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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Terms I hate

I suppose, if you spend part of your life writing dictionaries for trialists, you are going to have terms you hate. I wrote about one of those, endpoint, in an earlier note (10 November 2016). Here are a few more.

guinea pig as in references to persons studied in a trial (a slur to trialists)
informed as in informed consent (you have no idea if consents are informed; drop the adjective and save a word)
study in place of trial to downplay the fact that the study is in fact a trial (call a spade a spade)
subject in references to person enrolled in trials (disrespectful and dehumanizing to the people we study)
intervention as a generic name for the experimental variable in trials (all interaction are intervention, but only some are treatments; use the apt term)
interventional study as a substitute name for trial (call them what they are – trials)

guinea pig *n* - 1. A person needlessly or frivolously experimented upon. 2. A person subjected to untested procedures. 3. A person exposed to procedures having no intrinsic benefit. 4. A person exposed to procedures considered to entail more risks than benefits. 5. A person enrolled in a trial considered to violate existing ethics or norms for care. ***Usage note***: In regard to people, use with caution, especially in relation to implied claims or assertions of wrong doing. Usually evocative and emotion-laden and intended to suggest needless experimentation, experimentation so poorly done so as to have no benefit, or use of persons as objects of experimentation in settings involving undo risk or sacrifice. In the context of trials, often used in regard to a subset of persons considered to have been denied adequate treatment or to have been needlessly exposed to risk without the prospect of offsetting benefit; often in references to the subset receiving the control treatment in a placebo-controlled trial. Most uses in the context of trials, whether or not intentional, have the effect of impugning the judgment of sponsors of the trial for having funded it and of institutional review boards and ethics committees for having approved the trial.

informed *adj* - 1. Having information; based on possession of information. 2. Having information conveyed in an intelligible fashion. 3. Being in possession of information and for understanding it; knowledgeable. ***Usage note***: Most uses as a modifier of consent are in the sense of defns 1

or 2. Defn 3 implies an active process intended to ensure that the information conveyed is understood by the recipient. Uses in the sense of defns 1 or 2 imply a passive process with regard to understanding. Use should be assumed to be in the passive sense, unless accompanied with details of the process or evidence supporting use in the sense of defn.

informed consent *n* - A decision by a person or the person's parent, spouse, guardian, or representative to submit to some procedure or to be enrolled in a research project, after being informed of its purpose, possible risks and benefits, and of the consequences of refusing to consent. For trials, generally a consent, given after being informed of the purpose of the trial, why the person is eligible for enrollment, the treatments being evaluated and their potential risks and benefits, the method of treatment assignment, the level of treatment masking, and the options for treatment and care if consent is not given. ***Usage note***: Usually the modifier "informed" is more an expression of hope than of fact. Its use is best reserved for settings in which there are steps built into the consent process to ensure an informed decision based on evidence of comprehension of what is involved, or for settings in which the decision can be demonstrated to have been informed.

study *n* - 1. An investigation or analysis of a question, process, or phenomenon. 2. Any one of a variety of activities involving the collection, analysis, or interpretation of data. 3. Clinical trial, especially in a setting where there is a desire or need to de-emphasize the experimental nature of the investigation. 4. An investigation involving both a trial and nonexperimental investigation (as in the Coronary Artery Surgery Study, comprised of a clinical trial and an observational followup study). ***Usage note***: Widely and loosely used. Avoid in favor of more informative, less generic terms whenever possible (e.g., use trial rather than study when appropriate). As a label, limit use to defined sets of activities involving data collection not ordinarily characterized with a more informative, design-specific term (such as trial or followup study), or where a general term is needed to characterize a collection of activities involving a number of different designs (e.g., referring to a mix of trials and observational studies). Avoid as a synonym for a specified kind of investigation having a recognized term (as in referring to an investigation as a trial in the title or abstract of a paper and study in the body of the paper).

subject *n* - [ME, fr MF, fr L *subjectus* one under authority & *subjectum* subject of a proposition, fr masc & neut, respectively, of *subjectus*, pp of *subiere* to subject, lit to throw under, fr *sub-* + *jacere* to throw] study subject (defns 1, 2, 3, and 4) ***Usage note***: The term is widely used in human research, especially in experimental settings. The primary difficulty with the term for persons being studied in the setting of trials has to do with the implication that the persons are research objects. The term carries the connotation of subjugation and, thus, is at odds with the voluntary nature of the participation and requirements of consent. In addition, it carries the connotation of use without benefit; a misleading connotation in many trials and, assuredly, in treatment trials. Even if such a connotation is correct, the term suggests a passive relationship with study investigators when, in fact, the relationship is more akin to a partnership involving active cooperation. Avoid by using more humanistic terms, such as human being, person, patient, or participant.

study subject *n* - 1. A person serving as an active 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. See subject for usage note in the setting of trials. See also human subject.

intervention *n* - [trials] 1. A test treatment, especially one in a trial involving nonmedical treatments and well people such as in a diet trial involving different diet regimens. 2. Any study treatment; test or control treatment. ***Usage note***: Not recommended as a synonym for "treatment" in references to the experimental variable in trials. Technically, anything one does to another is a form of intervention, whether or not related to administration of study treatments. The most common use of "intervention" in reference to the experimental variable in trials is in settings where there is a desire to downplay clinical implications connoted by "treatment". However, even in those settings, the term "treatment" is a more apt descriptor of what is done than "intervention".

treatment *n* - 1. The act of treating, as in caring for a patient. 2. The specific regimen(s), method(s), or procedure(s) being tested in a trial; test treatment. 3. An application of a prescribed regimen to a person. 4. prescribed treatment 5. The regimen of treatment (including nil control treatments) and observation indicated by treatment assignment. 6. Any condition or variable that is purposely varied in an experiment to investigate its role in determining or influencing some measurement or outcome; may be a variable in a simulation process, level of a fertilizer in an agriculture experiment, type or combination of substances or factors (e.g., by using different drugs or different levels of the same drug) in an experiment involving animals or human beings, etc. ***Usage note***: The term, treatment, in references to design, such as in defn 6, refers to the handling, technique, or action customarily applied in a specified instance. It does not necessarily carry medical connotations, as implied by defn 1. Hence, control treatment in a trial may be devoid of “treatment” in the medical sense of usage. The treatment, as referenced in defn 2, may be a combination of treatments, e.g., as in a factorial treatment structure.

interventional study *n* - (fr glossary on ClinicalTrials.gov website) A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. ***Usage note***: See usage otes for **study** and **treatment**.

All entries above, except for the last one are from Clinical Trials Dictionary: Terminology and usage recommendation; Wiley; 2012).