e.g., federal or university policy changes). It is necessary for PIs on campus to feel that they are part of the process and to be allowed to provide feedback on proposed changes prior to implementation. In this manner, university researchers can adequately prepare for any required modifications to current or pending protocols.

3. **Teaching Labs Have not Been Historically Considered Under IBC Review and Efforts Should Continue in this Manner Unless Dictated by Federal Regulations.** It is the committee’s recommendation that the BSO continues to ensure that faculty oversight be provided in teaching labs where biological agents are used, ensuring that personnel are properly trained and are effectively monitoring the labs.

   The ORCS review committee recognizes that many of the IBC policies are federally mandated. We found the IBC to be very dedicated to its mission of ensuring MSU researcher compliance with federal and state regulations, and should be commended.

**IACUC**

1. **Efforts Should be Continued to Ensure that Expertise is Included on the Committee to Include Appropriate Coverage of Animal Species and Procedures.** It is also good practice to include a representative from departments that submit protocols regularly. One notable department currently not represented is Pathobiology and Population Medicine. A large animal veterinarian, or similarly qualified individual, is needed due to the agricultural focus of research on MSU’s campus.

2. **Allow Investigators to the Utilize a Developmental Protocol to Develop Methods for Sponsored Research.** As it is often necessary to develop aspects of a program prior to animal testing, the submission and acceptance of a developmental protocol should be sufficient to meet federal requirements for release of funding. Similar mechanisms exist for the IBC and IRB
that allow access to federal funds without having a full protocol approved. The approval does not allow for the conduct of research without a full protocol approval, but does allow access to funds for the developmental phases of the research.

3. **A Program Officer should be Defined for IACUC.** Currently, Ms. Trina Smith is serving as Compliance Administrator. While it appears that Ms. Smith’s duties are consistent with the IRB and IBC program officers (Dr. Cox and Mr. Miller), it is unclear if this is so. This role and administrative responsibilities need to be clearly defined.

4. **Research that is not AAALAC Specific Should not be Forced to be Meet these Requirements.** There are very specific regulations for AAALAC protocols. The current trend on the MSU campus is to increase the oversight of all animal research to conform to AAALAC standards. This is prohibitive to the research enterprise of the university.

The ORCS review committee recognizes that many of the IACUC policies are federally mandated. We did not find, in general, that MSU IACUC attempts to regulate above the federal mandates.
Section 2: Review of the Organization of ORCS

The Office of Regulatory Compliance and Safety (ORCS) review committee reviewed seven peer and peer-plus institutions (listed above, page 2) to determine the structure of both regulatory compliance and environmental, health and safety functions at those universities. Information was compiled as a spreadsheet to assist in reviewing the structure of these programs at these seven institutions. Some of the information in the spreadsheet was determined from university websites, while some of it was determined by personal phone calls to university personnel. In the spreadsheet each university is divided into two columns showing the division of responsibility and reporting lines (Appendix D). By using a spreadsheet we attempted to capture:

1. the reporting lines for directors of regulatory (research) compliance and safety;
2. the areas of service for which an office is responsible;
3. the credentials of the office director;
4. the number of FTE’s for the office; and
5. total student enrollment.

After reviewing the organizational structure of the seven peer and peer-plus institutions, it was noted that, for the most part, the research compliance functions and safety functions are separate and report through two separate reporting lines.

MSU’s Office of Regulatory Compliance and Safety currently serves two broad functions: (1) compliance with regulations that relate to research activities and (2) functions related to environmental regulations and safety. The committee is aware, however, that not all environmental regulations (air permitting, for instance), nor safety functions (exception MAFES) are under the ORCS reporting line at the current time. We will attempt, in this document, to make the case for bringing all regulatory compliance (Environmental, NRC, etc.) and safety functions into a single office.

In our estimation, it is an enormous task for one director to have purview over both research-related compliance and environmental, health and safety functions. After interviewing several personnel in the ORCS and reviewing how other universities divide these functions, this review committee recommends that a Director of Environmental Health and Safety be hired, necessitating that the current ORCS office be divided into two unique offices each with its own director:

- Office of Research Compliance (ORC)
- Environmental, Health and Safety Office (EH&S)

We advocate that the Office of Research Compliance (note name change) remain in the reporting line to the Vice President for Research and Economic Development. The committee recommends that the reporting line for the Environmental, Health and Safety Office be to Campus Operations. Our full set of recommendations, along with rationalizations, follow.

Recommendations:
1. **Institute the Organizations Depicted in the Organizational Charts Provided, Splitting ORCS into Two Offices (EH&S and ORC) Each with Separate Directors that Report at the Vice Presidential level.** Having a separate EH&S office with its own director allows all environmental, health, and safety functions to be housed together with the director being able to focus on EH&S only. This will allow more clarity in operation and long-term planning. The director would most likely be a subject area specialist with the designation of CSP, CIH, CHMM, PE, or CHP who also has the set of management skills necessary for a director position. The director should have at least 10 years of professional safety management experience. The entire campus should be served by the EH&S Office (student housing, teaching, grounds, custodial support, shipping/receiving, facilities, research, MAFES?*) and should be emphasized in the MSU organizational structure to reflect this. (*MAFES currently has two FTE’s involved in safety.)

   a. Safety functions would be pulled from the existing structure, leaving compliance functions that are solely research-oriented in the newly formed ORC. Suggest using the name Office of Research Compliance instead of Office of Regulatory Compliance. This would eliminate the assumption that all regulatory compliance is handled by this office and that all duties relate to regulations. Some regulatory issues would also be handled by the EH&S Office (Nuclear Regulatory Commission, Resource Conservation and Recovery Act, Clean Air Act, etc.).

   b. The research-based committees (IACUC, IRB, IBC, RCLS) would still report through the Office of Research Compliance to the VP for Research and Economic Development.

2. **Include all Environmental Compliance in Newly Formed EH&S.** Bringing all environmental compliance under one Coordinator of Environmental Compliance in the EH&S Office would consolidate environmental compliance to one office and eliminate any ambiguity as to the delegation of duties across campus. Audits from outside regulatory EH&S authorities (Mississippi Department of Environmental Quality, US EPA, Mississippi State Department of Health, Nuclear Regulatory Commission) would be handled by one office.

   a. Bring air permitting, storage tank management, and eventually all environmental responsibilities into new EH&S office.

3. **Create an EH&S Advisory Board.** The purpose of an EH&S advisory board will be to primarily serve as institutional memory of safety for the university and to be an advocate for resources for EH&S. The board will provide a long-term vision for EH&S, will determine needed capabilities, and will determine risks/benefits important to the interests (both immediate and future) of MSU.

   a. Provide feedback and serve as sounding board to EH&S Director.

   b. Assist with policy development, especially where there is no regulatory mandate.

   - Since MSU is not covered by OSHA standards, policies for instituting OSHA-type safety programs should be drawn up by an EH&S Advisory Board.

   c. Board should be composed of persons with experience in safety and environmental issues, an individual who compiles worker’s compensation claims, representation from MSU legal counsel and representation from department heads affected by the policies. This board could also include individuals from the private industrial sector. For example, the board could be composed of the following:

   - Assoc. Provost (e.g., Peter Ryan)
   - Department Head (e.g. Chemistry department head should be a permanent member.)
• Facilities Director
• University legal counsel (e.g., Joan Lucas)
• Centers & Institute Representative
• Safety Professional outside EH&S structure
• Center for Safety & Health (Kelly Tucker)
• Radiological, Chemical, and Laboratory Safety Committee Chair
• Industry Safety Professional representative from outside MSU (?)

Chair = selected from one of the above.
d. The committee recommends that the members of the board hold 5-yr terms (staggered among members) to maintain structure and memory.
e. Minimum of one meeting per fall and spring semester, and at request of the VP or Director.
f. Some policies will be regulatory driven. Others should be drawn up based on frequency of worker’s compensation claims and jobs considered high hazard (electrical, confined space entry, excavation etc.) Policies to be drafted must take into consideration risk to the University:
   1. Health and safety of employees
   2. Financial benefits and costs to MSU
g. Safety programs (including training as a major component) should be tailored specifically to the university climate. A blanket statement that MSU will follow OSHA regulations would probably be inappropriate. The idea of mandating unnecessary policies or requiring excessive paperwork is not the idea. The idea is to protect the university’s personnel and infrastructure.

3. **Determine, with assistance from Advisory Board, if MAFES safety functions should be brought under EH&S umbrella for efficiency and effectiveness.** There currently seems to be a disconnect between MAFES and campus functions. It is the committee’s recommendation that this be further analyzed by the Advisory Board to determine if this is the most efficient mechanism for ensuring safety.

4. **Allocate funds for facilities (non-laboratory) safety issues** (including \$__ K for contractual) since the outlined recommendations encompass more of the MSU campus than previous duties of ORCS.

5. **Allocate funds for air permitting & tank management** (including \$__ K for contractual) if these duties are brought under the EH&S Office.

6. **House all employees in a central office to allow for oversight by the EH&S director and sharing of ideas.** Space would be needed (especially for training) at satellite sites (ex: Facilities). However, the committee believes it is necessary to bridge cohesiveness to compliance and shared space is the ideal method to facilitate this.

