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20 Questions an IRB Can Ask to Assess the Risk of Therapeutic Misconception

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A therapeutic misconception occurs when a patient mistakes participation in a clinical study for clinical care. IRBs can ask the following questions to assess the risk of therapeutic misconception. By scoring the answers, the risk can be characterized and mitigated.

These questions do not apply to a study that constitutes standard of care. They require interpretation for a study that has *aspects* of clinical care. For example, if a study medication has no chance of improving a patient's health but participation in the study gives a patient access to procedures and assessment that would, otherwise, be unavailable to him or her, it is reasonable for the patient to conclude that the study has a reasonable chance of providing health benefits, even though they are not due to the study medication.

Therapeutic Misconception Risk Assessment Tool

Questions	Scoring	Score
The Patient		
1. Is the patient cognitively impaired by inherent mental capacity, medication, fever, stress or other reasons?	Low (0) to High (5)	
2. Is the patient under pressure to make a quick decision because of, for example, his or her medical condition?	Low (0) to High (5)	
3. Does the patient place a high degree of trust in medical professionals?	Low (0) to High (5)	
4. What previous experience, if any, does the patient have in clinical studies?	High (0) to Low (5)	
5. How well informed is the patient about clinical research?	Low (0) to High (5)	
The Setting		
6. Will the discussion occur in a clinical care setting, such as a medical office waiting room, an exam room in a clinic, or a hospital bed?	No (0) or Yes (5)	
7. If the patient has visited the setting previously, was it for clinical care?	No (0) or Yes (5)	
8. Does anything about the setting say "clinical research" or at least not "clinical care"? (For example, is there a sign that says "Clinical Research Center"?)	High (0) to Low (5)	
The Personnel		
9. Does the patient have a pre-existing clinical care relationship with the doctor or nurse?	No (0) or Yes (5)	
10. Does the patient have the expectation that he or she will be discussing clinical care?	No (0) or Yes (5)	

The Study		
11. Does the study appear to be offering treatment, e.g., with a medicine or medical device (experimental or not)?	No (0) or Yes (5)	
12. What is the chance of receiving a placebo?	High (0) to None (5)	
13. Does the patient understand the concept of "placebo"?	Yes (0) or No (5)	
14. Are the timelines, visits and procedures of the study consistent with a course of clinical treatment?	No (0) or Yes (5)	
15. Will the patient collect patient-reported-outcome data for the study?	Yes (0) or No (5)	
16. Will the patient receive payment for participating in the study?	Yes (0) or No (5)	
The Discussion		
17. Will the differences between clinical care and clinical research be discussed?	Yes (0) or No (5)	
18. Will the reasons why the study is not clinical care be discussed?	Yes (0) or No (5)	
19. Will clinical care options be discussed and distinguished from participation in the study?	Yes (0) or No (5)	
20. Will the patient's understanding that the study is research, not clinical care, be adequately confirmed?	Yes (0) or No (5)	
TOTAL SCORE		

Authors

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