The impact of paragraph 25 on informed consent for biobank samples

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Overview

1. Changes
2. Implications and benefits
3. 3 key issues
4. Conclusion

Previous versions 1964 - 2000

"22. In **ANY** research on human beings, each potential subject must be adequately informed of the aims, methods … the anticipated benefits and potential risks of the study and the discomfort it may entail… the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent…"

"1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects **INCLUDES** research on identifiable human material or identifiable data."

A new paragraph - 2008

"25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee."

Why discuss human material and data separately?

Obtainment – research and clinical

Samples stored, sometimes indefinitely

Possible uses far into the future – unknowable

Possible use of archived samples

No risk of physical harm

Potential for harms through identifiability

Ambiguous terms

"25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be **impossible** or **impractical** to obtain for such research or would pose a **threat to the validity** of the research. In such situations the research may be done only after consideration and approval of a research ethics committee."

Implications

In certain cases…

Not mandatory to obtain fresh consent every time a new study is proposed

Not mandatory to obtain consent when samples are included in biobank

Ethics committees will determine the permissibility of the study without accompanying consent

Benefits

May widen sample pools

Old samples could be useable

Research may be quicker/cheaper/less biased

Rare samples could be useable

Samples of the deceased could be useable

Three emerging issues

1. The importance of seeking consent

2. Public engagement and trust

3. Confusion over applicability and standards

1. Seeking consent

Safeguard for patients and physicians

Respect- recognition of autonomy

Dependent on meaning of impossible or impractical

Who decides? Puri *et al.*

2. Public trust

Public perception of biobank research: Kaufman *et al.*

Public views on consent/ re-consent: Eurobarometer, *Hoeyer et al., Johnsson et al.*

Future projects – place for broad consent?

3. Applicability

Primacy of Declaration and national/institutional rules

Use of the paragraph is not widely evidenced

Increased burden for ethics committees

Concluding comments

1. Clarification of the scope of «impractical» and «threat to validity» needed

2. Different implications for existing and new samples (collection) require clarification

3. Better understanding of the risks of biobank research needed

Thank You

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