**Recommendations Specific to Personnel in ORC and EH&S**
The structure of the MSU Office of Environmental Health and Safety would ideally be composed of several subject area specialists as the proposed organization chart shows.
• The Laboratory/Chemical Safety Officer would hold the credentials of Certified Chemical Hygiene Officer (CHO), or Certified Industrial Hygienist.
• The Facilities Safety Officer would ideally hold the credentials of Certified Safety Professional (CSP).
• The Fire Safety Officer would ideally hold the credential of Registered Professional Engineer (PE).
  o There is the potential for Fire Safety to be combined with Facilities Safety based on recommendations of the Advisory Board and the percent of activities that are contracted out.
• The Environmental Compliance Officer would ideally hold the credentials of Certified Hazardous Materials Manager (CHMM) or Certified Environmental Professional (CEP).
• The Radiation Safety Officer would hold the credentials of Certified Health Physicist (CHP) or Registered Professional Engineer (PE).
• There is the potential for Biosafety SAFETY (fieldwork) functions to be included in the Laboratory/Chemical Safety Officer’s job duties.

Having individuals responsible for various thrusts be credentialed (with specified skill sets) allows the individuals to make much better choices in day to day operations (knowledge and methodology to get things accomplished). This will also accelerate the rate with which issues are addressed by being knowledgeable enough not to require much outside assistance. The caliber of individuals that lead thrust areas has a direct impact on the reputation of the EH&S Office and impacts the university financially by having qualified individuals responsible for areas where fines from regulatory authorities are a possibility.

1. **Thrust Area Specialists Should have Complementary Sets of Skills with a Certain Amount of Overlap, Allowing for Some Redundancy in Duties/Skills.** If one person resigns or retires, the other personnel in the office would be capable of carrying out the necessary duties of this vacancy until a new hire could be made.

2. **One of the Officers Could Act as the Director of Environmental Health and Safety or a Separate Director Could be Hired.**

3. **Hire a Fire Safety Officer to coordinate all fire prevention activities.** This person should be a registered Professional Engineer (PE) with at least 5 years of professional safety management experience.

4. **Utilize someone in the current ORCS structure to function as Facilities Safety Officer.** This person needs to be an accredited Certified Safety Professional (CSP) with at least 5 years of professional safety management experience. Alternatively, hire someone to fill this position.

5. **Utilize someone in the current ORCS structure to function as Laboratory/Chemical Safety Officer.** This person needs be an accredited Chemical Hygiene Officer (CHO) or Certified Industrial Hygienist (CIH) (preferable) with at least 5 years of professional safety management experience. Alternatively, hire someone to fill this position.

6. **Determine the appropriate FTE allocations for regulatory compliance and safety personnel.** FTE allocations should be evaluated regardless of any proposed or existing structure.

7. **Determine whether Biosafety fieldwork (laboratory inspections, etc.) should be a part of the Laboratory/Chemical Safety Officer’s duties to avoid redundancy in lab inspections.**
8. Include a Records Specialist in the structure, likely utilizing someone in the existing structure of ORCS. A Records Specialist would maintain all regulatory required records, inspection records, shipping/receiving, dosimetry, transportation records (DOT and Air Shipper), waste shipment, etc.

**Proposed organizational chart for EH&S:**

The proposed organizational chart is the committee’s best estimate for FTE’s. If an Advisory Board is formed, it could be of great assistance in determining where the university should head to have an effective EH&S program. Current employees of ORCS could be utilized in the proposed structure. If necessary, the current employees could acquire training in order to elevate competency in areas seen by the university to be important.
Outline of Roles & Responsibilities of EH&S Office:

The MSU Environmental, Health and Safety Office would have the following charges:

- Ensure MSU’s compliance with applicable environmental regulations.
- Ensure MSU’s compliance with applicable fire code regulations and provide a comprehensive fire safety program.
- Provide risk assessment/management for MSU.
- Assist with emergency preparedness.
- Ensure MSU’s compliance with DOT/International Air regulations.
- Promote safety in laboratory settings.
- Promote safety in non-laboratory settings.
- Provide radiation safety for lab and non-lab settings.

Potential Job Responsibilities/Areas of Expertise for EH&S Personnel:

Facilities Safety Officer:

- Interface with building/demolition contractors (i.e. keep an eye on them)
- Develop safety and training programs for the following (not an exhaustive list):
  - Building Egress
  - Heavy Equipment
  - Cranes
  - Powered Industrial Trucks (Forklifts, etc.)
  - Ladders and Scaffolds
  - Fall Protection
  - Hand and Power Tools
  - Trenching and Shoring
  - Confined Spaces (includes air monitoring)
  - Electrical Codes/Safety
  - Arc Flash
  - Control of Hazardous Energy (Lockout/Tagout)
  - Hot Work/Welding
  - Steel Erection
  - Walking/Working Surfaces
  - Occupational Noise (and monitoring)

Fire Safety:

- Coordinate all fire prevention related activities:
  - Code compliance
  - Extinguisher contracts
  - Sprinkler systems and coordination with architect for design needs
  - Alarm systems
  - Building inspections
Emergency Evacuation Plans
- Fire drills
- Training

Environmental Compliance:
- Resource Conservation Recovery Act (RCRA) (Hazardous Waste, Brownfields, Underground Storage Tanks, Subtitles C and D)
- Toxic Substance Control Act (TSCA) (PCB’s, asbestos, radon, lead based paint)
- National Environmental Policy Act (NEPA) (Environmental Impact Statements)
- Federal Insecticide Fungicide and Rodenticide Act (FIFRA) (Pesticides)
- Clean Air Act (CAA) -Air Permits
- Clean Water Act (Spill Prevention, Control, Countermeasures (SPCC), Stormwater Pollution Prevention Plan (SWPPP), Concentrated Animal Feeding Operations (CAFOs), NPDES (National Pollutant Discharge Elimination System) -Lift Stations)
- Training (Hazardous Waste)

Radiation Safety:
- Approval of purchasing radiological materials
- Oversight of shipping and receiving of radiological materials
- Oversight of research utilizing radiological materials
- Disposal of radiological materials
- Monitoring of laboratories utilizing radiological materials
- Administration of MSU radiological broad scope license
- Dosimetry
- Training

Biosafety:
- Agent classification
- Risk assessment
- Assistance with laboratory certification
- Monitoring of labs
- Disposal of biohazardous waste
- Oversight of shipping/receiving biohazards
- Training

Laboratory/Chemical Safety:
- Chemical segregation, storage, and safe use
- Ventilation (general and local exhaust) and ventilation design for various projects
- Air monitoring of chemical exposures
• Compressed gases
• Material Safety Data Sheets
• Respiratory Protection and Chemical Personal Protective Equipment
• Use of lasers in laboratory
• Training
Proposed Organizational Chart for Research Compliance Office:

VP for Research

Director
Office of Research Compliance

IACUC
Compliance Administrator:

IRB
Program Officer:

IBC
Program Officer:

Committees:
IACUC
IRB
IBC
RCLS
Appendix A: Listing of Potential Benchmarking Universities

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Appendix B: Question Sets for ORCS Staff and Compliance Committees

Questions for Kacey Strickland visit 9/30

1. What are the strengths as you see them with the current ORCS structure?

   A strength of the current structure is the sharing of personnel resources such as only having one director and one receptionist. Also, having safety report to the VP for Research may facilitate an increased sensitivity for faculty members need to conduct research.

2. What are the challenges as you see them with the current ORCS structure?

   Sharing of monetary resources across programs that are vastly different. We are basically two departments that are each underfunded.

   Additionally, it was noted there are finite funds which essentially dictates a risk assessment in deciding where to focus efforts and resources. There are different priorities for compliance than for safety. Currently safety expenditures are somewhat reactive because it has been mostly overlooked by the University until recently whereas the compliance areas are more established and expenditures keep these programs at status quo. Therefore, IACUC and IRB often get moved from the top of the priority list.

   Note: In addition to the ORCS budget, for the past two years there is a separately funded $33,000 budget for safety from the VP for F&A. The funds must be requested annually so there is no guarantee these funds will be available next FY.

3. What are the strengths with having MSU policies that exceed federal regulations, as they pertain to your ability to support research on campus and your ability to do your job?

   Perception/reputation-potentially the public perception of research efforts at Mississippi State. May help avoid negative publicity.

   External Funding—there is no way to measure the impact of this on the ability to attract external funds.

   Protection of MSU and personnel and the environment. This may also help avoid negative publicity.

   Lessens confusion regarding when a project is required to have approval or not.

4. What are the challenges with having MSU policies that exceed federal regulations, as they pertain to your ability to support research on campus and your ability to do your job?

   Increased workload for those that must comply as well as for ORCS personnel to review.
Different interpretations of non-prescriptive policies and regulations (e.g., when the IACUC starts inspecting non-regulated animal facilities there is concern that requirements will be based on regulated facilities).

Some faculty resistance/ill feeling. ORCS may be “blamed” when policies exceed regulations but usually these decisions are approved by someone (committee or VP) outside of ORCS.

