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Exploring The Importance Of Informed Consent And Ethics Committee In Clinical Research

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ABSTRACT

Any research involving human subjects should be conducted in conformity with the 4 basic ethical principles, namely autonomy, beneficence, non-maleficence and justice. In biomedical research, two pillars have been identified – informed consent & independent review by an ethics committee. The process of obtaining an informed consent is an indispensable mechanism to ensure that all the four basic ethical principles are adhered to. In conclusion, in order to safeguard the health & well-being of the human participants in the research arena, the need of the hour is that the investigator and the institutional ethics committee should realize their responsibility and work in a collaborative manner giving due regard to informed consent.

General Terms

Research, Ethics

Keywords

Informed consent, Ethics committee, Clinical research

1. INTRODUCTION

Any research involving human subjects should be conducted in conformity with the 4 basic ethical principles, namely: autonomy (respect for participant), beneficence, non-maleficence (do no harm) and justice.[1,2] In fact, in biomedical research, two pillars have been identified – informed consent & independent review by an ethics committee.[2,3] The process of obtaining an informed consent is an indispensable mechanism to ensure that all the four basic ethical principles are adhered to.[1-3]

2. NEED OF INFORMED CONSENT

Although, the importance of informed consent has been realized from last six-seven decades, in the current research arena, it has lost its essentiality.[1,4-6] Amidst, the extensive upsurge in research activities in recent years (fraction of which may be because of the mandatory recommendations by different Medical Councils for academic promotions), the worth of informed consent document has been reduced to a mere paper.[5-8] The medical fraternity, off late, has also witnessed many occasions of violation of human rights due to lack of importance being paid to obtaining informed consent from the research participant in the standardized & recommended manner.[6,9,10] This has necessitated us to revisit the elements of an informed consent document so that interests & well-being of the human study participants can be safeguarded.



3. ETHICS COMMITTEE

The Institutional Ethics Committee plays a crucial role in the clinical research and remains a key link between the investigators and the study participants. Their main role is to ensure that all the research activities are performed in such a manner that interests of study participants are safeguarded. However, in the current era the integrity of institutional ethics committee with regard to the selection of members or amount of attention given to the informed consent document by the members, itself has become questionable.[11,12] Thus, it is one of the most important responsibility of the Ethics committee to carefully scrutinize & give due importance to the informed consent document and ensure that the principal investigator obtains the informed consent in an appropriate way from each of the study participant throughout the duration of the study.[2,3,8]

4. INFORMED CONSENT

Informed consent is consent given by a competent person, who is willing to participate in a study after being completely informed about the study & after comprehending all aspects of a study, making the decision to participate in absence of any compulsion or intimidation.[8,13] It ensures that the research is performed without compromising the freedom of subjects, and even enables the recording of provided information.[8,14] Consent is usually recorded through a written, signed / thumb impression in an informed consent form.[13]

The informed consent form consists of multiple elements incorporated into the form, namely: trial involves research; voluntary participation/right to withdraw; no coercion/undue influence; nature & purpose of study; description of study procedures & treatment options; associated risks and benefits; alternative options; responsibilities of the subjects; circumstances under which subjects' participation can be terminated; number of participants; duration of study; management & compensation provisions for study-related injuries; any compensation for participation; clause of confidentiality; and whom to contact in case of study related queries, to ensure comprehensiveness of the form.[2,3,13,15]

5. ROLE OF ETHICS COMMITTEE

An ethics committee should ensure that the language of the form is easy to understand (in simple & non-technical, layman friendly language); all essential elements are presented; voluntary participation is emphasized; additional protection for vulnerable groups is offered assuring the welfare and safety of the research participants.[8,16] Vulnerable persons who may not be able to make free and informed decisions about their participation in research or medical care include children, prisoners, pregnant women and fetuses, the cognitively impaired, illiterate subjects, etc.[3,16]

6. OBTAINING INFORMED CONSENT

Informed consent is given by either the study participant, or by the participant's legally acceptable representative, where subjects are unable to give consent – such as a child less than seven years old or persons with dementia.[17,18] For study subjects between the ages of 7 and 18 years, two consents should be obtained - one from parents or a legally acceptable representative and one from the child (assent).[17,18] In all cases, subjects should be informed to an extent compatible with their ability to comprehend, and consent sought and documented.[3,17]

7. WAIVER OF INFORMED CONSENT

It is recommended to obtain voluntary informed consent for every study involving human participants. However, under special circumstances this can be waived if research involves not more than minimal risk; when the participant and the researcher do not come into contact; and in emergency situations (like research in sensitive areas like HIV/AIDS, etc.), and there is no violation of the rights of participants.[2,3,16]



8. CONCLUSION

In conclusion, in order to safeguard the health & well-being of the human participants in the research arena, the need of the hour is that the investigator and the institutional ethics committee should realize their responsibility and work in a collaborative manner giving due regard to informed consent.

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