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Improving the Biosafety Protocol Review Process at UW-Madison

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Introduction

At UW Madison, the Office of Biological Safety (OBS) is the administrative home of the Institutional Biosafety Committee (IBC). In the spirit of continuous programmatic improvement, in 2020-2021 we conducted a comprehensive review of the biosafety protocol process.

Method

Initially, OBS conducted an internal review in which each step of the protocol process from pre-submission to post-approval was evaluated from the perspectives of the principal investigator (PI) and research team, the IBC, and OBS staff. We evaluated the outcomes, constraints, and prior improvements with the goal of identifying ways to reduce PI burden and increase the efficiency of OBS operations without compromising safety, compliance, or service. The results were compiled and reviewed by the IBC. To engage our research community, the report was shared, and a public comment period was offered. This feedback was used to draft an implementation plan.

Results

Many notable strengths were identified during this analysis, including high rate of compliance, expertise of IBC and OBC staff, and efficiency and design of the biosafety protocol. Areas of opportunity were identified, and specific recommendations were proposed to improve the review process, electronic biosafety protocol, and communications. These were reviewed by the IBC and modified based on their feedback. Then these were shared for public comment. More than 80% of comments submitted during the public comment period supported the proposed changes.

Figure 1. UW-Madison bioresearch at a glance

48K Students

24K Employeees

$1.3B Annual research spending (2020)

80+% PIs work with microbes or infectious agents

50+% PIs work with animals

85% PIs approved to work at BSL2

26 PIs approved to work at BSL3

UW-Madison is a **Big 10** University with research-intensive medical, veterinary, agricultural, and graduate schools.

UW-Madison also has cooperative agreements for biosafety services with local affiliate organizations.

Figure 2. OBS organizational chart

OBS is a unit within Environment, Health and Safety. OBS has 25 full-time staff members organized into four teams: (1) IBC and Laboratory Operations ("Ops"), (2) Animal Research Safety, (3) Select Agent/Dual Use Research of Concern (DURC), and (4) Biocontainment. Each team has different roles in supporting the IBC and protocol review process.

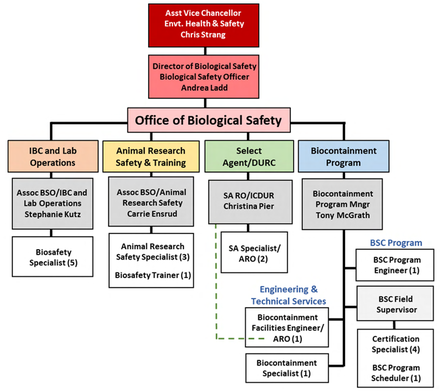


Figure 3. Biosafety protocol process workflow

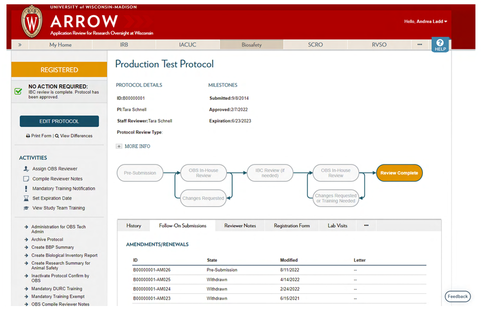
Activity	Number
IBC meetings organized	12
Principal Investigators (PIs) with active biosafety protocols (as of 06/30/22)	574
Total number of active biosafety protocols (as of 06/30/22)	606
Protocols and amendments that underwent full review (i.e., OBS followed by IBC review)	302
Total new biosafety protocols reviewed by OBS	35
Total biosafety protocol renewals and research amendments reviewed by OBS	467
Total grant/personnel amendments reviewed by OBS	1562

Table 1. Biosafety protocol and IBC administrative functions for FY22

OBS is the administrative home of the IBC. The IBC and Laboratory Operations ("Ops") team within OBS receives and processes all new biosafety protocols, renewals, and amendments.

The Ops team conducts a pre-review of each protocol or amendment to look for compliance with the NIH Guidelines, IBC policies and requirements, and biosafety best practices as outlined in the UW-Madison Researchers' Biosafety Manual and BMBL. The Ops team also determines whether IBC review is required and communicates decisions of the IBC to the research team. Where applicable, the Animal Research Safety team conducts a congruency check between the biosafety protocol and animal protocol. All OBS teams support the IBC as subject matter experts.

Figure 4. Bio-ARROW online protocol system



Application Review for Research Oversight at Wisconsin (ARROW) is an online workflow system used for the submission, review, and tracking of biosafety (IBC), animal care and use (IACUC), human subject (IRB), stem cell, and drone safety research protocols. First implemented in 2015-2017, OBS works with a UW-Madison IT team to make continuous improvements to Bio-ARROW.

Figure 5. Evaluating the biosafety protocol review process

Evaluate each step in the protocol process from the perspective of the Principal Investigator

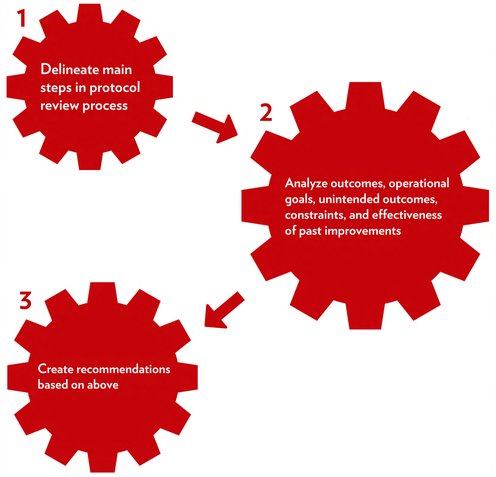
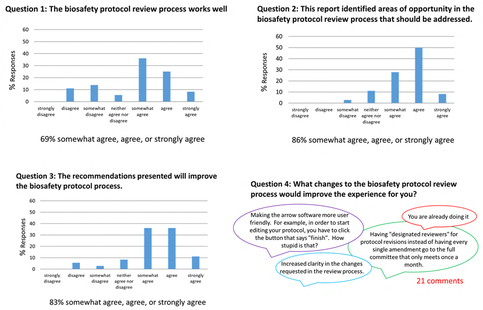


Figure 6. Public comment period for recommendations

To increase transparency about the process, performance, challenges, and proposed changes, the biosafety protocol process review summary report was posted on the OBS website.

A one-month public comment period was held to solicit feedback from the research community:
- Email blast to 1400+ personnel
- 60% open rate, 286 clicks total (2x norm)
- 36 survey responses



Common themes identified in the feedback included:
- Improve clarity of requests for revision
- Desire for designated review
- Make ARROW more intuitive

Conclusions

Even in a robust biosafety program, opportunities for improvement can be identified. When implemented, these should enhance safety, compliance, and service while supporting the UW Madison research mission. By engaging stakeholders in this process, we are building relationships, increasing safety awareness, and reinforcing safety as a core value.