There was discussion about Lab Safety being a process that isn’t based on regulation; therefore, the inspections are only intended to provide recommendations for best practice. It was noted by a committee member the inspection process might be misinterpreted by the lab practitioner and be intimidating. There was additional discussion about the need to ensure proper feedback processes were in place to allow individuals being asked to comply with policies or regulations to clarify the requirements and recommendations. (Note: the email that accompanies the lab safety inspection report was revised to stress this point… “These reports provide laboratory safety recommendations for your laboratory... These recommendations are based on fire code regulations, good laboratory practices (GLP), and other government safety entities... If you have any questions, please contact either Alicia Musselwhite (325-4607) or Erin Kiess (325-8543).”)

5. What time issues do you see as the result of the current structure?

6. What time issues do you see as a function of having policies exceed federal regulations?

  More time required to complete work-initially, but hopefully less time and money spent on damage control.

7. If you had a choice, what would the ideal structure of the ORCS look like?

  I suggest that the committee do some benchmarking to investigate our peer and peer-plus institutions. But I believe all safety functions could be consolidated across campus.

  It was stated there are currently four units on campus who have safety oversight responsibilities. These were Facilities Management, Housing, MAFES, and the ORCS.

  a. Who would each branch/individual report to?
    Typically compliance reports to VP-Research; EH&S reports to VP-Finance.

  b. What do you think are the appropriate credentials for individuals serving in leadership roles of this structure, if any?
    Again, I suggest benchmarking to determine. I think there will be extreme differences at each institution.

8. In your opinion, do any conflicts of interest exist within the current structure?

  One committee member suggested that there is a conflict with the ORCS Director having input on appointments to the IRB, IBC, IACUC, and Rad Safety Committees.
9. In your opinion, what gaps in coverage currently exist within the ORCS? Expertise, coverage, etc.?

DOT/Shipping - personnel signing shipping manifests without the appropriate training. This could be due to a lack of knowledge, training, or limited FTEs.
Conflict of Interest (no annual disclosures or CoI Committee)
Faculty have asked for more customized and more convenient training (i.e., live training on-demand) which consumes considerable ORCS personnel time. They have also asked for online submission capabilities.
Additional Gaps were identified during the meeting. These potentially are:
Fire Suppression Systems and checking if these systems meet fire code.

10. In your opinion, are there redundancies within the current ORCS structure?

None within but some safety functions located outside ORCS (environmental permitting, fire suppression systems, housing, MAFES) decrease efficiency.

11. For the various compliance review committees (IBC, IRB, IACUC, Rad Safety):

There was considerable discussion focusing on selection of individuals for specific review committees. In this discussion it was indicated the process of identifying potential committee members often starts by identifying individuals who have been users of the specific committee or have open protocols. The final decision on committee membership is determined by the Vice President for Research and Economic Development. Regulations list minimum committee membership requirements and there are currently SOPs in place which describe the process for naming the committee members but these policies do not describe the specific composition of expertise required on the committee. These SOPs do outline the term of service and renewal but do not define term limits. The committee discussed the potential for members to remain on a committee for too long.

a. How are the recommendations for members determined
   Usually the Chair, Director of ORCS and Office/Administrator come up with recommendations
b. Who are the recommendations submitted to typically
   VP-ORED who is the Institutional Official (regulatory term)
c. Is coverage of departments/colleges/etc considered in these recommendations
   Yes, as well as expertise. Intangible qualities such as the person’s ability to listen to the opinions of others and reasonably discuss a topic are also considered.
d. What specifically is your role in the appointment of individuals to the committees
   Work with the Chair and Officer/Administrator to come up with recommendations
e. Does a graduate student sit on each committee? If so how is that person selected?
   Yes for IACUC and IRB. Selected by availability as suggested by committee members.
12. What is your current role in the compliance check process?

   Is this Post Approval Monitoring (PAM)? If so, my role is only as a committee member.

   a. For each compliance committee, how is it decided who undergoes a compliance check? Can be targeted or random. Decided by a subcommittee for IBC and IACUC and by the IRB Officer for IRB.
   b. Do you participate in the check? Not always. Have only participated in one IACUC PAM

13. What is your general role? Do you serve more in a supervisory capacity?

   Kacey is a voting member of IBC and IACUC. She sits in on all other safety and compliance meetings. She manages the ORCS budget. She works with each ORCS employee to set annual goals and does annual reviews of each employee. Kacey assists with writing/revising/reviewing SOPs for each of the committees while trying to focus on special projects (e.g. most recent project is revising the IACUC protocol form). She plans annual retreats and other development opportunities for the office.

   Kacey does give input on the overall direction of different programs but she does not second-guess the technical expertise of the program officers (e.g., rad lab or BSL-2 lab inspection findings)

14. Does MSU fall under any federal regulations for safety compliance?

   Yes for haz waste, rad materials, fire code, rDNA, DOT. Mississippi is not an OSHA state so MSU is not required to be OSHA compliant.

15. Is your office working toward having a comprehensive safety program? If so, to include what aspects of safety?

   Yes, recently added Safety to our name to better encompass the safety functions and to let campus know where to go for help.
   New personnel: Full-time Biosafety Officer, Haz Waste Coordinator, Lab and Env Safety Coordinator, and Safety Officer.
   Added training programs in occupational safety and lab safety.
   Fire extinguisher maintenance (except for MAFES buildings and Student Housing)
   Building Safety inspections and lab safety reviews.
   Would like to get all safety related positions in one department.
Additional committee notes/comments: Kacey noted all responsibilities of the ORCS are successfully completed. It often takes some re-prioritization based on the importance of individual tasks or responsibilities. Having everything in one physical location could enhance the efficiency of the operation. Streamlining the safety structure reporting process could greatly enhance the operation as currently Housing, MAFES, Facilities Management, and ORCS have different reporting structures. Lastly the ORCS is grossly understaffed.
Questions for Terry Coggins on 10/07/10

Terry indicated in his initial statements he was happy to see this review undertaken, it is the first time since either 1990 or 1991 this process has been completed.

1. What are the strengths as you see them with the current ORCS structure?

   Most of the broad safety and compliance areas are covered. The consolidated structure allows the sharing of staff. Terry indicated previously there was a direct reporting responsibility to the VP. It was not until 2000 that budgets were consolidated within the current ORCS structure. At the moment there are 3 physical locations that are included in the current budgetary structure. Additional comments from Terry indicated the Morgan and Dorman locations could be combined. It would be very advantageous to ensure the Radiation storage remains on or near campus. Lastly, Terry indicated in this consolidation there should be a standardized reporting structure.

2. What are the challenges as you see them with the current ORCS structure?

   The can be a lack of consistency in approaches to compliance. Decisions and resource allocation are not always based on risk or regulation (in my opinion).

   Terry indicated within the ORCS there are inconsistent approaches that vary between authoritarian and authoritative. Terry suggested best practice can usually develop from using a more authoritative approach in which safety and compliance officers work as part of an integrative team.

   An additional challenge was noted in that it does not appear that resource allocation logically follows risk or regulation.

3. What are the strengths with having MSU policies that exceed federal regulations, as they pertain to your ability to support research on campus and your ability to do your job?

   There are not many examples of regulation beyond what is required in my area. In the instances where they do exist, they are mainly designed to provide the safety (occupational) training to lab/facility personnel. Currently, the focus is training for departmental safety reps, some safety training for lab workers, facilities workers, etc.

   When we develop the necessary infrastructure around campus (trained departmental safety reps) and develop campus buy-in, safety programs can be fully implemented.

   Terry indicated the current effort to develop departmental safety reps allows for a smaller ORCS staff which without the departmental safety reps a much larger safety office is necessary.
Terry was asked about to what extent the implementation of the safety programs has progressed. He indicated each Rad Safety, Haz safety, DOT, and General Safety, although this is generally overseen by facilities management, are improving but are not complete yet. This might be related to some lack of regulatory force directing this effort. Terry was asked if facilities safety has suffered. He indicated moving safety out of facilities had a positive effect as now the training efforts for facilities is overseen by the ORCS.

4. What are the challenges with having MSU policies that exceed federal regulations, as they pertain to your ability to support research on campus and your ability to do your job?

Concerns include: 1. Internally generated regulations are not usually based on a detailed risk assessment, 2. Take funds away from areas where there are regulations and/or higher risk, 3. Potentially end users are not consulted before the internally policies are put into force.

Terry indicated there are challenges between establishing need and assessing risk. With budgetary limitations these processes might not result in best or most appropriate practice.

Terry also addressed there is not a great need to establish a campus-wide set of standard operating procedures as long as the ORCS program officers do their best to be flexible when possible and to act in a fashion that best facilitates the research efforts of the university.

Terry was asked about a formal appeals process or formal feedback mechanisms for end users of the ORCS. He indicated there is no general feedback mechanism or formal appeals process.

5. What time issues do you see as the result of the current structure?

There are no major time problems in my areas that I am aware of that impact researchers or the campus community. At least in my areas, some functions are contracted out – fire extinguisher checks. This approach saves money and ensures work is done by trained experts. Some other safety programs are candidates for outsourcing as well.

Terry indicated there have been some savings as a result of outsourcing (i.e. fire extinguishers) and that additional cost savings and improvements in expertise could be realized by contracting out other safety efforts. An example he provided was contracting out training sessions.

6. What time issues do you see as a function of having policies exceed federal regulations?
Priorities are established (1) regulatory functions, (2) other functions.

