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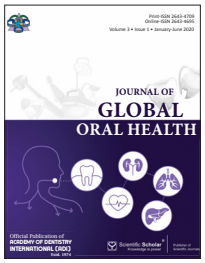

Review Article

Blanket consent - "The safety blanket for research"

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ABSTRACT

Every individual has the right to make decisions concerning health. Informed consent covers only known uses of samples/models/specimens. Hence, that cannot be considered purely informed consent because of complexity of genetic information. Blanket consent implies that there are no restrictions to the scope and duration of the consent. Which is given only once, but includes consent for any use of the samples at any time in the future. It is particularly important for scientific research in which new projects or experiments might be devised years after the subjects have given their consent and deposited their specimens/models etc. However, there are chances of misuse of information/specimen and there may be a breach of privacy and confidentiality.

Keywords: Consent, Blanket, Research, Informed consent, Confidentiality

INTRODUCTION

"*Blanket Is Never A Blanket Until It Covers The Entire Body*"

Research is essential for advancing medical and dental science knowledge. Because it is often useful in devising better treatment modalities, as well as in making policy suggestions. Like all kinds of medical and healthcare research, dental research also involves human subjects. Participants have the right to know entire details about it. Based on the ethical principle of respect for persons, the goal of informed consent is to ensure that subjects are aware of the risks and potential benefits, which enables them to make a voluntary decision about participating in the research.[1] Informed consent usually covers the known or specific or planned uses of specimens or models or records obtained from patients.[2] Informed consent is a cornerstone of the ethical conduct of research involving humans.[2]

As advances in medicine, genetic, and genomic research are increasing, it has challenged the traditional conceptions of informed consent. Changes occur so fast in the field of medicine that the time required to reflect on ethical implications often seems to be too short. However, there can be situations, where the clinician treating the patient with a different clinical presentation may not be aware of new diagnostic aids, methods, techniques, etc., for assessment or management of the condition/patient at that moment. Storing interesting models/samples/records, etc., will enable them to conduct research with new tools or novel methodologies in the future. Therefore, newer concepts are desirable to offer robust moral guidance, while keeping the reality of the dynamics of ethics in mind. One such new concept is open blanket consent. Therefore, biological specimens, records, X-rays, models, etc., can be stored and used in the future for research. The consent for such future research could be obtained through blanket consent. It is consent that

is given only once but covers any future use of the material. It is also called open, broad, generic, or blanket consent.[3] Therefore, it prevents ethical issues regarding the usage of samples for research, which might not be planned when the consent was obtained.[2] Perhaps, it is impossible to describe the details of forthcoming research for which those can be used, at the time of collection. In addition, the usage of such samples for which a new informed consent to be obtained from the subject at that time could considerably diminish the validity of a scientific study.[3] It might introduce selection bias.[3] Clayton *et al*. justify the use of blanket consent. First, practical difficulty to obtain consent for previously collected specimens. Second, he argues that blanket consent may cause very small or non-existent risks to those participants.[3]

Further with the rapid advancement in technology, the future risks associated with research using biospecimens/models/samples/records, etc., are unpredictable.[4] Therefore, legal and ethical requirements of informed consent for all future uses cannot be satisfied at the time, such data are collected.[4] Existing biological materials were allowed to be used for research without consent if they were deidentified.[5] The organizations such as UNESCO and WHO have recommended the use of blanket consent for the data in biorepositories and genetic research in general.[6] Other institutions and laws favoring blanket consent are as follows:[3] (1) Council of Europe's convention on human rights and biomedicine, (2) the Danish council of ethics, and (3) the national bioethics committees of various countries, such as the French national consultative ethics committee for health and life sciences (2003), and the German national ethics council (2004).

