From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, January 23, 2004 10:17 AM
To: [Redacted]
Subject: RE: Question regarding Part 50
Dear Ms. [Redacted],

Our regulations don't define "experimental" or "experiment" specifically. Rather the word "experiment" is used in the context of defining what we consider to be a clinical investigation. The same is true for the Common Rule regulations (45 CFR 46); neither experiment nor experimental are specifically defined or codified.

In a Health and Human Services Departmental reference entitled "Institutional Review Board Guidebook", these terms are present in the glossary (http://ohrp.osophs.dhhs.gov/irb/irb_glossary.htm) and are as follows:

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Institutional Review Board
Guidebook
* GLOSSARY *

GLOSSARY OF TERMS
EXPERIMENTAL Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (See also: Research.)
EXPERIMENTAL STUDY A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (See also: Quasi-Experimental Study).
QUASI-EXPERIMENTAL STUDY A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups. (See also: Experimental Study.)
These terms present in this reference are meant to be used as a guide and, as I mentioned, are not codified in either CFR Titles 21 or Title 45.
I hope this information is helpful.
Sincerely,
Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]
Sent: Thursday, January 22, 2004 10:55 AM

To: GCPQuestions@OC.FDA.GOV
Subject: Question regarding Part 50
Dear FDA:
Could you please provide a definition or guidance with regard to what is meant by "experimental" in part 50.25(a)(1)? I recently ran across a section from an IDE Memorandum, which is a an Interagency Agreement (looks like between HCFA and FDA) that describes categories for Medicare coverage....

"Category A - Experimental - innovative devices believed to be in class III for which "absolute risk" of the device type has not been established (i.e. initial questions of safety and effectiveness have not been resolved). That is, FDA is unsure whether the device type can be safe and effective."

"Category B - Non-experimental/Investigational - device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e. underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example other manufacturers have obtained FDA approval for that device type."

Realizing that this document came out much later than part 50, the definitions and distinction between investigational and experimental still seems relevant and applicable. In practice, we do not use these words interchangeable. Please advise if this is correct, and if not, do you have specific definitions that we could refer to?

Thank you in advance for your time.
[Redacted]