7. If you had a choice, what would the ideal structure of the ORCS look like?
   a. Who would each branch/individual report to?

   Divide the current structure into functional areas: (1) Risk management (workers comp), (2) Safety and Environmental (Rad Safety, lab/chemical safety, OSHA type safety, fire safety, waste management), & (3) compliance (human subjects, animals, biosafety??, etc.)

   Compliance should remain in Research since all activities are research related.

   Based on discussions with IHL Risk Management for the previous review, Worker’s Comp probably should be housed in HRM.

   Safety and Environmental Compliance could remain in Research or be relocated to the Provost where FM is currently located. I think Research benefits from managing safety – many of the more significant challenges are research related. I am not sure researchers will get as good a service if we were located outside ORED.

   Terry provided an individual example of changes that have occurred in the safety office specific to the Risk management position working with Workers comp. This position was initially intended to assess data on workers comp claims to enhance safety practices. This position was initially listed as a University Safety Officer position. It was restructured approximately 3 months later to re-assign responsibilities. It is not clear if the initial job responsibilities for this position have been addressed or completed.

   b. What do you think are the appropriate credentials for individuals serving in leadership roles of this structure, if any?

   Officer level positions should have a minimum of 5 years and professional certification/license (PE – environmental, CSP/CIH – safety, CHP* – rad materials) or 8-10 years direct professional safety experience and an educational degree in a relevant area. Other essential skills include good people skills and a knowledgeable of how a university and state government works. Certifications significantly increase the program respect from outside campus.

   Terry indicated it is necessary to ensure proficiency of all safety and compliance officers to alleviate faculty time concerns. It is essential that reporting and organization functions are outlined or clarified prior to deciding on the appropriate reporting structure to upper level university administration. At this time it is indicated most day-to-day reporting is delivered to Kacey.
c. At the director level, management can decide what is needed either someone with technical/management skills or someone with management skills. The former is more expensive, but should be well suited to provide technical oversite of the program. A technically capable manager allows the use of less experienced personnel in the office and provides backup to positions when vacated. A good or bad the director establishes the program direction and collective attitude of the programs.

*Currently a licensing condition

Terry indicated either possibility for a director’s qualifications can work for the university. He noted if the director has more management skills the staff will need to ensure they are more proficient in their tasks. If the director is someone who has good technical safety and compliance skills than the staff can rely more heavily on them to fill-in gaps in safety and compliance to make-up for any existing technical gaps the staff might possess. He indicated secondary reviews might be more likely to occur than they currently do with a director who is more technically proficient.

8. In your opinion do any conflicts of interest exist within the current structure?

I am not aware of any conflicts of interest in my area. I am not a voting member on the Rad, Chemical, and Lab Safety Committee. I will discuss this in more detail.

9. In your opinion, what gaps in coverage currently exist within the ORCS? Expertise, coverage, etc.?

I think most areas have some coverage. ORC has some less experienced personnel and some with moderate experience. The use of contract personnel is a cost effective way to really enhance these programs.

10. In your opinion, are there redundancies within the current ORCS structure?

Sometimes there is a little overlap in the chemical area and lab safety. Generally, this is not a big problem. We just have to make sure we provide a consistent message.

11. For the various compliance review committees (IBC, IRB, IACUC, Rad Safety):
   a. How are the recommendations for members determined

      Usually by the chair, RSO, and ORC director

   b. Who are the recommendations submitted to typically
VP of ORED

c. Is coverage of departments/colleges/etc considered in these recommendation?

We attempt to get someone from covered departments with specific expertise. I will discuss in the meeting.

d. What specifically is your role in the appointment of individuals to the committees

I help put together recommendations and they are usually accepted.

e. Does a graduate student sit on each committee? If so how is that person selected?

No and nor does a public member. (There are some licensing conditions that must be considered.)

12. What OSHA regulations does MSU fall under?

The Hazwoper requirements (maybe) via EPA RCRA regulations but only for the hazardous waste storage building workers.

OSHA standards for MSU are just good practices.

13. What is your current role in the compliance check process?
   a. For each compliance committee, how is it decided who undergoes a compliance check?
   b. Do you participate in the check?

Both a and b – all rad labs and points of waste generation are checked routinely. All building facilities other than housing and MAFES farm facilities are checked under the building review program.

I will discuss this in more detail in the meeting.

14. What is your general role? Do you serve more in a supervisory capacity?

I provide supervision to Ben, some to Erin when working in my areas, and a student. I also do hands-on field work, paperwork, etc. just like everyone else in my group.

My official breakdown of duties is provided below as of 7/2010.

“Terry has all rad safety/waste disposal responsibilities. Terry has all ORC fire protection program responsibilities including fire extinguishers, fire drill coordination, and chemical
segregation. Safety program components including machine guarding, lockout/tagout, hazwoper, confined space, etc. (basically 29 CFR 1910 other than 1450 issues and 29 CFR 1926) will be his responsibility. Terry will manage the building safety review process and he will compile the inspection report for all buildings. Terry will be the principal technical contact for DOT Haz Material shipping matters. Terry will be responsible for implementation for the chemical/radiological/fire protection systems software. He will coordinate and deliver OSHA 10 hour, 30 hour, and hazwoper classes.”

In addition to the above -

I serve as the emergency spill contact for campus. I am first callout on 3 existing alarm systems (soon to be four alarm systems).

We (Ben and I) do the biological waste pickups for everyone except CVM and the SHC.

Occasionally, I provide technical assistance to researchers around campus (ICET, CVM-Hart, sample counting, mold/air sampling, PSS STS contract, etc).

Terry provided us with some summary statements at the conclusion of the meeting. He noted certain committees have licensing requirements. As a result of this it is essential each safety committee needs to ensure they are reviewing that which is appropriate for them to review and not expand the scope of their efforts beyond what is required. He also noted there are cases in which it is inappropriate for every safety officer to be a voting member of the committee.

Lastly he noted much progress has been made (i.e. building reviews) and the end users have been supportive of these efforts. He believes this is because of the efforts of the officers to be accommodating and facilitating of all responsible parties.
General Questions

1. Provide an estimate of your perceived %FTE spent on each of your job responsibilities.
   30% Workers’ Compensation – trends, department head reports, and safety related investigations
   40% Safety training – CPR/1st, AED, Defensive Driving, Lifting Techniques
   30% Lab Safety – Lab Safety Reviews

2. Of the job responsibilities you identified above, are there any that you think should be removed? If so, whom do you think should be responsible for that role?
   No

3. You are responsible for worker’s compensation data mining and investigation. Do you feel that this responsibility should be housed in ORC or would be more appropriate in HR?
   I feel that the safety investigations, the department head reports, and the trend database should continue to be housed in ORC&S. This is typically risk management/loss control for the university. HRM processes the claims, and then submits the claims to FARA and myself. I look at the claims for safety issues that might have resulted in the injury. If a safety issue is noticed, then I try to fix the problem through repairs or safety training/education. I also look at the trends of the claims to determine where my efforts should be placed for development of safety training.

4. For the job of Safety Officer of MSU, what professional development or training do you feel is necessary for who holds this job?
   I believe that at least 1 safety conference should be attended annually. In addition, safety related certification would be beneficial, i.e: OHST, CSP, etc. I am in the process of pursuing my OHST certification. In addition, I believe that instructor certifications should be kept up-to-date, i.e: CPR/1st, Defensive Driving, etc.

5. Your job description, as provided by Kacey Strickland, indicates that you are responsible for maintain a number of databases. Please list what databases you maintain and a basic description of the information contained and purpose of the database.
   I maintain a Workers’ Compensation database. This database contains information for all the claims that are submitted on campus. This information allows me to find the areas within the university that safety training/concerns should be focused.

Lab Inspection Procedures—As the safety officer, lab inspections (with noted exceptions, such as hazardous materials) are your responsibility. Please answer the following questions relating to the lab inspection process.

   1. Number of labs you are responsible for inspecting. If possible, provide a general listing of the laboratories.
4 labs in Agricultural & Biological Engineering
8 labs in Animal & Dairy Sciences
9 labs in Biochemistry & Molecular Biology
12 labs in Biological Sciences (Harned and Etheredge)
19 labs in Chemistry
2 labs in Civil Engineering
26 labs in CVM
2 labs in Electron Microscope Center
8 labs in Entomology & Plant Pathology
11 labs in Food Sciences (including Bedenbaugh)
11 labs in Forest Products
2 labs in Forestry
4 labs in LSBI
2 labs in Petroleum Products
8 labs in Plant & Soil Sciences
5 labs in Poultry Sciences
19 labs in Chemical Engineering

2. Time line for completing inspections (how often is a lab inspected). If some labs are inspected more frequently, please explain why.

When the program started, the laboratories were being reviewed every 6 months. However, we have decided to change the reviews to 1X/year.

3. What federal regulations/policies exist that you must follow in the performance of lab inspections? How are these related to any forms you use in the inspection process for noting deficiencies and/or identifying recommendations for improvement?

No, there are no federal regulation/policies that exist.

4. What MSU policies exist that you follow in the performance of lab inspections? How are these related to any forms you use in the inspection process for noting deficiencies and/or identifying recommendations for improvement?

