

## Publication

Trust trumps comprehension, visceral factors trump all: A psychological cascade constraining informed consent to clinical trials: A qualitative study with stable patients

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This paper addresses psychological factors that might interfere with informed consent on the part of stable patients as potential early phase clinical trial participants. 36 semi-structured interviews with patients who had either diabetes or gout were conducted. We investigated stable patients' attitudes towards participating in a fictitious first-in-human trial of a novel intervention. We focused on an in-depth analysis of those statements and explanations that indicated the existence of psychological factors impairing decision-making capacity. Three main themes emerged: insufficient comprehension of the inherent logic of clinical trials (actual comprehension), the recourse to trust over comprehension (prioritization of trust), and visceral factors that override deliberative process (visceral factors). Overall, our results indicate a limited psychological capacity on the part of stable patients to meet the requirements of informed consent as set by Declaration of Helsinki. A redesigned informed consent procedure should take account of these psychological realities.

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