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The Review

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Therapeutic Misconception

Therapeutic misconception (TM) was first defined by Paul Appelbaum in 1982 as "the failure of research participants to appreciate the difference between research and standard clinical care". The National Bioethics Advisory Commission (NBAC) defined TM as "the belief that the purpose of a clinical trial is to benefit the individual patient rather than to gather data for the purpose of contributing to scientific knowledge." Members of the IRB, investigators and clinical research staff often misunderstand this difference. Therefore, it is easy to see why potential research participants may overestimate the nature or likelihood of benefit to themselves and may not be able to make meaningful decisions as to whether to enroll in a clinical trial.

Failure to distinguish among the types of benefits in consent forms may contribute to the potential subjects misunderstanding or confusion.

First, the benefits to subjects that are obtained by participating in the study should be distinguished from the benefit to society or future patients that may be obtained from the study results. However, most consent forms describe the mechanism of action of the experimental intervention or the ultimate goal of the study without differentiating these from potential direct benefits to the subject.

Benefits to subjects are further divided into two types: direct benefits from receipt of the experimental intervention and inclusion benefits (also called collateral or indirect benefits), which result from participating in a study regardless of whether or not the subject receives the experimental intervention. Potential direct benefits that may be described in a consent form depend on the nature of the experimental intervention and the subjects' disease or condition. Inclusion benefits may include a promise of free goods or services provided as an enrollment incentive; diagnostic testing and standard treatments provided at no cost; the opportunity to be monitored closely by disease experts, and sometimes, potential psychological benefits from "doing everything possible" for oneself and/or for others. The inclusion benefits may not even be stated in the consent form but are perceived to be there by the potential participant during the consent process.

Therapeutic misconception is difficult to completely eradicate, because when subjects are ill and desperate, they will hear and believe what they want to hear and believe about the potential benefits of research. Therefore, consent forms should avoid vague, inconsistent and overstatement of the benefits, all of which may promote confusion about what the subjects can expect from receiving the experimental intervention.

By reviewing the consent form, IRBs are in a unique position to make recommendations for changes prior to use by the investigator. The form should be reviewed for consistent language regarding risks and benefits; avoiding misleading statements regarding the ultimate goals of the research and potential direct clinical benefit; and assuring that direct and indirect benefits are described precisely.

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