JOHNS HOPKINS
UNIVERSITY

Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

28 April 2014

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: On the definition of protocol

Protocol in the SPIRIT statement (www.annals.org 8 Jan 2013) is defined as a document that provides sufficient detail to enable understanding of the background, rationale, objectives, study population, interventions, methods, statistical analyses, ethical considerations, dissemination plans, and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigor from ethics approval to dissemination of results.

Protocol and study protocol in Meinert's 2nd edition of *Clinical Trials Dictionary* (Wiley; 2012) is defined as below.

protocol - 1. Specifications, rules, and procedures for performing some activity or function. 2. study protocol 3. data collection schedule 4. treatment plan 5. The research plan submitted to study investigators by a sponsor, study chair, or coordinating center in a multicenter trial for submission to their respective IRBs. 6. A research plan involving human beings, as approved by an investigator's IRB.

study protocol - 1. study plan 2. General rules and procedures for carrying out a study. 3. data collection protocol [trials] 4. A written document specifying eligibility requirements, treatments being tested, method of assigning treatment to treatment units, and details of data collection and followup; also trial protocol. 5. treatment protocol ***Usage note***: May refer to unwritten document when used loosely. Assumed to refer to a written document in formal usage; in the context of trials, a written document that is submitted to IRBs for approval and followed by investigators in conduct of the trial.

The term is defined on various websites for IRBs. The definitions below are as found on IRB websites for the top twenty universities receiving NIH funding in 2010. Only nine of the websites had definitions for protocol.

Emory University: The formal design or plan of an experiment or research activity. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Johns Hopkins University: The formal design or plan of an experiment or research activity – akin to a blueprint – which is submitted to an IRB for review or often also used in applications to funding agencies. The protocol includes a description of the proposed research design and methodology, eligibility requirements for prospective participants, informed consent process, treatment regimen(s), and methods of analysis that will be

performed on the data collected. The body of HIRB applications for new research consists of the research protocol.

Princeton University: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Stanford University: A detailed plan for conducting research.

University of California (San Francisco): A document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project.

University of Michigan: The formal design or plan of an experiment or research activity; specifically, the plan submitted to a scientific or peer review committee for review and to an agency for research support. The protocol usually includes a description of the research design, methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a project, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

University of North Carolina: A document that identifies the plan or set of rules for conducting a specific clinical trial, and states the objectives, design, methodology, statistical considerations, and organization of a trial.

University of Pittsburgh: The research plan of a scientific experiment or treatment.

Washington University: The methodology used in conducting a sponsored project.

Protocol is a currency word in trials. The most common usages are in relation to treatments used in trials and what persons enrolled in trials are subjected to by way of data collection and followup. As noted in a posting to trialsmeinertsway.com 3 December 2013, many of the elements considered part of the protocol in the SPIRIT definition are covered in other documents produced in the trial.