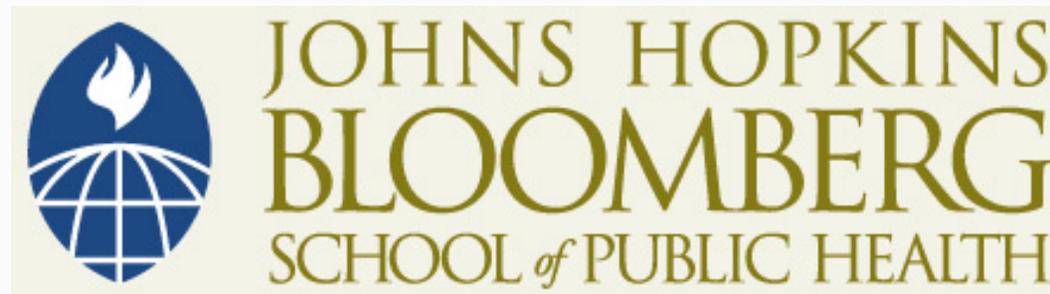


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JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section B

What Do the Guidelines Say on Privacy and Confidentiality?

The ICMR Guidelines for Biomedical Research

- The Indian Council for Medical Research (ICMR) guidelines include the principles of privacy and confidentiality as one of the guiding principles

Principles of Privacy and Confidentiality

- Principles of privacy and confidentiality whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential, and that no details about the identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the human subject concerned, or someone authorised on their behalf; and after ensuring that the said human subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the research or experiment

Safeguarding Confidentiality

- Safeguarding confidentiality—the investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual participants

- Data of individual participants can be disclosed under the following circumstances:
 - a. Only in a court of law under the orders of the presiding judge or
 - b. There is threat to a person's life or
 - c. In cases of severe adverse reaction may be required to communicate to drug registration authority or
 - d. If there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority

ICMR Guidelines: Confidentiality with Respect to Publications

- Investigator's publication plans should not threaten the privacy or confidentiality of subjects
 - Obtain consent for publication
 - In case of photographs, slides, videos, etc., of the participant, it is ideal to obtain prior consent to do so beforehand; identification features should be camouflaged if needed

A Before and After Photograph



Before

After

Source: Courtesy of Indian Journal of Dermatology, Venereology, and Leprology

ICMR Guidelines: Epidemiological Studies

- Maintaining confidentiality of epidemiological data is absolutely essential
- Some population data may have implications for issues like national security and these need to be carefully evaluated at the beginning

ICMR Guidelines: Human Genetic Studies

- Pedigree studies: special privacy and confidentiality concerns arise in genetic family studies because of the relationship between the participants
 - Family members are not entitled to know each others' diagnosis

- One needs to address issues related to breach of confidentiality if other family members find out
 - If proband is used, he/she might put pressure on other family members to participate
 - Direct recruitment through phone calls could invade privacy and contact through personal physician may have implications for continued health care access

ICMR guidelines: Human Genetic Studies

- Genetic screening: Confidentiality should be maintained in handling of results with emphasis on responsibility of individuals with a positive (abnormal) result to inform partners and family members
- Genetic data should be normally delinked to maintain confidentiality
- Law protects confidentiality of medical information but this is not absolute

ICMR Guidelines: Human Genetic Studies

- Anonymous testing: researchers may conduct anonymous testing on general population in order to establish prevalence of genetic trait diseases
- For individual benefit, code of anonymity may be broken only with the approval of IEC

ICMR Guidelines: Disaster Research

- Makes research participants especially vulnerable
- Special care needed to protect the privacy and confidentiality of research participants in disaster context

Open access, freely available online

Essay

Should Health Professionals Allow Reporters Inside Hospitals and Clinics at Times of Natural Disasters?

Health professionals must protect their patients' dignity and privacy

Anant Bhan



PLoS Medicine | www.plosmedicine.org

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Limitations of Protections Offered

- Certificates of confidentiality
- DHHS/NIH U.S.A.
 - It helps researchers to protect the privacy of subjects in research against compulsory legal demands (e.g., court orders, subpoenas)
 - This is found useful in cases of genetic information, psychological well-being, sexual attitudes and preferences, substance abuse, reputation employability and finances, socially stigmatising conditions
- Such protections are not available in an Indian context, hence, one needs to be cautious while collecting such data or undertaking research on these issues