



Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

7 August 2019

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Subject, patient, or participant?

Remember the old days when journals had a section labeled “material and methods” where the people studied where the “material”? Times have changed.

So now, when writing a protocol or writing up results of a trial, what is your convention in references to persons enrolled in the trial: subject, patient, or participant? Definitions below are from the 2nd edition of my dictionary; John Wiley and Sons, 2012.

study subject, subject *n* - 1. A person serving as an object of study as evidenced by consent. 2. A person enrolled in a study. 3. A person actively studied or to be actively studied in a study. 4. A person serving as the passive object of study by use of existing data, documents, records, or specimens collected on the person in the past. **Usage note:** Note that the defns have different connotations. Defns 1 and 3 imply settings involving some form of contact or interaction of the subject with the researcher. Uses in the sense of defn 4 are devoid of such contact or interaction because the studying takes places without knowledge of the subject.

research subject *n* - 1. study participant; study patient 2. One who is the object of study. 3. An aspect of a person that is the object of study, such as the person's medical record or a specimen collected from the person. 4. Focus of a research topic. **Usage note:** Broadly defined in regulations for institutional review boards to include defns 1, 2, and 3. The prerogative for IRB review and approval extends to research to be performed without any contact with those being studied, as in defn 3 with a case-control study based on a review of medical records. The review and approval requirement is independent of whether or not the persons in question are or will be aware of being studied.

study patient *n* - 1. One who has a specified health condition or disease and is enrolled in a study; study subject; research subject. 2. One enrolled in a study, even if not a patient in the true sense. 3. A patient being considered for enrollment in a study (not recommended; use study candidate). **Usage note:** Limit use to settings involving persons with an illness or disease; avoid in settings involving well people or when there is a need to avoid connotations of illness or of medical care by using a medically neutral term, such as study participant.

study participant, participant *n* - 1. A person enrolled in a study; study subject; research subject. 2. study investigator (not recommended) **Usage note:** Used in place of study patient for studies involving well people to avoid the connotation of illness, as in a prevention trials; not to be confused with study participant: one being considered or evaluated for enrollment in a study.

The randomization unit in trials is typically person, but may be an aggregate of persons. Of the 133 papers indexed to the publication type [randomized controlled trial] appearing in the NEJM in 2016 all but 3 involved persons as the randomization unit. Based on information in abstracts of the 130 publications, *patient* was the descriptor in 74 of the publications, *participant* in 10 publications,

and other generic descriptors like women, men, infants or children in the others. None used “*subject*” as a descriptor.

“*Subject*”, as a noun, is Middle English, from Middle French and from Latin *subjectus* meaning one under authority; from *subjectus* meaning to subject or to throw under.

The primary difficulty with the term as a descriptor for persons enrolled in trials is the implication that they are objects of research. The term carries the connotation of subjugation and is at odds with the voluntary nature of participation and requirements of consent as a prelude to being studied.

In addition, the term carries the connotation of study without benefit; a misleading connotation in many trials and, assuredly, in treatment trials. Even if such a connotation is accurate, the term suggests a passive relationship with study investigators when, in fact, the relationship is usually more akin to a partnership.

Best avoided except in uses requiring a nonpersonal generic descriptor.

“*Clinic*” is from French *cliniquē* meaning medical practice, pertaining to the sick bed. Often, persons in trials are seen in clinics but are not patients. Indeed, a vast number of trials do not involve patients in the technical sense of usage, but often people in them are referred to as “patients”, partly because of the adjective “*clinical*” in “*clinical trial*”. Usually the adjective modifier serves only as a reminder that the trial involves people, as opposed to animals or in vitro trials having nothing to do with the “sick bed”.