

SYNBERC POLICIES ON SAFETY AND SECURITY FOUR PRINCIPLES AS GUIDES TO PRACTICE

I. COMPLIANCE: SynBERC is committed to full compliance with Federal regulations, including NIH, EPA, USDA, FDA and Commerce Department regulations and guidelines.

Academic researchers in biological engineering are generally familiar with institution oversight procedures and NIH Guidelines. Other Federal regulations bearing on Synthetic Biology are not as well understood. As a consequence, we will inform researchers on other Federal requirements and encourage researchers to internalize such requirements.

SynBERC commissioned “The Regulation of Synthetic Biology: A Concise Guide,” a review of EPA, USDA, FDA and Commerce Department regulations and NIH Guidelines for the internal use of SynBERC researchers; and set up a workshop on “Safety, Security and Preparedness” to raise awareness of obligations among SynBERC researchers. We will continue to update and extend this programming for our research groups.

II. MINDING GAPS: SynBERC is committed to identifying gaps in existing regulations on safety, security and sustainability, and to recommending both regulatory and voluntary measures to fill gaps.

Public policies established to address risks associated with conventional RDNA manipulation and other earlier technologies may be insufficient to address issues raised by Synthetic Biology. We encourage our researchers to work with regulatory agencies, firms, nongovernmental organizations, insurers and other research groups, in the US and abroad, to identify emerging risks, to flag policy gaps, and to suggest regulatory and voluntary measures to fill gaps. Engagement with a broader-than-usual spectrum of actors with a wider-than-usual range of concerns and areas of expertise may help flag sources of uncertainty, identify blindspots, and question priors.

SynBERC has funded assessments of safety and security risks and now support a project evaluating existing regulations. Our PIs have worked on the Sloan Foundation “Synthetic Genomics” project, the NSABB/RAC Roundtable on Synthetic Biology, the International Risk Governance Council workshop on Synthetic Biology and other risk management initiatives. Our PIs work with European and US regulatory agencies on safety and security issues and are encouraging formation of professional organizations to encourage safer and more secure practices.

III. PROACTIVE MEASURES: SynBERC is committed to continued development of proactive measures to improve safety, security and sustainability beyond regulatory requirements and in advance of problems.

Taking note of exponential advances in DNS synthesis, design and assembly, the 2007 NSABB/RAC Roundtable on Synthetic Biology asked biological engineers to rise to the challenge of developing proactive approaches to addressing potential risks. We agree that reactive approaches are not enough.

SynBERC has provided seed funding for a project by the Arkin / Church / Knight / Oye groups on the design and testing of biological chassis for safety and sustainability, with attention to limiting chassis survivability and genetic exchange on release. We will support work on evaluating the security implications of modularity, with sustained attention to the design and testing of protocols and standards that may reduce risks of malicious modification of biological devices.

IV. OUTREACH: SynBERC is committed through outreach to improve practices on safety, security and sustainability issues within broader communities of biological engineers.

Synthetic Biology methods and applications are diffusing rapidly across international boundaries and from institutional to non-institutional settings. As advanced capabilities diffuse, a focus on safety and security within this broader community is required.

SynBERC will partner with this expanding community of biological engineers to increase awareness of safety, security and safety issues, to encourage adoption of appropriate technical practices, and to increase awareness of regulatory obligations. To this end, we are developing materials on safety and security suitable for outreach to iGEM teams, firms and unaffiliated researchers.