Greely proposed a variation on blanket consent which adds extra protection. His approaches involved informing subjects regarding method of storing their models/samples and an explanation regarding the possibilities for its use for the future research. The participants were given option whether to consent or not for the future use of the specimens/samples/records, etc.[7] Weir and Olick suggested a hybrid approach wherein the subjects would have provision to consent for the specific type of research study at the present. Regarding the future research, the subjects are given options to consent for studies that fell within certain categories or satisfied certain conditions. For example, subjects may consent to research on any known medical conditions, but not for studies related to genetic components research.[7]

Advantages

1. It allows multiple usage of the samples in the future, leads to the development of new diagnostics and therapy

In case of studies related to role of genes in complex diseases using advanced technology, assessing the sensitivity of new diagnostic aid against gold standard, checking the efficacy of various drugs, etc., helps in understanding the etiology of diseases and can lead to improved diagnostics, intervention, and treatment. These findings are anticipated to benefit the population at large through improved mortality, morbidity, workforce production, and decreased health expenditures.

2. It is advantageous for the researchers, as the cost and time-consuming recontact procedures are avoided
3. On an individual level, the practice of healthcare can move toward individualized medicine.

Limitations

1. Inherently vague, as subjects would not know exactly what their records/samples will be used for in the future. It also appeals the generic risk of undermining the meaning of consent[3]
2. Models/samples might be used in future studies that may conflict with individual interest/values; therefore, restrictions are essential.
   That is, the researchers can again contact the participants, to obtain consent for additional use of their data/models/samples. However, this may give the participants the thinking, of why only their specimen or data have been selected and also cause practical hurdles and expenses. This, in turn, may have an adverse impact on study validity due to non-response and loss of follow-up.[2,6] Hence, it can potentially undermine the value of research with such samples.
3. Misuse of information such as invalidated research results can cause anxiety and stress. In turn, it could lead to stigmatization, psychological harm, or insurance discrimination against the participant. Although the capacity to identify an individual's details among the collective dataset is limited,[8] but with the hasty technological advancements, there lies a constant prospect of unforeseen risks
4. Breach in confidentiality
   It cannot be guaranteed.
   Bio-specimen/models/records collections should state the procedures clearly for protecting the participant's personal information. The procedures include data encryption, coding, establishing limited access, use of non-disclosure agreements, and use of an honest broker system.[9]
5. Option for withdrawal

Research subjects must be allowed to discontinue their participation at any time without any loss of benefits to which they would otherwise be entitled.[10,11]

6. Commercial use of research derivatives

Participants should be informed about any costs or payments associated with participation, as well as the possibility that the research could lead to the development of commercial products. Furthermore, regarding the allocation of profits generated if any from such products.

TEMPLATE FOR BLANKET CONSENT

The aim of the present review was to propose a template for blanket consent thorough literature exploration. Only PubMed indexed full text articles available in English language from January 01, 2011, to December 31, 2021, highlighting blanket consent were searched. Articles published in any other language, only abstracts, and other types were excluded from the study. Search criteria (Blanket [All Fields] AND consent [All Fields] AND pro forma [All Fields]) AND ("2011/01/01"[PubDate]: "2021/12/31"[PubDate]).

RESULTS AND DISCUSSION

The results of a PubMed search revealed 33 articles, but on thorough screening, results showed that there is no specific pro forma related to blanket consent. Considering the necessity for informed consent for biological specimens'/ samples/models/X-rays storage and usage a blanket consent form must be prepared and consented by the participants for reuse of their samples. An attempt has been made to prepare a consent form. A template for the blanket consent form has been designed by considering the points and format as given by the WHO research ethics review committee.[12] The researcher can adapt their blanket consent form according to the necessities of their study. The form consists of two parts, that is, the participant information and consent form. Two separate forms need to be prepared for literates and illiterates, to enable the subjects to voluntarily consent. The form should be printed on the respected institution/research center letterhead along with the logo [Section 1 and 2].

CONCLUSION

Blanket consent for future studies can be considered valid, provided the personal information of research participants is handled safely. Participants should be allowed to withdraw consent at any time, and every study should be reviewed by the ethical review board. The committee must determine the following requirements. The research is of general interest, there is no explicit objection to the research and the confidentiality of individual information is safeguarded.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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