

When to release preliminary findings: Ethical considerations

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Questions

- When ought preliminary findings be released to research participants, other scientists, and the public?
- When ought data for re-analysis be shared with other scientists and the public?



Moral framework

- To answer moral questions, we need a moral framework
- An articulation of the background of moral relationships and norms
- Distinguish three types of relationship:
 - Researcher-participant
 - Researcher-other scientist
 - Researcher-society
- Each is a *trust relationship* characterized by *trust-preserving norms* and reinforced by *trust enforcing mechanisms*

Trust

- “Trust...is reliance on another’s good will.” (Baier)
- Trust relationships are a subset of relationships of reliance, in which one person depends on another
- Trust is placed in circumstances of dependence engendered by inequality, e.g., of expertise, power
- Trust creates vulnerability as it may be exploited
- Trust is essential to cooperation, which is in turn necessary to achieve personal and communal ends in civil society
- Accordingly, there are trust-preserving norms and social sanctions for trust violations

Physician-patient relationship

- The end is protecting and enhancing the welfare interests of the patient in health
- There is inequality as the patient must depend on the physician to exercise her power and expertise beneficially to improve health
- Established social roles make the placement of trust, and basic expectations arising as a result, reasonable
- Without trust, the ends of the relationship could not be achieved
- Accordingly, there are trust preserving norms, e.g., duties of loyalty, and trust enforcing mechanisms, e.g., fiduciary law

Application

- How does a trust analysis apply to the three kinds of relationship in this case?
 - 1. Researcher-participant
 - 2. Researcher-other scientist
 - 3. Researcher-society
- Specifically, how is each a trust relationship?
- What are the trust-preserving norms in each?
- What are the trust-enforcing mechanisms for each?



1. Researcher-participant

■ Trust relationship

- End of the relationship is the production of knowledge and, when the participant is a patient, protecting or promoting the health of the participant
- Researcher possesses special expertise, giving rise to inequalities of knowledge and power
- Participant entrusts researcher with her care and confidences
- Thus, the participant must rely on the good will of the researcher



1. Researcher-participant

- Trust-preserving norms
 - Balance of benefits to harms
 - Equitable distribution of benefits and harms
 - Free and informed consent
 - Protect confidentiality
 - Inform participants of material changes to risks
 - Inform participants of research results



1. Researcher-participant

- Trust-enforcing mechanisms
 - Civil and criminal law
 - Regulation and regulatory authorities (e.g., Common Rule and IRBs)



On Being A Scientist (1995)

“The scientific research enterprise, like other human activities, is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias. The level of trust that has characterized science and its relationship with society has contributed to a period of unparalleled scientific productivity. But this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct.”



2. Researcher-other scientists

■ Trust relationship

- “The object of research is to extend human knowledge of the physical, biological, or social world beyond what is already known.”
- Experiential inequality: no direct observation of the experiments of others
- Direct verification of each scientific result every time it is relied upon is effectively impossible
- Scientists must rely on the honesty and accuracy of written reports and other communications



