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Select Agent Research: Considerations for "Optimal Personnel Characteristics"

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Association of
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AAMC Group on Research Advancement and Development (GRAND)

- The AAMC represents all 129 accredited U.S. medical schools; nearly 400 teaching hospitals and health systems, and about 90 academic societies.
- GRAND is a professional development group for research deans and deans of clinical research at AAMC member institutions.

AAMC Group on Research Advancement and Development (GRAND)

- Our member institutions and research deans strongly support biomedical research to strengthen national security, as well as other aspects of public health and safety.
- AAMC strongly supports and commends the work and deliberations of the NSABB, and has communicated this work to our constituents.

“Optimal Personnel Characteristics”

- Scientific productivity depends on a robust, vibrant community of investigators, heavily reliant on trust and scientific mores and norms. Enforcement of right behavior depends in great part on the community itself to identify and initiate steps toward correction.
- This research is vital to understanding the biology of Select Agents and related pathogens, as well as to detection, remediation, development of countermeasures, etc.

Considerations for new requirements

- It is critical to national security that we guard against the misuse of select agents and that we adhere assiduously to applicable rules and safety standards.
- It is also critical to national security (as well as public health and safety) to sustain a productive research establishment in select agents and other biological research.

Considerations cont.

- Even well-intended and well-formulated regulation can inadvertently undermine scientific productivity and communication by creating disincentives for investigators to pursue particular fields or lines of investigation, or by diverting institutional resources.
- Thus any regulation designed to enhance safety and security should be tailored, targeted, and as free as possible from disincentives for responsible investigation.

Considerations cont.

- A persisting difficulty for my and other institutions is coping with the compounding “compliance burden” from multiple regulations, no matter how well founded these regulations often are.
- The Federal Demonstration Project has estimated that more than one-third of a principal investigator’s time is now taken up addressing matters of compliance.

Conclusions

- Experience indicates that the most effective regulatory programs advance performance-based standards, allow for flexibility and discretion in application, and provide for local enforcement.
- Any new requirements should be carefully articulated and focused, and have the best chance of success if they embrace the support of the investigator community and their institutions.

Conclusions

- Any new requirements should be considered as dynamic, incorporating the opportunity for continuous evaluation and refinement for effectiveness.
- A critical component should be extensive and appropriate training for new investigators.

Conclusions

- Similar to NSABB's earlier recommendations on dual use research of concern, new requirements should promote communication and encourage development of professional standards within the scientific community.
- Should provide for direct funding to support compliance, education/training, and professional development and communication



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