Yes – The MSU policy on Building Safety Reviews, The University statement on “Sharps” disposal. The electrical safety, fire safety, and some of the compressed gas safety are included in the policy of building safety reviews. The sharps disposal/broken glass box are listed in the university statement on “sharps” disposal.

5. What process was used in the development of any forms that you use in the lab inspection process?
I have spoken with several other safety officers that are responsible for laboratory safety at different universities (including SEC schools and non-SEC schools). They were happy to share their review forms with me. My checklist is based on OSHA recommendations for laboratory safety, MSU policy, and Good Laboratory Practices. The checklist has changed recently. Instead of the “No” column, we have replaced it with a “See Recommendation” column, if a recommendation was found. In addition, there is a “N/A” column, this would be used if the item does not apply to that specific laboratory. I have included a copy of the revised checklist with the email.

6. What flexibility is provided to lab directors in meeting/reconciling noted deficiencies, etc.?

The reviews offer recommendations only. It is up to the lab director/PI to implement the recommendations.

7. Are there specific units/labs/departments/etc. that consistently have deficiencies? If so, please identify those units, etc.

There are no units/labs/departments/etc. that have been unwilling to implement the recommendations noted in the laboratory safety reviews, if they are able to do so.

8. What training is in place for lab directors related to any policies/regulations for maintaining labs? What is your role in conducting that training?

At this time, there is no training related to MSU Building Safety Review policy. The Environmental & Laboratory Safety Coordinator has recently developed an Introduction to Laboratory Safety training (trained over 100 people). She is in the process of developing additional trainings: Good Lab Practices (what are they/how to implement) & How to Make a Risk Assessment workshop.
IBC/Biosafety Program Responses

For each of the questions below, please try to provide data for the past 3 years if possible, where applicable.

1. Provide a number of protocols reviewed per committee member for all levels of review (if applicable). Please provide this information by member name.
   See previous email.

2. How is the length of membership for a board member determined?
   Unknown, was in existence before I started in 2007 - 3 yrs is what the other committees have, I assume it is based on that. 3 years seems to work well. It takes almost a full year to become comfortable with the process, then have another two years to be fully engaged. Have a lot of trouble finding people with the appropriate expertise who want to serve too.
   Is there a maximum? No
   Do any members have a “permanent” membership? 4 (Medical Director, LSHC, Lab Animal Vet, Director of RC, and BSO)
   Why? unknown, ex officios already on the committee when I started.
   Provide current membership tenure.
   5 have been on longer than 3 years (2 of the 5 are ex-officio)
   2 have been on 3 years both ex officio
   8 are first term

3. How many non-compliance reports/cases do you handle in a year? Please provide data on #’s and type of non-compliance if possible without violating confidentiality.
   Note: Noncompliance in the biosafety world is called “incidents” and can include noncompliance, accidents and laboratory-acquired infections.
   2008 – one failure to meet IBC request deadline – took 6 months
   numerous inappropriate clothing (flip flops) incidences in labs, eating in BSL-2 labs
   2009 – 5
   potential exposure due to contaminated equipment and expired IBC app
   potential exposure with Listeria by a custodian
   break-in/vandalism in a lab
   infected large animal escape
   BSC not certified – delay in updates/certification 5 months
   several potential exposures from sharps injuries including animal bite (rickettsia, salmonella)
   numerous inappropriate clothing (flip flops) incidents in labs, eating in BSL-2 labs
2010
unauthorized personnel eating in a foodborne pathogens lab
numerous inappropriate clothing (flip flops) incidents in labs, eating in BSL-2 labs

4. What amount of flexibility do you provide individuals in meeting deadlines to have protocols reviewed at the full board level?
two days (Friday after the Wednesday deadline)
Does a deadline exist?
yes (10 working days before next meeting)
What percentage of protocols request or are granted flexibility for review if they submit past the deadline?
Depends upon whether they have contacted me or not. Usually a PI will submit that week for review. I will send it back with edits. Sometimes it can take until that Friday to get it right. The IBC Chair needs to get all the IBC applications by that Friday in order to generate a packet which I then upload usually at the beginning of that week prior to the week of the meeting. This is to give the primary reviewers and the rest of the committee plenty of time to review the applications. So, as long as the PI contacts me and I know one is coming, I can notify the Chair and work with the PI to get it done by Friday. If I get an application out of the blue on that Thursday or Friday, it is held for the following month.

5. Is there a “development” protocol for your respective board?
Research Review for Biosafety
What percentage, or number, of protocols falls into this category?
25% for 2010
20% for 2009
14% in 2008 – instituted in mid 2008
If this category does not exist, provide a justification for this.

6. What is the policy for a protocol that is going through a review level lower than full board to come before the full board?
IBC-SOP-013 Research Review for Biosafety (RRB)
Registers exempt rDNA research;
Registers research which can be conducted at biosafety level 1;
As a way to determine if a full IBC application is needed.

IBC-SOP-008 Admin Review of Research Applications Using Human/Nonhuman Primate Cell Lines
Reviews research using cell lines that have not been deliberately infected with biohazardous material, altered through rDNA technology or known to contain biohazardous material.

What percentage of protocols are increased in review level?
unknown – very rare, if ever – the PI and I usually have a conversation about the research to determine what oversight, if any, it requires.
7. What training or other methods are used to help members create a critique and ensure that it follows the purpose of the board (e.g., not focusing on scientific merit of the research)?

SOP-IBC-017 IBC Member Training

IBC Reviewers checklist (for primary reviewer of an IBC app)

8. How are policies developed, approved, and enforced?

1. The majority of SOPs were developed from the NIH OBA self-assessment tool called “IBC and Program of Oversight for rDNA Work”. *NIH Guidelines for Research Involving Recombinant DNA Molecules*

2. Other policies based on federal/state law – Mississippi State Department of Health Adopted Standards for Medical Waste, DOT 49 CFR 171-175 (shipping of infectious substances), CDC Select Agent program, USDA/APHIS permitting, Department of Commerce for exports

3. IBC-SOP-008: administrative review (BSO, IBC Chair) of human cell culture work - instituted to expedite research using human cell lines.

enforced primarily by the VP-ORED with support from the VP-DAFVM

What policies are beyond current requirements by federal, state, etc. bodies (providing a number is sufficient)? 1. review of biohazardous material other than recombinant DNA. There are no federal laws other than the Select Agent program which require institutional oversight of infectious disease research. This includes pathogenic organisms, biologic toxins, biologic allergens, venom, nanoparticles, animals, anything that may potentially contain any of the above including wastewater, hog lagoon effluent etc. The IBC, as part of it scope as defined in its Charter, considers not only recombinant DNA hazards but all biohazards that may affect not only humans but animals, plants and the environment.

Just to give you an example: we have a PI who is working with an exotic canine influenza virus in a specific lab animal species. This particular strain is not seen in the US and hence our canine population is immunologically naïve. The virus is highly contagious and has a high mortality rate in dogs in its country of origin. Loss of containment of this virus could have an extremely deleterious effect on not only our community dog population but also on the reputation of the University if it were found to have originated from MSU. However, there is no regulation that says MSU has to provide oversight for this type of research. ORED policy (through the IBC Charter) says that we do.

2. OSHA 29 CFR 1910.1030 Bloodborne Pathogens Rule which covers research involving human body fluids, tissue, cell culture lines. ORED policy states that MSU follows the OSHA BBP rule. VP-ORED believes that the risk is unacceptable by not following 1910.1030 due to the devastating nature of the diseases (Hepatitis B,C and HIV).

A different question should be what policies are not in place and should be? Mandatory BSL-2 training. We are one of the few universities that do not require biosafety training for any biosafety level lab. Section IV-B-7-d-(2), IV-B-1-h of the *NIH Guidelines*. We are not in compliance!!!!!!!!!!!!!!!!!!!!!!

9. What training is provided to all members of your respective boards?
SOP-IBC-017 IBC Member Training

How frequently is this training provided?
August of their first year, any changes/updates in federal or state laws or best practices are relayed to the IBC during a meeting as an agenda item.

Does the content differ significantly from what researchers undergo to become eligible to conduct research that falls under the purview of your respective boards?
No, the IBC application is a risk assessment. To do one or to review one means that one needs to be familiar with federal/state laws, best biosafety practices, and the biohazardous material to be used.

However, PIs bear ultimate responsibility for the conduct of work in their labs (NIH Guidelines, BMBL). As such they have additional responsibilities that are described on MSU biosafety web page, in IBC application, and in the NIH Guidelines and should be relayed by mandatory training. Have tried optional training but attendance was consistently low. At this point, PIs are on their own to meet knowledge/training requirements.

If so, in what way? Justification for this difference?

10. How are the forms used for protocol submission developed, revised, etc?
Forms developed based on NIH Guidelines, BMBL, OSHA exposure control plan (ECP) template
All biosafety forms are reviewed annually but especially the following: IBC app, RRB, BSL-2 checklist, ABSL-2 checklist, ECP
Are there any plans to modify any of the existing forms?
currently revising lab and animal BSL-2 inspection checklist based on new guidance from CDC.
Will also review the IBC app as part of the development of an on-line training on how to fill out the application properly based on input from this fall’s PI survey.
An updated version of the NIH Guidelines is expected to be released by the end of the year. This will most likely require a review of the recombinant portion of the application.