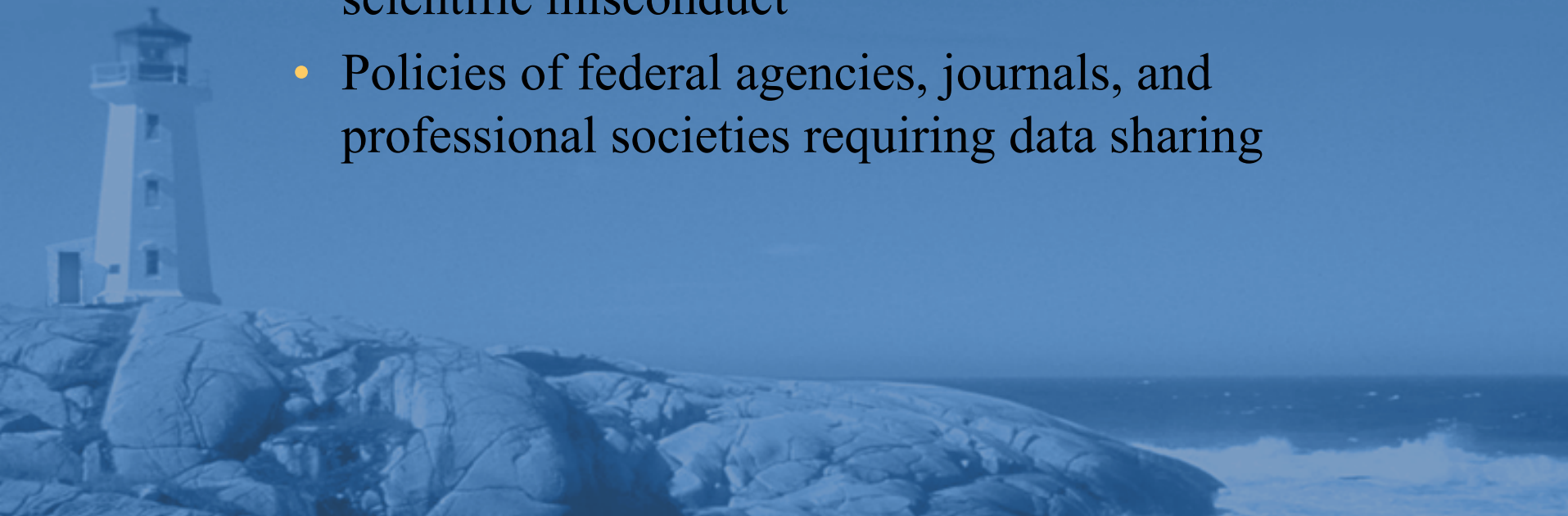
2. Researcher-other scientists

- Trust-preserving norms

- “[R]esults of research reflect an honest attempt by scientists to describe the world accurately and without bias”
- Carefully plan and conduct experiments
- Use unbiased methods to analyze results
- Report results completely and accurately
- “After publication, scientists expect that data and other research materials will be shared with qualified colleagues upon request.”

2. Researcher-other scientists

- Trust-enforcing mechanisms
 - Peer review by professional journals and other bodies
 - Institutional provisions to investigate and punish scientific misconduct
 - Policies of federal agencies, journals, and professional societies requiring data sharing



3. Researcher-society

■ Trust relationship

- End is to translate knowledge into the furtherance of important social projects
- Inequalities of knowledge, expertise, and experience
- Important social projects cannot proceed without societal reliance on scientific results and scientific expertise
- Achieving these ends requires that members of society trust scientists



3. Researcher-society

- Trust-preserving norms
 - Provide honest and accurate information to funding agencies and regulatory authorities
 - Conduct research and report results honestly, accurately, and without bias
 - Avoid conflicts of interest, and report them when they cannot be avoided
 - Employ expertise responsibly and without bias



3. Researcher-society

- Trust-enforcing mechanisms
 - Federal law regarding the provision of inaccurate information to the government
 - Criminal sanctions for fraud
 - Peer review
 - Policies of federal agencies, institutions, and public bodies regarding conflicts of interest



Back to the questions

- 1. When ought preliminary findings be released to research participants, other scientists, and the public?
- Research participants
 - Consent is premised on understanding and acceptance of material risks of participation
 - If material risks change substantially during the conduct of research, participants must be informed
 - Obligation to inform participants of study results
 - Generally, this would occur after peer-review of study results for publication

Back to the questions

- 1. When ought preliminary findings be released to research participants, other scientists, and the public?
- Other scientists and the public
 - Preliminary results are just that; they are results subject to verification and change
 - Practise of routine and widespread dissemination of preliminary results undermines trust as preliminary conclusions fail verification and are changed
 - Process of peer review protects trust in part by third party review of the robustness of study results

Back to the questions

“[I]f publication practices, either new or traditional, bypass quality control mechanisms, they risk weakening conventions that have served science well. An example is the scientist who releases important and controversial results directly to the public before submitting them to the scrutiny of peers. If the researcher has made a mistake or the findings are misinterpreted by the media or the public, the scientific community and the public may react adversely. When such news is to be released to the press, it should be done when peer review is complete—normally at the time of publication in a scientific journal.” *On Being a Scientist* (1995)

Back to the questions

- 2. When ought data for re-analysis be shared with other scientists and the public?
- Other scientists
 - Share data with qualified colleagues after publication
 - When data is confidential, proprietary, or classified sharing data openly is not possible
 - Trust may be promoted by special mechanisms to allow for some degree of scrutiny of data and the protection of confidentiality

Back to the questions

- 2. When ought data for re-analysis be shared with other scientists and the public?
- The public
 - Obligation to disclose data extends only to properly qualified scientists, and not the public
 - Individuals with scientific qualifications who have ceased to seek to “describe the world...without bias” have ceased to be scientists
 - Public dissemination of data will prompt incompetent and tendentious analyses that will undermine trust in the scientific enterprise

Conclusion

- These questions are situated in the context of analysis of trust relationships, each with trust-preserving norms and trust-enforcing mechanisms
- Potential solutions must be judged by the degree to which they further trust in a variety of relationships

