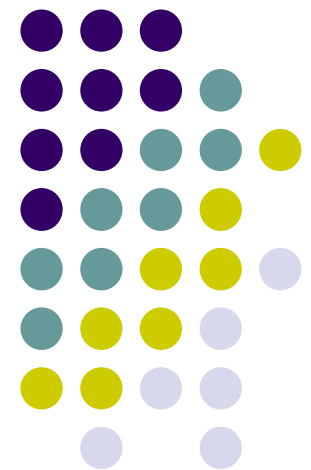


Biotechnology Research: Biorisks and Biosecurity Responses

Elisa D. Harris

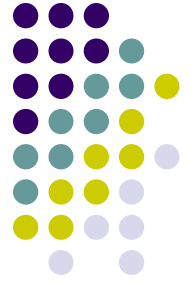
**Center for International and Security
Studies at Maryland**



Confronting Biological Threats: Biosecurity,
Biological Weapons Nonproliferation, and Regional
Cooperative Mechanisms

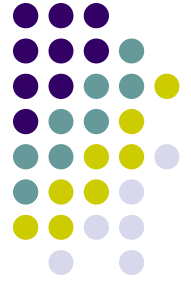
Amman, Jordan

October 27-29, 2008



The Problem

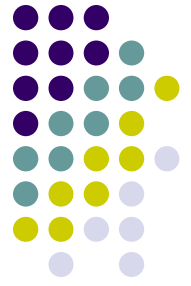
- Increasing concern about dual-use research: research that can have both highly beneficial & highly destructive consequences
- New dangers arising from:
 - Unexpected or unintended results
 - Misuse of legitimate research
- Not a future problem; well-known examples:
 - Mousepox
 - Poliovirus
 - 1918 Influenza
- Thus far, no mechanisms in place to address:
 - Biosafety rules protect lab workers/environment
 - Biosecurity rules control access to dangerous pathogens
 - **No** rules governing conduct of research



Importance of Balance

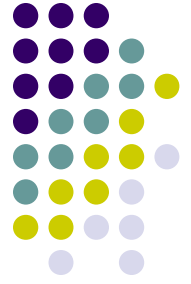
- Measures to address dual-use issue must be balanced:
 - Protect right of scientific investigation *and* norm against destructive applications of biology
 - Provide reassurance to scientists they will not be subject to excessive regulation *and* to society that power of biology is being used appropriately

CISSM Controlling Dangerous Pathogens Project



- Oversight ideas product of multi-year effort:
 - What is potentially dangerous?
 - How can we manage risk without impeding necessary research?
- Domestic workshops with multi-disciplinary group
- Regional workshops: Hungary, Brazil, Singapore, Thailand, South Africa; Middle East next

Essential Features of CISSM Model



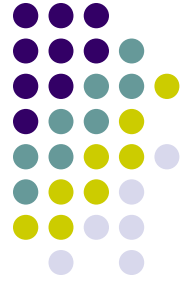
- **Narrowly focused:** excludes most biomedical/pathogen research
- **Readily implemented:** areas subject to oversight clearly defined, based on specific, objective criteria
- **Equitably applied:** requirements apply to all relevant research, without exception
- **Uniformly enacted:** requirements harmonized across countries, regions, internationally
- **Efficiently designed:** system links level of oversight to nature and extent of risk, with local review predominant
- **Legally based:** rules embodied in mandatory regulations, not voluntary guidelines



Key Elements of CISSM Model

- Licensing or registration of certain personnel and facilities
- Independent peer review of certain research projects before they are undertaken

Licensing/Peer Review Precedents



- National licensing/registration:
 - Personnel background checks/registration for US select agents
 - Facility licensing for radioactive materials
 - Dual-use licensing/registration consistent with existing requirements
- Independent peer review of projects in advance:
 - Local approval of rDNA/human/animal research
 - National (NIH) approval 2 categories rDNA
 - Internat. (WHO) approval US/Russian smallpox research
 - Dual-use review could be added to existing review processes



