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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: You cannot study those who do not consent!

First item in Nuremberg War Code

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

I am reminded of the item by a flier for a course over the headline:

Lack of Diversity in Clinical Trials: An Issue We Can No Longer Ignore

The reality is that **all** trials involve select, nonrepresentative, study populations because you can only study those who consent to being studied. The strength of randomized trials lies in the assumption that the baseline composition of the treatment groups will be comparable and hence that differences observed are due to treatment.

Trialists can carry out subgroup analyses by baseline characteristics, but it is tough enough to find an effect for the design variable, let alone for subgroup differences.

In an ideal world, all trials would be microcosms of the true underlying populations at risk for the diseases or conditions studied, but within broad limits the information generated in randomized trials is applicable to the broader population, regardless of who is studied.