To what extent can there be a “ORC” form that would cover all ORC committees?
not possible, other than to collect PI contact info and maybe some training/education/work experience info and a general overview of the research. The IBC application assesses risk to lab personnel, the community and the environment and hence asks very specific questions about the proposed material, how the material will be manipulated, where it will be manipulated and by whom. IACUC is concerned with the humane treatment of the animal and as such asks how will the animals be housed, manipulated, anesthetized, etc, and IRB is concerned with treatment of human subjects (confidentiality, recruitment, societal benefits etc.). We ask very different questions. There is definitely synergy between the committees, but we have different mandates.
11. Are there individuals, departments, colleges, etc. that consistently submit incomplete, poorly developed, etc. protocols? Can you provide an estimate of the amount of time your staff/board spends on these protocols compared to other protocols?
   
a. Do you feel that something needs to be done to minimize your time/effort spend on these protocols?

Most of my PIs are very conscientious and will contact me for help so when it is time for the IBC review it goes very smoothly. There are some who do not contact me, and their applications usually receive a more time-consuming review by the IBC with numerous contingencies since they did not answer questions appropriately or not at all. We are trying to come up with ideas to encourage PIs to contact me (any suggestions?). There is one PI who is extremely difficult to work with because he does not recognize/understand/accept the necessity of registering his work with the IBC. But ultimately he does comply even though it is an extraordinarily painful process for both of us.

The more relevant issue is lack of compliance to basic biosafety practices and poor lab and animal facilities.
1. Provide a number of protocols reviewed per committee member for all levels of review (if applicable). 2008 – 61 protocols, 2009 – 75 protocols, 2010 - 115 protocols. Since August 2010 approximately 38 protocols have reviewed at the Designated Review (DR) level and 32 protocols have been reviewed at the Full Committee (FCR) level. Prior to this date, most all protocols were sent to the Full Committee unless a PI requested Designated Review. Please provide this information by member name. Since August 2010, using Designated Review, Brian Rude has reviewed 15 protocols, Guiming Wang has reviewed 1 protocol, Robert Meyer has reviewed 10 protocols, Chuck Mischke has reviewed 4 protocols, Bill Herndon has reviewed 1 protocol, Aaron Kiess has reviewed 8 protocols, and Chris Brooks has reviewed 1 protocol.

2. How is the length of membership for a board member determined? Each new member is appointed for a 3-year term. This term is based on historical precedence. Is there a maximum? No, members may be reappointed. Do any members have a “permanent” membership? Yes, the Director of ORC, Kacey Strickland and the ULAV, Lucy Senter. Why? Historical precedence for the ORC Director. We are required by regulation to have a Veterinarian on the IACUC committee. It has always been the ULAV. Provide current membership tenure. You can exclude names.

Chris Brooks, 2nd year
Pat Cox (Alternate for Kacey Strickland), 4th year
Jeffrey Eells, 1st year
Jack Forbus (Community Member), 15th year or longer
Russell Gaines (Community Member), 3rd year
Mark Guyton (Community Member), 4th year
Cary Herndon, 9th year
Ray Iglay (Student Representative), 1st year
Aaron Kiess, 1st year
J. Mike Martin, 1st year
Robert Meyer, 7th year
Chuck Mischke, 2nd year
Brian Rude (Chair), 13th year
Lucy Senter (ULAV), 6th year
Kacey Strickland (ORC Director), 4th year
Guiming Wang, 3rd year
James Warnock, 2nd year

3. How many non-compliance reports/cases do you handle in a year? In 2008, there were two. In 2009, there were 5. One report in 2010. Please provide data on #’s and type of non-compliance if possible without violating confidentiality. In 2008, the issues were in regards to 1.) failure to use an approved Veterinarian for animal care procedures and 2.) deviation from
protocol, animal was donated to private individual instead of returned to production herd. In 2009, the issues were in regard to 1.) unrestricted play time for an animal which caused the animal to be injured, resulting in the animal having to be euthanized, 2.) no protocol for an animal, 3.) more animals on a protocol than there should be, and non communication for the euthanasia of animals, 4.) pest control problem which killed anoles, and 5) animal health issues resulting from improper procedures conducted on the animal. In 2010, there was one issue in regards to inappropriate use of personnel.

4. What amount of flexibility do you provide individuals in meeting deadlines to have protocols reviewed at the full board level? There is some flexibility as long as the PI has communicated with IACUC administrator, Chair, or ULAV the problem that has arisen and it does not hinder the packet from going out to the committee members on time. Does a deadline exist? Yes. There is a submission deadline of 2 weeks before the committee meeting if the PI has not already gotten the signature of the ULAV. One, week if PI has already gotten it. What percentage of protocols request or are granted flexibility for review if they submit past the deadline? 5% or less.

5. Is there a “development” protocol for your respective board? Yes. What percentage, or number, of protocols falls into this category? So far, we have only approved 2 developmental protocols. All approved in 2010. If this category does not exist, provide a justification for this.

6. What is the policy for a protocol that is going through a review level lower than full board to come before the full board? For IACUC, technically, there is no “lower level” review. We now handle protocols with a pain category of B or C by what we call Designated Review. The full committee must still be provided information about that protocol, and have the right to call for full committee review for ANY reason. What percentage of protocols are increased in review level? 5% or less from Designated Review to Full Committee Review.

7. What training or other methods are used to help members create a critique and ensure that it follows the purpose of the board (e.g., not focusing on scientific merit of the research)? In addition to the training described in the answer to Question 9, all contingencies are discussed and must be accepted by a majority of the IACUC committee.

8. How are policies developed, approved, and enforced? Policies are developed as regulations and working procedures change within the IACUC structure. They are usually drafted by the Director of ORC or the IACUC Chair. Once drafted, they go before the IACUC committee for approval. Once they are approved by the IACUC, usually in the form of SOP’s they are added to our website and followed accordingly by the IACUC and Principal Investigators. What policies are beyond current requirements by federal, state, etc. bodies (providing a number is sufficient)? Ag based research is currently excluded from federal regulations. However, MSU Policy and Procedure Statement on Lab Animal Welfare (OP 79.05) http://www.msstate.edu/dept/audit/7905.html requires all animal research to be reviewed
and approved by the IACUC. Additionally, all protocol are pre-reviewed by a committee member (there is no federal requirement for this) and all protocols are pre-reviewed by the ULAV (only some protocols with surgical procedures are required to do this at the federal level).

9. What training is provided to all members of your respective boards? All new members go through an overview of how the IACUC operates from the IACUC Chair. New members also have to go through the “Essentials for IACUC Members” module through CITI. All members attend an annual retreat. How frequently is this training provided? Annually. Does the content differ significantly from what researchers undergo to become eligible to conduct research that falls under the purview of your respective boards? Yes. Training for members is an addition to the training you would need to become eligible to conduct research. However, the vast majority of our members are also researchers so they also go through the Animal Handler Training via MyCourses or they may complete the “Working with the IACUC” modules in CITI; as well as Occupational Health and Safety (OHSP). The Animal Handler training is good for 4 years. The OHSP is to be reviewed on an annual basis. If so, in what way? Member training focuses more on the regulations and the IACUC processes. Justification for this difference? Member training is used to help ensure that protocols are reviewed properly, while animal handler training is to ensure proper care and use of research animals.

10. How are the forms used for protocol submission developed, revised, etc? They are developed in order for the IACUC Committee to effectively do their job. The forms are written in order for the IACUC to understand what the PI plans to do to the animal and to make sure they are compliant in their research. During the daily IACUC working procedures, if ideas arise that will help to understand parts of the research more adequately, the form may be revised to make that area more clear. Are there any plans to modify any of the existing forms? We have recently modified our IACUC Animal Use Protocol Form (revised, October 2010) as well as our Annual/Update Amendment Form (revised January 2011). To what extent can there be a “ORC” form that would cover all ORC committees? An electronic form that would at least allow you to type in either your netid or other identifying number and your identifying information (Name, Department, etc.) would appear, beyond that, the information that the IACUC needs does not overlap with any of the other ORC regulatory committees.

11. Are there individuals, departments, colleges, etc. that consistently submit incomplete, poorly developed, etc. protocols? Not really a problem for me. This could be because the protocol has to be pre-reviewed by an IACUC member prior to submission. Can you provide an estimate of the amount of time your staff/board spends on these protocols compared to other protocols. N/A.

   a. Do you feel that something needs to be done to minimize your time/effort spend on these protocols? N/A.
IRB Question Responses

IRB Report to the ORCS Review Committee

1. Provide a number of protocols reviewed per committee member for all levels of review (if applicable). Please provide this information by member name. 

2. How is the length of membership for a board member determined? Is there a maximum? Do any members have a “permanent” membership? Why? Provide current membership tenure. You can exclude names.

3. How many non-compliance reports/cases do you handle in a year? Please provide data on #’s and type of non-compliance if possible without violating confidentiality.

4. What amount of flexibility do you provide individuals in meeting deadlines to have protocols reviewed at the full board level? Does a deadline exist? What percentage of protocols request or are granted flexibility for review if they submit past the deadline?

5. Is there a “development” protocol for your respective board? What percentage, or number, of protocols falls into this category? If this category does not exist, provide a justification for this.

6. What is the policy for a protocol that is going through a review level lower than full board to come before the full board? What percentage of protocols are increased in review level?