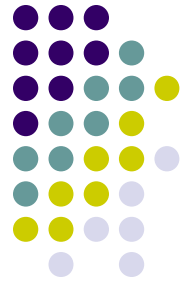
CISSM Model

- **Global Implementing Body:** Oversee & approve research of extreme concern (i.e., involves more dangerous pathogens than now exist):
 - Work with eradicated agent
 - Work with agent assigned BSL4/ABSL4
 - *De novo* synthesis of above
 - Expanding host or tissue range of listed agent
 - Construction of antibiotic/vaccine resistant listed agent



CISSM Model - Cont'd

- **National Review Body:** Oversee & approve research of moderate concern (i.e. involves pathogens already identified as public health threats):
 - Increasing virulence of listed/related agent
 - Insertion host genes into listed/related agent
 - Increasing transmissibility/environmental stability listed/related agent
 - Powder or aerosol production of listed/related agent
 - Powder or aerosol dispersal of listed/related agent
 - *De novo* synthesis of listed/related agent
 - Construction of antibiotic/vaccine-resistant related agent
 - Genome transfer, genome replacement or cellular reconstitution of listed/related agent



CISSM Model – Cont'd

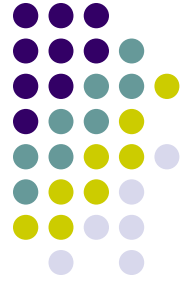
- **Local Review Body:** Oversee research of potential concern (i.e., increases destructive potential of benign pathogens)
 - Work with listed agent not covered above
 - Increasing virulence of nonlisted agent
 - Increasing transmissibility/environmental stability of nonlisted agent
 - Powder or aerosol production of nonlisted agent
 - Powder or aerosol dispersal of nonlisted agent
 - *De novo* synthesis of nonlisted agent
 - Genome transfer, genome replacement, or cellular reconstitution of nonlisted agent

System in Practice

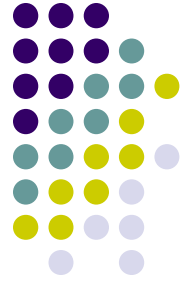


- Researcher submits proposed project to peer review body
- Risk-benefit assessment conducted:
 - Biosafety Rating: whether proposed research plan minimizes risk to public and environment
 - Adequacy of Research Plan: incl whether there are scientific reasons why the same outcome cannot be pursued through other means
 - Public health rationale: incl whether research will advance understanding of disease causing properties of existing pathogens
 - Biodefense rationale: incl whether work being done in response to validated or theoretical threat
 - Current necessity of work: incl whether there are medical countermeasures available for use against agents to be constructed
 - Potential impact: incl whether proposed results will inform policy

Impact of CISSM Model



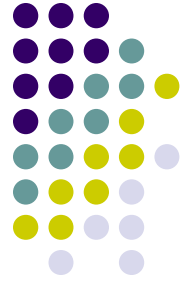
- Review of journals 2000-mid2005 suggest minimal impact on US researchers:
 - <1% publications involving bacteria, viruses, prions would have been affected
- Overall: 310 US facilities 2,574 researchers (53 facilities 137 researchers in multiple levels)
 - International: 12 facilities 185 researchers
 - National: 14 facilities 133 researchers
 - Local: 231 facilities 2,119 researchers
- Impact in other countries would be much more limited



Conclusion

- Recognize an internationally harmonized, mandatory oversight system is an ambitious goal; pending achievement, other more incremental measures should be pursued:
- Education, awareness raising, codes of conduct to sensitize individual scientists
- Inclusion of dual-use review requirement in national biosafety arrangements
- Harmonization of standards by like-minded countries
- Building on existing WHO guidelines for laboratory biosafety & biosecurity through dual-use guidelines for use by member states

Thank You!



Further information available at:

<http://cisism.umd.edu/projects/pathogens.php/#papers>

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