

RISKS, BENEFITS, AND ETHICS IN GAIN-OF- FUNCTION STUDIES

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General Ethical Principles

- **Beneficence:** Research risks should be justified by potential benefits to society
- When is it justifiable to seek certain benefits despite risks involved?
- When should possible benefits be forgone because risks are too great?
- Minimize risks as much as possible

General Ethical Principles, cont'd

- **Respect for Persons:** Give individuals freedom to decide whether to accept research risks after disclosing risks and other important study information
- **Justice:** Fair distribution of research risks and benefits among individuals and groups

Respect and Justice in Risk Exposure

- Require notice? Require consent?
- GOF laboratory workers
- Clinicians caring for affected people
- Others present in facilities
- Close contacts of above
- General public

Public Notice/ Participation Options

- Review committee members
- Information transparency
- Community engagement
- Deliberative approaches (e.g., citizen panels, deliberative polls)

Research Precedents and Decisions

- Xenotransplantation studies in humans
- Nuclear-powered artificial heart
- Recombinant DNA

GOF Features

- Unlike other situations, no identifiable beneficiaries; potential benefits and harms are both statistical
- Alternatives issues: promoting alternatives; requiring alternatives

From the Literature

- **Risks and Benefits of Gain-of-Function Experiments with Pathogens of Pandemic Potential, Such as Influenza Virus: a Call for a Science-Based Discussion, Casadevall, Imperiale, August 2014** *mBio* vol. 5 no. 4 e01730-14
- If pro- and anti-GOF research proponents reach an impasse, perhaps the debate could refocus on identifying the important questions in influenza virus research that both groups feel should be answered and in finding new creative experimental alternatives that satisfy both camps.

From the Literature

- **The ethics of biosafety considerations in gain-of-function research resulting in the creation of potential pandemic pathogens**, Evans, Lipsitch, Levinson, *J Med Ethics* doi:10.1136/medethics-2014-102619
- Whatever one's views on the scientific merits of GOF/PPP work, the humanitarian goal of preventing and mitigating influenza may be approached by a large number of alternative paths, some of which may have considerable practical advantages over GOF/PPP studies.