7. What training or other methods are used to help members create a critique and ensure that it follows the purpose of the board (e.g., not focusing on scientific merit of the research)?

8. How are policies developed, approved, and enforced? What policies are beyond current requirements by federal, state, etc. bodies (providing a number is sufficient)?

9. What training is provided to all members of your respective boards? How frequently is this training provided? Does the content differ significantly from what researchers undergo to become eligible to conduct research that falls under the purview of your respective boards? If so, in what way? Justification for this difference?

10. How are the forms used for protocol submission developed, revised, etc? Are there any plans to modify any of the existing forms? To what extent can there be a “ORC” form that would cover all ORC committees?

11. Are there individuals, departments, colleges, etc. that consistently submit incomplete, poorly developed, etc. protocols? Can you provide an estimate of the amount of time your staff/board spends on these protocols compared to other protocols?

Appendix 1 - Protocols Reviewed by Board Members

Appendix 2 – SOP: Membership of the IRB

Appendix 3 – Current IRB member tenure

Appendix 4 – SOP: Developmental Approval

Appendix 5 – Reviewer’s Comment Form

Appendix 6 – SOP: Management of HRPP Documents

Appendix 7 - Other Resources
For each of the questions below, please try to provide data for the past 3 years if possible, where applicable.

1. **Provide a number of protocols reviewed per committee member for all levels of review (if applicable). Please provide this information by member name.**

   Please see Appendix 1 for Expedited and Convened IRB review statistics by board member. These numbers may not be exact as they are compiled from various sources (i.e., hard copy manual log for new expedited reviews, agendas for convened board meetings, Microsoft Access database for modifications and continuing reviews).

   These numbers do not include files reviewed by the IRB staff through Administrative review, which are noted in the table below.

<table>
<thead>
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<th>Administrative/Exempt Applications</th>
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<td>2008</td>
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<tr>
<td>New</td>
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<tr>
<td>Modifications</td>
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   Factors affecting number of reviews by board members include the number of submissions from represented areas, board member tenure, expertise, and experience, as well as the type of research and related risk.

2. **How is the length of membership for a board member determined? Is there a maximum? Do any members have a “permanent” membership? Why? Provide current membership tenure.**

   You can exclude names.

   Please see Appendix 2 for the SOP on Membership of the IRB. Per this policy, board members are appointed for renewable terms of three years. There is no term limit. The Director of the Student Health Center and the IRB Officer are standing members of the Board. Having the Director of the Student Health Center on the IRB ensures there is someone with appropriate biomedical expertise to review relevant protocols, in addition to familiarity with other areas of campus (e.g., Student Affairs). The IRB Officer’s appointment as a Board member allows this individual to serve as an expedited reviewer of applications, which would not otherwise be in compliance with the regulations.

   Please see Appendix 3 for current IRB member tenure.

3. **How many non-compliance reports/cases do you handle in a year? Please provide data on #’s and type of non-compliance if possible without violating confidentiality.**

   IRB minutes reflect three instances of noncompliance in 2008. Two of these instances were cases in which the investigators did not realize they needed IRB approval for their activities. In
the other instance, the investigator altered his research methods without obtaining approval of those modifications. He also failed to appropriately obtain and document consent from participants, including minors.

There were three instances of noncompliance in 2009. In the first instance, the faculty advisor instructed the student researcher to obtain IRB approval. The student then proceeded to conduct her research without IRB approval. In the second instance, the researcher had not previously conducted human subjects research and did not realize his survey required IRB approval. In the third instance, the researcher indicated he thought he had IRB approval based on an e-mail from IRB staff that requested modifications in order to obtain approval. Upon realizing his mistake, the investigator misrepresented the facts in an attempt to cover up this mistake.

There have been three instances of noncompliance in 2010 (one other allegation is outstanding). In the first instance, the investigator submitted an application but thought the external evaluator at another institution had secured approval at MSU. She documented this with correspondence from the external evaluator. In the second instance, investigators reacting promptly to a disaster did not realize they were conducting human subjects research in their haste. In the third instance, the investigator did not realize his use of existing data constituted human subjects research.

4. **What amount of flexibility do you provide individuals in meeting deadlines to have protocols reviewed at the full board level? Does a deadline exist? What percentage of protocols request or are granted flexibility for review if they submit past the deadline?**

   We allow a great deal of flexibility if it is requested. Deadlines are set at 10 business days prior to convened IRB meetings in order to allow staff time to review the protocol, request changes if needed, and distribute to board members prior to the meeting. Very few IRB protocols require convened board review (11/985, or 1.1% for 2008-2010). IRB staff do not recall such a request that has been denied.

5. **Is there a “development” protocol for your respective board? What percentage, or number, of protocols falls into this category? If this category does not exist, provide a justification for this.**

   Developmental approval as it is used by the IRB is specifically allowed under 45 CFR 46.118 of the regulations (which is why IRB developmental approval is also called “118 designation”). This approval only allows for the release of funding to investigators in order for them to develop procedures, instruments, etc. in order to obtain IRB approval. Per the regulations, “no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB” (i.e., approval of all procedures, instruments, etc. after they have been developed and before any conduct of the actual research).
All requests for developmental approval are granted. There is no way with our current tracking systems to search for projects over the past three years that have been given developmental approval. There are currently 25 applications with developmental approval.

Developmental approval is requested by investigators via submission of the regular application with as much information as is known at the time, along with a timeline for development of the project. There is a box on the application to indicate developmental approval is being requested.

See Appendix 4 – SOP: Developmental Approval

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.118

6. What is the policy for a protocol that is going through a review level lower than full board to come before the full board? What percentage of protocols are increased in review level?

Protocols undergo one of three levels of review by the IRB – Administrative/Exempt, Expedited, or Convened IRB. Administrative reviews are conducted and approved by IRB staff. Expedited reviews are conducted by one member of the IRB. If that member is uncomfortable with approving the application (e.g., due to risk level of the research), the reviewer can refer it to Convened IRB review (in accordance with SOP: Expedited Review of Applications and 45 CFR 46.110(b)).

As has been mentioned previously, very few protocols undergo convened IRB review in the first place. Current IRB staff only recall one protocol in the past three years that has been referred to convened IRB review.

7. What training or other methods are used to help members create a critique and ensure that it follows the purpose of the board (e.g., not focusing on scientific merit of the research)?

New IRB members receive an orientation conducted by IRB staff on the regulations, MSU policies and procedures, forms, website, resources, etc. Board members and staff also participate in an annual day-long retreat for training, in addition to regular educational sessions at board meetings. Reviewers are provided with a checklist to guide them in the review of an application. The checklist is based on regulatory requirements for approval (see Appendix 5 – Reviewer’s Comment Form).

In regard to focus on scientific merit, such review is under the purview of the IRB (unlike some other compliance committees). In accordance with 45 CFR 46.111(a)(1)(i), the IRB must find in order to approve the research that “risk to subjects are minimized”… “by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.” If research is not designed such that the anticipated benefits of the research will outweigh the risks, such problems must be corrected before the IRB may approve the research in accordance with the regulations. However, the IRB is very judicious with advice on
research design, and unless there are blatant problems, these are generally presented as recommendations only.

8. **How are policies developed, approved, and enforced? What policies are beyond current requirements by federal, state, etc. bodies (providing a number is sufficient)?**

See Appendix 6 – SOP: Management of HRPP Documents which describes how policies are created and approved. New policies may be suggested by anyone (IRB staff, member, investigator, etc.). The IRB Chair and Officer will determine if the new policy should be pursued. If so, it is drafted by the IRB staff and presented to the IRB for approval at a convened IRB meeting. Policies are enforced through actions of the board and IRB staff, including post-approval monitoring in accordance with the IRB SOP on Audits and Monitoring.

Federal regulations require IRB review of non-FDA regulated human subjects research (HSR) activities only when those projects receive federal funding. However, it is commonly accepted that not reviewing HSR based on funding status would be unethical in that it would create “classes” of research participants – those who receive protection only because their project receives federal funding and others who do not receive those same protections. The Federalwide Assurance document which MSU must complete for eligibility to receive federal funding for HSR provides the opportunity for an institution to extend federal oversight to all HSR activities at an institution regardless of funding. For many years, this was considered the appropriate action. However, more recently, experts in the field have suggested it advisable to not “check the box,” and instead, to have institutional policies that extend review to all projects regardless of funding. That has been our course of action for the past several years.

Additionally, there are categories of HSR that meet criteria for exemption under the Common Rule. In accordance with longstanding guidance from the DHHS Office for Human Research Protections (OHRP), the MSU IRB reviews these projects so that investigators do not make an independent determination that research is exempt. We have traditionally placed many of the same requirements on exempt projects as those that undergo higher levels of review. However, we have been working to reduce the burden for these projects. We no longer require annual continuing review for exempt projects. In accordance with principles of AAHRPP (prospective accrediting agency), we have reduced required consent elements to four specific disclosures for these projects. Additionally, to take greater advantage of regulatory flexibility in regard to these projects, the MSU IRB staff has drafted an application specifically for projects that investigators feel meet the requirements for an exemption determination (referred to as administrative review here at MSU). While there will still be some requirements placed on investigators conducting exempt HSR in accordance with AAHRPP requirements and other federal guidance (such as training and consent requirements), the new administrative review application should be less burdensome for investigators to complete and for IRB staff to review.
9. **What training is provided to all members of your respective boards? How frequently is this training provided? Does the content differ significantly from what researchers undergo to become eligible to conduct research that falls under the purview of your respective boards? If so, in what way? Justification for this difference?**

New IRB members receive an orientation conducted by IRB staff on the regulations, MSU policies and procedures, forms, website, resources, etc. upon appointment to the board. Board members and staff also participate in an annual day-long retreat for training, in addition to regular educational sessions at board meetings.

