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Considerations for ethics review of big data health research

by M Ienca · 2018 · Cited by 229 — In this **study**, we conducted a **scoping review** of the literature using five databases to identify and map the major challenges of **health**-related big data.

AI Overview

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A scoping review in PLoS One identifies challenges for ethics review committees (ERCs) in health big data research, including the need for stronger oversight, updated ethical frameworks for privacy, consent, and data ownership, and a potential mismatch between traditional ethics review models and the complexity of big data. The study highlights key considerations for ERCs and researchers, such as **data protection, potential for informational harm and algorithmic discrimination, and the role of data literacy and complementary oversight bodies**.

Key Ethical & Technical Considerations:

Privacy and Confidentiality:

A dominant concern involves protecting sensitive health information in large, complex datasets, which often involves data sharing, de-identification, and re-identification risks.

Informed Consent:

Traditional consent models are challenged by the volume and nature of big data, requiring new approaches to ensure transparency and effective communication of data uses and risks to participants.

Data Ownership and Control:

Questions arise regarding who owns the data, who controls access, and how data ownership can be used to protect individuals.

Harms and Risks:

Beyond physical harm, there is an increased risk of informational harm, including privacy breaches, surveillance, and algorithmic discrimination, particularly when linking datasets.

Transparency and Trust:

Building and maintaining public trust is crucial, necessitating greater transparency about data uses and potential benefits and harms.

Data Linkage and Heterogeneity:

The technical challenges of linking diverse datasets and managing data heterogeneity can complicate ethical analysis and assessment.

Challenges for Ethics Review Committees (ERCs):

Lack of Specific Guidance:

There is a general lack of specific, normative guidelines for big data ethics review, with existing guidance often derived from broader methodological or auxiliary fields.

Epistemic & Expertise Gaps:

ERC members may lack the necessary expertise and experience to critically evaluate the complex methodological and ethical issues in big data research.

Inadequate Traditional Frameworks:

Existing conceptual tools and ethical frameworks, developed in a pre-digital era, may be insufficient to assess the novel and unforeseeable risks posed by big data studies.

Proposed Reforms & Solutions:

Building Capacity and Data Literacy:

Enhancing data literacy and capacity among ERC members to understand and address big data's ethical nuances.

Complementary Oversight Bodies:

Establishing data-focused oversight bodies, such as data boards or security committees, to work alongside or complement ERCs.

Expanding IRB Functions:

Encouraging IRBs to extend their ethical oversight throughout the entire data lifecycle, from planning to dissemination, with the ability to audit data management and identify potential ethical violations.