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Letter to the Editor

On the use of human tissues in research and practice

Sir,

The use of human tissues in research has greatly contributed to scientific advance. However, there are complaints from researchers and practitioners about growing difficulties concerning the professional use of human tissues. Even acquisition of tissues for control blocks needed by laboratories, e.g. for verification of immunohistochemical or other methods may be complicated. In the past, all operating room waste could be used if there had been no explicit objections. Today, a written consent to the use of tissues may be required similarly to anesthesia before surgery.

The development of informatics and genome sequencing has raised new problems concerning identifiability of specimens and protection of research participants [1]. The 2013 revision of the declaration of Helsinki (hereinafter declaration) includes a paragraph on the use of human tissues and data: "For medical research using identifiable human material or data … physicians must seek informed consent for its collection, storage and/or reuse" [2]. The current regulations and ongoing policy proposals such as the US Common Rule and FDA Human Subjects Regulations [1,3], World Medical Association Declaration on Ethical consideration regarding human health databases and biobanks [4], or the Data Protection Regulations by the European Union [5], all require informed consent for human specimen research. Relying on the term "identifiable" to designate samples that could be traced to the donor is impossible if the meaning is not universally accepted [6]. In the author's opinion, specimens may be regarded unidentifiable if there is a procedural barrier to identification, not necessarily the absence of a technical possibility of a link to identifying information. The use of unidentifiable samples should be not considered human subjects research, i.e. fall under the jurisdiction of the Declaration [6], a consent thus being unnecessary. Anonymization makes the body materials ownerless since an assignment to a person is not possible [7]. The question should be also discussed, whether genetic information must remain a matter of secrecy under all circumstances. For example, it might be reasonable for a spouse candidate to be informed on his or her partner's recessive alleles, etc., which might be of significance for the offspring. In certain cases, genetic information is of importance for employers, e.g. markers of certain neurological conditions for pilots, bus drivers, etc. Here, is nothing new for medicine, where information about patients is generally protected by medical secrecy but in certain circumstances may be disclosed for public safety reasons, etc.

Furthermore, a clear distinction must be made between research using already removed cells and tissues and invasive methods applied to a living person including those aimed at collection of cells and tissues. If not clearly separated, the attitude to both might become relaxed: Too much attention to tissue material with references to the declaration of Helsinki contributes to the devaluation of the declaration as a whole. Note that removal of cells and tissues from a living person is an invasive procedure falling under the jurisdiction of the Declaration and requiring informed consent. On the other hand, research using already removed cells and tissues must be set free from unnecessary difficulties, e.g. the donor's right to withdraw specimens from further research [8] as nobody can be seriously interested in such withdrawal. Moral, religious, and cultural concerns regarding research on specimens of human tissue [9] are unfounded, because a "donor" in no way can suffer from such research, but potentially harmful as they put cell-and-tissue research into one ethical category with invasive manipulations on persons potentially resulting in less responsible attitude to both. By analogy, a haircut requires consent but research on removed hair would be possible if not explicitly objected. Admittedly, one can speak about the donation of hair. In the author's opinion, the use of cells and tissues removed according to clinical indications in research for public benefit should not be regarded donation. After the removal, the specimen must automatically become anonymous and ownerless. A voluntary gift of cells or tissues, removed without clinical indications, can be regarded donation, but even in such cases the specimen taken for research must become anonymous and ownerless as it happens with donated blood, other body fluids, or hair. The concept of the broad or blanket consent [10,11] is only a half-measure.

Today, full identities of personal genomes can be exposed via surname inference from genetic genealogy databases followed by Internet searches [12]. However, persons can be identified in different ways, from recognizing external appearance to fingerprinting. To prevent identification by genetic material, such identification should be prohibited. If necessary for a study, researchers may get access to potentially identifying information, as they, similarly to medical personnel, must be bound by professional secrecy. Tissues should be collected, processed, stored, and handled under quality control [13], in particular, to avoid confusion of specimens [14]. It is essential to establish clear policies for data sharing, to educate all participants and adequately develop legislation on proper usage of genetic information [12].

In conclusion, there can be no valid ethical or other arguments against bona fide scientific or practical use of cells and tissues if they are already removed from human bodies. Moreover, there should be no obstacles also to the use of cells and tissues, removed from living individuals for unrelated reasons, for transplantation aimed at preservation of health or life. Certainly, strict control is needed to prevent all kinds of violation. Similarly to animal experiments, research on human tissues needs integrity of all participants. In particular, tissue specimens such as organ biopsies [15] may be collected only in accordance with clinical indications and informed consent.

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