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## Gain-of-Function Research: Ethical Analysis

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### Abstract

Gain-of-function (GOF) research involves experimentation that aims or is expected to (and/or, perhaps, actually does) increase the transmissibility and/or virulence of pathogens. Such research, when conducted by responsible scientists, usually aims to improve understanding of disease causing agents, their interaction with human hosts, and/or their potential to cause pandemics. The ultimate objective of such research is to better inform public health and preparedness efforts and/or development of medical countermeasures. Despite these important potential benefits, GOF research (GOFR) can pose risks regarding biosecurity and biosafety. In 2014 the administration of US President Barack Obama called for a "pause" on funding (and relevant research with existing US Government funding) of GOF experiments involving influenza, SARS, and MERS viruses in particular. With announcement of this pause, the US Government launched a "deliberative process" regarding risks and benefits of GOFR to inform future funding decisions-and the US National Science Advisory Board for Biosecurity (NSABB) was tasked with making recommendations to the US Government on this matter. As part of this deliberative process the National Institutes of Health commissioned this Ethical Analysis White Paper, requesting that it provide (1) review and summary of ethical literature on GOFR, (2) identification and analysis of existing ethical and decision-making frameworks relevant to (i) the evaluation of risks and benefits of GOFR, (ii) decision-making about the conduct of GOF studies, and (iii) the development of US policy regarding GOFR (especially with respect to funding of GOFR), and (3) development of an ethical and decision-making framework that may be considered by NSABB when analyzing information provided by GOFR risk-benefit assessment, and when crafting its final recommendations (especially regarding policy decisions about funding of GOFR in particular). The ethical and decision-making framework ultimately developed is based on the idea that there are numerous ethically relevant dimensions upon which any given case of GOFR can fare better or worse (as opposed to there being necessary conditions that are either satisfied or not satisfied, where all must be satisfied in order for a given case of GOFR to be considered ethically acceptable): research imperative, proportionality, minimization of risks, manageability of risks, justice, good governance (i.e., democracy), evidence, and international outlook and engagement. Rather than drawing a sharp bright

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line between GOFR studies that are ethically acceptable and those that are ethically unacceptable, this framework is designed to indicate where any given study would fall on an ethical spectrum—where imaginable cases of GOFR might range from those that are most ethically acceptable (perhaps even ethically praiseworthy or ethically obligatory), at one end of the spectrum, to those that are most ethically problematic or unacceptable (and thus should not be funded, or conducted), at the other. The aim should be that any GOFR pursued (and/or funded) should be as far as possible towards the former end of the spectrum.

**Keywords:** Biosafety; Biosecurity; Decision theory; Dual-use research; Gain-of-function research; Risk-benefit assessment.

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