

An Ethical Review Framework for Studies of Leaked Data Reviewed Under Exempt Category 4(i)

Ben Mooso

UCSD

Outline

- Background
 - The exempt category
 - Definitions
 - The IRB's Purview
- Why do we need an ethical framework?
- Developing a Modern Ethical Framework
- Putting the Framework into Practice

Exempt Category 4(i)

- Applicable to human subjects research subject to all Subparts of the Common Rule
 - 45 CFR 46.104(b)
- Not applicable to FDA regulated clinical investigations
- 45 CFR 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (i) The identifiable private information or identifiable biospecimens are publicly available

Identifiable Private Information

- Private Information [45 CFR 46.102(e)(4)]
 - “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).”
- Identifiable Private Information [45 CFR 46.102(e)(5)]
 - “private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.”

Data Leaks

- Generally involves an unauthorized transmission of data from within an organization to an external destination or recipient.
- May be unintentional/accidental, intentional, and/or malicious.
- May involve benign, confidential, sensitive, or protected data.
- May involve identifiable, coded, anonymous, or de-identified data.
- Data may be held privately, shared amongst a small group, or made publicly available.

Not Always Under the IRB's Purview

- Leaked data could be argued to meet the “reasonable expectation of privacy” standard in all cases
 - May want to perform a case-by-case analysis
- Leaked data may not always meet the “readily identifiable” standard
- Exempt research is, by definition, not subject to the IRB review criteria of the Common Rule
 - Institutions may still require IRB review/assessment to ensure it is exempt

We Reviewed It. Now What?

- Leaked data which has been made publicly available may meet Exempt 4(i) criteria
 - Assuming it is identifiable data
 - Previous discussions at PRIM&R indicate WikiLeaks data would be fair game under this exemption
- IRBs are both regulatory bodies and ethics boards
- Regardless of the regulatory status of such research, may present an “ick” factor
- An ethical framework for review helps satisfy the “ick” factor and local news test

Developing a Modern Ethical Framework

- The Belmont Report
 - Considers important issues such as risk/benefit (Beneficence), who is burdened and who benefits (Justice), and how people have control over their data (Respect for Persons).
 - Seems to be lacking in addressing this specific context.
- “Aspects of Data Ethics in a Changing World: Where Are We Now?” Professor Hand
 - “In striving to strike an appropriate balance between benefit and risk, we need to be clear about who benefits and who incurs the risk. If these are borne by different actors, imbalances can occur—and indeed ethical disasters can result.”
 - Again we see the principle of Justice

Developing a Modern Ethical Framework

- “Analyzing the Ethical Implications of Research Using Leaked Data” Bousted and Herr
 - Primarily relies on the traditional Belmont Principles
 - Adds two additional questions to consider:
 - Is the research transparent and accountable?
 - Were any laws violated?

Developing a Modern Ethical Framework

- “Is it ethical to use hacked data in scientific research?” Ienca and Vayena
 - Proposes six tests for a research study to be considered ethical:
 - Risk-Benefit Assessment – Justice/Beneficence
 - Consent – Respect for Persons
 - Privacy – Respect for Persons/Beneficence
 - Uniqueness – Are the data unique and not obtainable from another conventional source?
 - Traceability – How and where have the data been obtained? The researchers should not have been involved in the hack or other illicit activity related to the data.
 - IRB Approval – Formal assessment of the above criteria by a trained ethics body.

Developing a Modern Ethical Framework

- Local ethics experts also suggest a seventh element: authenticity
 - Hackers/leakers may have their own agenda and may manipulate data prior to release
 - Manipulated data may lead to harmful research conclusions
 - Researchers should have a plan for assessing authenticity once they access the data
 - Research may need to be discontinued if data are found to be manipulated

Putting the Framework into Practice

- Researcher Jones wants to use a leaked dataset about country A's military
- The data was leaked by journalists in country B who is engaged in armed conflict with country A
- Jones believes the data will allow an analysis of ethnically biased promotions in country A's military
- Jones will combine the leaked data with non-identifiable data about country A surnames and their general ethnic origin from a previous study

Putting the Framework into Practice

- Who are the subjects?
 - Country A military personnel
- Ethical concerns
 - No consent for use of identifiable private information
 - Does the research benefit the same people who bear the risk burdens?
 - Are the foreseeable risks reasonable in relation to the foreseeable benefits?
 - Can the research be accomplished in another way or with other data?
 - How do we know these data are reliable?

Putting the Framework into Practice

- Risk-Benefit Assessment – Might need consultant review for expertise on country A
 - In our review our consultant identified that the research would likely merely confirm what military personnel in country A already knew.
- Consent – After consultant review, research would otherwise meet criteria for waiver of consent.
- Privacy – Researchers provided a plan for adequate practices to ensure privacy related to new inferences developed in the course of the research.
- Uniqueness – Researcher confirmed that the data are not able to be obtained through another more conventional channel (e.g. FOIA request)
- Traceability – Researcher confirmed that they were not involved in the hack
- Authenticity – Researcher was asked to include a plan for determining authenticity based on known ethnic diversity in country A generally as well as country A's military
- IRB Approval – Sent to social/behavioral committee. Determined ethical considerations were met and study was eligible for Exempt 4(i) determination.

DISCUSSION