Board members are educated on the same topics as investigators in regard to historical aspects of human subjects protections, ethical principles, and MSU policies and procedures. However, board members also receive regular educational activities on topics pertinent to specific research being reviewed, such as FDA regulations, regulatory and federal guidance issues related to noncompliance, etc. While investigators should have an understanding of the principles governing human subjects research, the board members need additional training in pertinent regulatory aspects. Resources are provided to investigators too though in order to assist them with compliance (e.g., the informed consent template includes all elements of consent required by the regulations).

10. **How are the forms used for protocol submission developed, revised, etc? Are there any plans to modify any of the existing forms? To what extent can there be a “ORC” form that would cover all ORC committees?**

See Appendix 6 – SOP: Management of HRPP Documents which also describes how documents other than policies, to include forms, are created and approved. Forms are developed in the same way as policies in that new or revised forms may be suggested by anyone, with those suggestions being decided upon by the IRB Chair and Officer. The IRB staff draft the forms. The IRB Officer may adopt new and revised forms. However, major changes to forms may be discussed with the convened IRB or investigators.

As part of the IRB’s efforts to acquire AAHRPP accreditation, the IRB staff has been conducting an extensive self-evaluation of all policies, procedures, forms, etc. Many new forms have been created through this process with the intended goal of better meeting regulatory and accreditation requirements, while making the process more intuitive and less burdensome for investigators (e.g., introduction of new administrative review application). These new forms were introduced in late Summer 2010, with an open comment and training period conducted through Fall 2010, and an anticipated implementation in Spring 2011. Investigators have had the option to use either the old or new forms through Fall 2010 in order to become familiar with the new forms before they are required. Additionally, feedback has been sought at training sessions conducted throughout the fall semester on both the main campus and at Meridian in regard to items that are unclear or otherwise present problems.
Given the very different areas covered by ORCS committees, it seems the only common elements of forms that could be used would be those related to staffing and funding. The subject matter and required regulatory decisions on protocol-specific information would make it impractical to share other such elements of these forms among committees.

11. Are there individuals, departments, colleges, etc. that consistently submit incomplete, poorly developed, etc. protocols? Can you provide an estimate of the amount of time your staff/board spends on these protocols compared to other protocols?

There are certainly problem areas that consistently submit incomplete or inconsistent applications. These reviews probably take 2-3 times as much time as other reviews given the required correspondence between IRB staff and the investigator(s) to correct these deficiencies before approval may be granted.

a. Do you feel that something needs to be done to minimize your time/effort spend on these protocols?

The IRB has always and continues to strive for good customer service, including a very educational approach with investigators, many of whom are students. As such, the IRB has never sent applications back to an investigator without clear direction as to what needs to be corrected. In fact, 45 CFR 46.109(d) states, “An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity.”

Unfortunately, it seems that some faculty advisors (as well as some faculty researchers themselves) have thus pushed their duties onto IRB staff in that they will sign an application without reviewing it or with disregard to its deficiencies since the IRB will point out all needed changes anyway. This creates a bottleneck with IRB reviews that take an inordinate amount of staff time and which could be prevented with better quality submissions. In general, these poor submissions are not a matter of educational problems, but with disregard for the quality of submission in the first place.

With that said, the IRB staff would welcome advice on improving the quality of submissions in this regard.
Appendix 1 - Protocols Reviewed by Board Members

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Remaining appendices were removed from this report but can be made available if needed.
Appendix C: University of Wisconsin Madison Appeals Board Description

Purpose: This document describes the roles and responsibilities of the UW-Madison Human Research Protection Program Advisory Committee (Advisory Committee).

Policy
I. Advisory Committee Responsibilities
   A. The Advisory Committee is responsible for:

   1. Advising the UW-Madison Institutional Official on issues relating to human research protection.
   2. Oversight of the Human Research Protection Program (HRPP), including the UW-Madison Institutional Review Boards (IRBs).
   3. Development and approval of all policies for the HRPP.
   4. Facilitating communications and exchange of information about human research protection among the IRBs, between the IRBs and the UW-Madison’s research community and the UW-Madison community as a whole.
   5. Communicating directly or through the UW-Madison IRBs with University institutions, officials, faculty, and staff, as necessary, about regulatory requirements governing human research protection and interpretations of those requirements.
   6. Facilitating access by researchers to cross-disciplinary information and training about human research protection through the UW-Madison Graduate School.
   7. Advising the IRBs on issues relating to human research protection.
   8. At the request of a UW-Madison IRB, reviewing an IRB decision in a case of noncompliance, unanticipated problem or suspension or termination of research.
   9. Advising the Institutional Official regarding the suspension of human research privileges and reporting to federal authorities in matters involving noncompliance, unanticipated problems and suspension and termination of research.

   B. The Advisory Committee may review a UW-Madison IRB’s determination of noncompliance, unanticipated problem or suspension or termination of research relating to a human research protocol at the request of an investigator. The Advisory Committee’s review of a UW-Madison IRB’s decision will be limited to determining whether the UW-Madison IRB has:

   1. followed its own procedures,
   2. correctly applied federal regulatory criteria or state law, or
   3. correctly applied UW-Madison policies.

In the event the Advisory Committee determines that a UW-Madison IRB has failed to follow its own procedures, has not correctly applied federal regulatory criteria or state law, or has not correctly applied UW-Madison policy, the Advisory Committee will return the matter to the UW-Madison IRB with recommendations for correction or additional review. The Advisory Committee does not make independent findings of fact when conducting its review of a UW-Madison IRB’s decision but may request that the UW-Madison IRB conduct additional fact finding.
If an IRB disapproves a protocol, defers a protocol application or requires protocol modifications as a condition for approval, neither the Advisory Committee nor any other UW-Madison official or committee may overturn the IRB’s decision nor apply undue pressure on the IRB to reverse a decision or may approve research that has not been approved by an IRB. However, research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. 45 CFR 46.112.

A protocol application that has been reviewed by a UW-Madison IRB may not be resubmitted by the investigator to another UW-Madison IRB unless the original IRB refers the protocol to the other IRB. (See, Review by Experts Policy)

II. Selection of Advisory Committee Members.
A. The Chancellor of the UW-Madison appoints all Advisory Committee members, who include:

1. The UW-Madison Institutional Official, who serves as chair of the Advisory Committee.
2. The chair of each of the UW-Madison IRBs.
3. Other members at large selected by the Chancellor.

B. The Chancellor may also appoint a representative from outside the UW-Madison community (a public member).

C. Ex-officio members, non-voting, include:

1. The director of the UW-Madison HRPP.
3. The primary administrators from each of the UW-Madison IRBs.
4. Other ex-officio members at large selected by the Chancellor.

D. Alternates for Committee Members. Committee members may designate an alternate who may exercise all the authority of the committee member at the meeting for which he or she acts as an alternate. Alternates may include, but are not limited to, the Director or Manager of the IRB for which the member serves as chair. To conduct a meeting with alternates present, at least a simple majority of the required quorum must be committee members who are faculty or have been granted voting rights by their department.

III. Conflict of Interest for Advisory Committee Members.
The Advisory Committee applies the UW-Madison IRB Member Conflict of Interest Policy to Advisory Committee members and consultants.

IV. Advisory Committee Meetings.
A. The Advisory Committee meets monthly and at the call of its chairperson.

B. Advisory Committee business is not initiated without a quorum, which is a simple majority. The Advisory Committee uses Roberts’ Rules of Order to conduct its business. The Advisory Committee makes decisions about the matters that come to it through discussion followed by voting.

C. The Advisory Committee makes and keeps minutes for each of its meetings.
V. University Services to the Advisory Committee.
   A. The Research Policy Office in the UW-Madison Graduate School provides staff support for the Advisory Committee in fulfilling its responsibilities as listed in Section A.1.a-g, above.

   B. The Office of the Secretary of the Faculty conducts annual orientation seminars for new faculty members that inform them of the purposes and processes of the Advisory Committee and the four UW-Madison IRBs.
Appendix D: University Structure Comparison Matrix
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<th>Universities for Comparison with MSU OCRCs</th>
<th>ORCS (2022-21)</th>
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<td><strong>College of Medicine</strong></td>
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</table>

- **ORCS**: Organizational Research Compliance Systems
- **MSU**: Michigan State University
- **UM**: University of Michigan
- **Univ.**: University
- **ORCS (2022-21)**: Data for the 2022-21 academic year

*Wisconsin Statutes section 133.001 requires the Wisconsin Department of Commerce to adopt and enforce safety and health standards that will provide protection to public employees at least equal to that provided to private sector employees under standards promulgated by Federal Occupational Safety and Health Administration.*