MONASH University
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Gain of Function Research: Ethical Analysis

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GOF Research Ethics White Paper

I. Review and summarize ethics literature on GOF research

II. Identify and analyze existing ethical- and decision-making frameworks relevant to (1) evaluation of risks and benefits of GOF research, (2) decision making about the conduct of GOF studies, and (3) the development of US policy regarding GOF research

III. Develop ethical and decision-making framework to be considered by NSABB when analyzing information provided by risk-benefit analysis, and when crafting its final recommendations

→especially focused on policy issues regarding funding of GOF research.

→Neutral/objective analysis explicitly requested.

Ethical/Decision Framework for GOFRC Funding

1. Research Imperative
2. Proportionality
3. Minimization of risks
4. Manageability of risks
5. Justice
6. Good Governance—Democracy
7. Evidence
8. International Outlook and Engagement

Preliminary Comments

- Should not expect formula/algorithm—judgments will inevitably need to be made.
- Suggested framework aims to highlight ethical desiderata rather than state necessary conditions.
- Emphasis on importance of democracy.

Preliminary Comments

- Judgment that a study should not be published entails judgment that it should not be funded (given HHS policy)—but need not entail judgment that the research in question should not occur.
- Decision not to fund in light of concerns about publication less weighty than decision to censor would be—because former does not involve (negative) liberty violation or interference with science.

1. Research Imperative

- Ethical acceptability of GOFR posing extraordinary risks partly depends on the importance of the research question it aims to address.
  - The more important the target research question, the more ethically acceptable a study posing a given magnitude of risk would be.
  - The riskier the research would be, the more important the research question would need to be in order for the research to be justifiable.

2. Proportionality

- The ethical acceptability of extraordinarily risky GOFR partly depends on the extent to which there is reasonable expectation that the research in question will (1) yield answers to the target public health question, and (2) ultimately result in benefits that outweigh risks involved.
  - The greater the confidence that (1) and (2) are satisfied, the greater the ethical acceptability of funding/conducting/publishing a study posing a given magnitude of risk, and vice-versa.
  - Other things being equal, the greater the expected benefits of any given case of GOFR posing a given magnitude of risk, the more ethically acceptable the study would be.

3. Minimization of Risks

- Other things being equal, the ethical acceptability of (a case of) GOFR is a function of the degree to which (1) there is confidence that no less risky forms of research would be equally beneficial and (2) reasonable steps have been made to minimize risks of the GOFR in question.

- Standard idea in human research ethics, much appealed to in GOF debate.
- Parallel to “least restrictive alternative” principle in public health ethics.
- This principle does not (necessarily) imply that a less risky study should be preferred to a more risky study if the former would be less beneficial.

4. Manageability of Risk

- Other things being equal, the more manageable the risks of GOFR study, the more ethically acceptable the study would be. Conversely, the more important/beneficial (a case of) GOFR is expected to be, the more we should be willing to accept potentially unmanageable risks.
  - Some unmanageable risks may be less severe than others.
  - GOFR might itself aim to address (other/severe) unmanageable risks.

5. Justice

- Justice: fair sharing of burdens and benefits (of research).
- Ethical acceptability of GOFR depends on the degree to which (1) risks fall on some people more than others, (2) risks fall on those who are unlikely to benefit, and/or (3) any resulting harms are uncompensated.
  - Inter alia, this principle entails that countries conducting/funding GOFR should aim to mitigate risks for those who are especially vulnerable, ensure wide availability of GOFR research benefits, and compensate those who suffer harm.

6. Good Governance--Democracy

- Hard questions about GOFR turn on important questions—about ultimate values, value weightings, and risk-taking strategies—regarding which there is reasonable disagreement.
- In a democracy, decision- and policy-making regarding GOFR should reflect the values and risk-taking strategies, etc. of the people.
- Thus need systematic ongoing engagement with key stakeholders and community at large—e.g. via processes of deliberative democracy.
- Need for transparency.
- Important r/e value of public/confidence trust.

7. Evidence

- Need for evidence based policy making r/e: risks, benefits, risk-minimization, who is likely to benefit or be harmed, values and risk-taking strategies of the people.
  - Ongoing RBA, etc.
  - Social research (r/e values and risk-taking strategies of people)
  - Monitoring of GOFR

8. International Outlook and Engagement

- Because risks and benefits of GOFR (can) affect the global community at large, the ethical acceptability of GOFR partly depends on the extent to which it is accepted abroad. Decision- and policy-making regarding GOFR should (insofar as possible) involve consultation, negotiation, coordination, and related forms of active engagement with other countries.

Notes on Framework

- Ethically relevant dimensions/desiderata (and epistemic state r/e them) are matters of degree (rather than either-or).
- Ethical acceptability of any give study will come in degrees: a spectrum of cases.

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