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Abstract

The accrual of medically stable subjects into trials testing highly novel interventions presents ethical challenges, because such trials can involve contentious levels of risk. Restrictive safety standards potentially frustrate the autonomy of subjects and the fulfillment of their aspirations. Standards that are too permissive raise concerns about whether clinicians are adequately safeguarding their subjects from harm. Because risk assessment is an intrinsically value-laden process, mechanisms are needed to ensure that risk judgments are calibrated to the interests of persons who might be invited into a trial. This commentary proposes that investigators and ethics committees might consult with patient constituencies whenever novel agents are proposed for first in human studies using medically stable subjects. The advantages and limitations of patient-community consultation are briefly described.