ESTABLISHING A SEAL OF APPROVAL TO INCENTIVIZE ADHERENCE TO BIOSECURITY NORMS

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The goal of this work is to incentivize adherence to norms of responsible conduct by bioscience researchers around the world, and this paper explores the concept of a "seal of approval" as a means toward that end.

A key challenge to developing widely held biosecurity norms stems from the lack of institutional incentives within the organizations where research is conducted, including academic institutions, private research laboratories, and commercial R&D enterprises. For example, the current structure of the academic research enterprise leads to strong institutional incentives for scientists to publish—driven by universities, funders and academic prestige—and few incentives to hold off on conducting potentially risky research or to refrain from publishing results that may contain information hazards. For private research laboratories, service providers that synthesize and sequence DNA-based products and commercial R&D enterprises, key priorities are maintaining profitability, protecting intellectual property and driving innovation. Like academia, these organizations have few structural incentives to build biosecurity best practices into their operations—with the possible exception of avoiding reputational risk and protecting intellectual property.

To strengthen biosecurity without unduly hindering bioscience research and innovation, the scientific community should develop a shared set of norms regarding responsible research, which take into account the different institutional drivers across academia and industry, and develop new structural incentives for researchers to adopt those norms.

These norms can be built around several key ideas: (1) Careful risk assessment before conducting potentially dangerous dual-use research that would be problematic if materials were accidentally released into the surrounding community or the environment, (2) careful consideration of information hazard risks before publishing sensitive scientific research, and (3) careful risk assessment when providing potentially dual-use goods and services to a public customer base.

The two communities of particular interest for this approach are the synthetic biology and virology communities, both of which are engaged in research that is valuable for scientific innovation and human health, but which lends itself to particularly acute dual-use risks. The synthetic biology community has a focus on developing new tools for reading, writing and editing genetic material, as well as and genome engineering that dramatically alters the genotypes and phenotypes of cells and organisms. The virology community is focused on studying, modifying and developing countermeasures against pathogens of pandemic potential.

A Proposed Solution

One way to strengthen norms within the bioscience research community is to start by building them into the operations of organizations and consortia, which provide services and materials necessary for bioscience research. Examples of potentially relevant types of organizations include: DNA synthesis providers, organizations that share genetic parts, organizations that share pathogen samples, and journals that publish scientific research. If these gatekeepers of resources for the bioscience research community hold up certain standards of practice, or norms, as essential for gaining access, this is likely to strengthen institutional incentives for scientists in the community to abide by said norms.

To lay the groundwork for this new kind of relationship between researchers and gatekeeper organizations, this paper explores the possibility of setting up a "seal of approval." Specifically, gatekeeper organizations could provide a seal of approval for researchers who abide by a set of agreed upon best practices or norms, and that seal could be required for gaining access to materials or services from the organizations in question.

This seal of approval concept could be explored through an initial pilot project with one to two organizations to demonstrate a proof of principle. If shown to be effective, this approach could then be scaled to a wider group of entities.

More specifics about how to implement this idea

There are several types of organizations and consortia that could be relevant partners for this initiative:

- Organizations that are repositories of pathogen samples or plasmids. For example ATCC sells a wide variety of bacterial strains, viruses and cell cultures for research purposes, and Addgene is an global non-profit repository that facilitates plasmid sharing among scientists.
- WHO Collaborating Centers, including the centers focused on influenza and the broader network of centers focused on communicable disease.
- Synthetic biology consortia, such as GP Write, Bionet, the Engineering Biology Research Consortium and SynbiCITE.
- Members of the International Gene Synthesis Consortium (IGSC) as well as other non-member DNA synthesis companies.
- Commercial foundries, such as Ginkgo Bioworks, which provide materials and design services that are more complex than DNA synthesis.
- Journals, or consortia of journals, which publish academic research.
- National academies of science in countries that are leading and funding research on pathogens with pandemic potential and technology development for synthetic biology.

In discussing the concept of a seal of approval, it is useful to think concretely about the criteria that would be considered for obtaining it. Examples of the kinds of practices that this system could incentivize for individual researchers, principal investigators or entire organizations include:

- Conducting a self-assessed risk evaluation before undertaking new research projects. For example, the International Genetically Modified Machine (iGEM) competition is developing a risk assessment tool that student teams can use to evaluate their synthetic biology projects. This tool, if shown to be effective, can be applied in other contexts.
- Signing onto a normative statement or public pledge to consider dual-use risks when designing research projects and when considering whether to publish research results.
- Establishing and regularly conducting biosecurity training for lab personnel, which is not currently standard practice.
- Committing to only purchase synthetic DNA and RNA from members of the IGSC or companies that abide by IGSC best practices.

Challenges and Open Questions

There are a number of challenges in setting up such a seal of approval system.

- **Responsibility and Oversight.** Who would take responsibility for developing the criteria for a seal of approval? One option is to start by developing a set of criteria within a single gatekeeper organization as part of a pilot project. The benefit of this approach is that it could move forward quickly and efficiently. However, any set of criteria developed by a small group would need to be revisited later in order to get wider buy-in from the broader research community.
- **Compliance and Verification**. How would compliance with seal of approval criteria be verified? This would require staff time and organizational support that is not currently established.
- **Determination of Benefits**. How would seal of approval compliance be rewarded? There are a couple approaches that could be considered. One option is to require the seal of approval for access to the goods or services provided by the consortium or organization in question. The benefit of this approach is that it's straightforward to operationalize. The downside is that it could be considered draconian or excessively restrictive. A second possible approach is that researchers with the seal of approval would have speedier access to resources provided by the consortium. While this less stringent approach may be more readily accepted by the research community, it is difficult to implement in practice.
- **Level of Engagement**. Would the seal apply to individuals, laboratories or at the institutional level? For academia and in some parts of industry, awarding seals of approval at the principal investigator (PI) level, encompassing entire laboratories, is likely to be effective at incentivizing participation and compliance with norms. In other parts of industry where research is structured differently, applying the seal of approval concept to entire organizations may be more practical.

What Would a Pilot Look Like?

As discussed above, one way to approach setting up a seal of approval is to arrange a pilot with one to two organizations to show a proof of principle and attempt to create a replicable model that can be scaled up.

GP Write, a consortium of academic researchers from around the world, is one potential partner for a seal of approval pilot project. GP Write aims to use synthesis and genome editing technologies to increase understanding of living systems and to develop improved tools for engineering and testing large genomes within cells. The consortium is housed at the Center for Engineering Excellence, which plans to administer funding from a range of public and private sources and support a series of pilot research projects to advance GP Write goals. One option for applying the seal of approval approach in this context is to require that all pilot project participants meet the criteria for such a seal. An alternative option is to require a seal of approval for any consortium member that will gain access to shared resources, such as pooled patents and common licensing agreements or pooled data.

How Can This Effort Be Scaled Globally?

While the initial step for an effort like this would involve a pilot project, it is also important to have a vision for how this could scale globally. Preliminary ideas on how to approach this are provided below:

- DNA synthesis consortia can increasingly incorporate companies from around the world.
- Any best practices regarding sample sharing that are piloted in WHO collaborating centers could be expanded to other labs and academic consortia globally.
- National academies can accelerate scaling by making seal of approval compliance a consideration in evaluating prospective members.
- Develop a formal gatekeeper organization with trained biosecurity officers.
- Develop education and training for Biosecurity Officers for each type of organization and institute.