EMORY UNIVERSITY | Environmental Health and Safety Office
Research Administration

#19

IMPROVING EMORY UNIVERSITY'S BIOSAFETY PROTOCOL SUBMISSION PROCESS TO BE MORE EFFICIENT, A TRAINING TOOL, & A FIRST STEP TOWARDS E-SAFETY

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OBJECTIVE:

To show how Emory University's Environmental Health and Safety Office (EHSO) improved their Biosafety Protocol Form to make it more clear, efficient, and comprehensive. The form revision was also used as an initial step towards implementation of a fully electronic E-Safety protocol submission system and as a tool to train researchers on the NIH Guidelines for Research Involving Recombinant DNA Molecules.

This was achieved through internal review, benchmarking with other institutions, and beta testing with Principal Investigators (PI), EHSO, and IBC members.

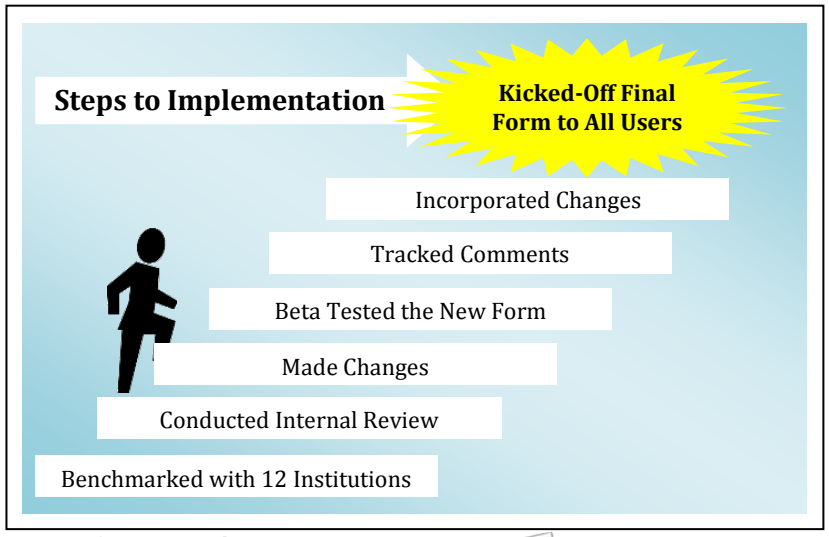
METHODS/IMPLEMENTATION:

Emory's Biosafety Protocol Form has undergone two major revisions (the last revision was in 2008). This third revision was recommended to:

- Improve the clarity of all questions
- Help resolve program gaps in recombinant DNA training

Steps towards Implementation:

1. Critically examined the current form to see what our internal gaps were.
2. Benchmarked with 12 other academic and government institutions with strong biosafety programs to see what strategies and lines of questioning they use in their biosafety protocol review processes.
3. Edited the form to encompass our perceived gaps and the opportunities we discovered through benchmarking.
4. Kicked off the revised, beta test version of the Biosafety Protocol Form to a group of eight PIs selected from various departments with a variety of research disciplines.
5. Reviewed forms submitted by the beta testers.
6. Documented and considered all feedback for further form revision.
7. Revised the beta test version of the form to include all validated recommendations.
8. Implemented the new form to the entire University and began to track metrics of the review process to see if our process improved via use of the new form.



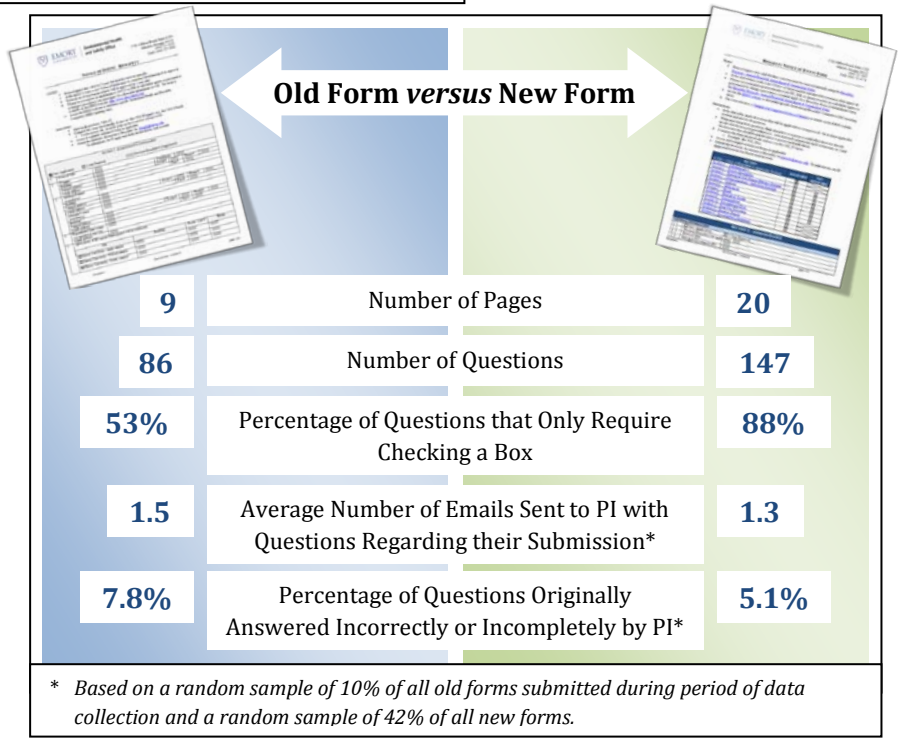
RESULTS/DISCUSSION:

New Form is More Efficient

- Although the new form is much longer than the previous version, we found that the new form is less time consuming for the PI, EHSO, and IBC members.
- We believe that this improvement is largely due to the improved questioning, structure, and clarity in the new form.
- The new form is structured in a way that the researchers are only directed to review a selection of questions based on the materials they use in their research.
- When the questions in the form are implemented as part of E-Safety, the process should be even faster since PIs will not see non-applicable questions. Also, the percentage of check box questions increased from 55% in the old form to 88% in the new form.

New Form is a Training Tool

- By including more aspects of the NIH Recombinant DNA Guidelines, we were able to use the form as a way to train PI's on the Guidelines.
- This made it easier for the PIs and EHSO to classify recombinant DNA experiments and determine review/approval requirements.



CONCLUSIONS/FOLLOW-UP:

Through collaboration with reviewers, end users, and benchmarking with our peers, we were able to improve our Biosafety Protocol Form so that it is more efficient and trains researchers on other EHSO programs and the NIH Recombinant DNA Guidelines. This revision has allowed us to verify the questions asked in the form before they are introduced formally into the E-Safety online protocol process, expected to launch in 2013.

The revision also provided a few unexpected benefits:

- Included questions regarding researcher collaboration
- Resolved IACUC issues
- Focused on a broader perspective on who the project effects

This process is in line with the management system's PDCA (Plan, Do, Check, Act) method. We recognize that the current form continues to present some challenges for the researchers: the most significant being completing the project description. Soon, we hope to publish a completed sample Biosafety Protocol Form to our website to continue to improve the process.