The following definitions of “intervention” have been given to us to assist in the interpretation of what activities might or might not be considered interventions. We use these definitions mainly in the determination of whether particular research studies fall within the parameters of Exemption Category B2, or must be reviewed instead at the Expedited level.

45 CFR 46.101(f) – Federal regulations governing the conduct of research involving human subjects:
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Official from the Federal oversight body for the protection of human subjects in research, OHRP (Office for Human Research Protections), DHHS (Department of Health and Human Services), 6/26/07:
An intervention is an experimental manipulation intended to effect change in behavior, cognition, etc.

A research study is exemptible under Category B2 only if it exclusively uses one or more of the following research activities:
• Educational tests
• Survey procedures
• Interview procedures
• Observation of public behavior

If an activity that falls within the above definitions of “Intervention” is used as a part of / in conjunction with any of these, the research study is not exemptible under Exemption Category B2. Such a research study would require Expedited Review by the IRB, unless it was exemptible under another Exemption Category.

* Exemption Category B2 includes further restrictions, which are not addressed within this guidance document.